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FEDERAL REGISTER

Vol. 83 Friday,

No. 160 August 17, 2018

Book 1 of 3 Books

Pages 40931–41142

OFFICE OF THE FEDERAL REGISTER

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Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

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Contents

Federal Register

Vol. 83, No. 160

Friday, August 17, 2018

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR
1205.....40931

12 CFR
1016.....40945

14 CFR
39 (3 documents) 40959, 40961, 40963
73.....40967
97 (2 documents) 40968, 40971

Proposed Rules:
71.....41021

21 CFR
803.....40973

Proposed Rules:
876.....41023
878.....41023
886.....41023

26 CFR

Proposed Rules:
1 (2 documents) 41026, 41954
301.....41954

32 CFR

Proposed Rules:
199.....41026

33 CFR
117 (2 documents) 40985, 40986

Proposed Rules:
100 (2 documents) 41029, 41032

40 CFR
9.....40986
52.....41006
721.....40986

Proposed Rules:
52.....41035
721.....41039

42 CFR
412.....41144
413.....41144
424.....41144
495.....41144

Proposed Rules:
88.....41039
414.....41786
425.....41786

48 CFR
6101.....41009
6102.....41009

50 CFR
622.....41018
679 (2 documents) 41019, 41020

Rules and Regulations

Federal Register
Vol. 83, No. 160
Friday, August 17, 2018

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1205

[Doc. #AMS–CN–18–0013]

Cotton Board Rules and Regulations: Adjusting Supplemental Assessment on Imports (2018 Amendments)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Direct final rule.

SUMMARY: The Agricultural Marketing Service (AMS) is amending the Cotton Board Rules and Regulations, increasing the value assigned to imported cotton for the purposes of calculating supplemental assessments collected for use by the Cotton Research and Promotion Program. This amendment is required each year to ensure that assessments collected on imported cotton and the cotton content of imported products will be the same as those paid on domestically produced cotton. In addition, AMS is updating the Harmonized Tariff Schedule (HTS) statistical reporting numbers that were amended since the last assessment adjustment in 2017.

DATES: This direct rule is effective October 16, 2018, without further action or notice, unless significant adverse comment is received by September 17, 2018. If significant adverse comment is received, AMS will publish a timely withdrawal of the amendment in the **Federal Register**.

ADDRESSES: Written comments may be submitted to the addresses specified below. All comments will be made available to the public. Please do not include personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publically disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. Comments may be submitted anonymously.

Comments, identified by AMS–CN–18–0013, may be submitted electronically through the *Federal eRulemaking Portal at http://www.regulations.gov.* Please follow the instructions for submitting comments. In addition, comments may be submitted by *mail or hand delivery* to Cotton Research and Promotion, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia, 22406. Comments should be submitted in triplicate. All comments received will be made available for public inspection at Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia 22406. A copy of this document may be found at: *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Shethir M. Riva, Director, Research and Promotion, Cotton and Tobacco Program, AMS, USDA, 100 Riverside Parkway, Suite 101, Fredericksburg, Virginia, 22406, telephone (540) 361–2726, facsimile (540) 361–1199, or email at *Shethir.Riva@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Amendments to the Cotton Research and Promotion Act (7 U.S.C. 2101–2118) (Act) were enacted by Congress under Subtitle G of Title XIX of the Food, Agriculture, Conservation, and Trade Act of 1990 (Pub. L. 101–624, 104 Stat. 3909, November 28, 1990). These amendments contained two provisions that authorize changes in the funding procedures for the Cotton Research and Promotion Program. These provisions provide for: (1) The assessment of imported cotton and cotton products; and (2) termination of refunds to cotton producers. (Prior to the 1990 amendments to the Act, producers could request assessment refunds.)

As amended, the Cotton Research and Promotion Order (7 CFR part 1205) (Order) was approved by producers and importers voting in a referendum held July 17–26, 1991, and the amended Order was published in the **Federal Register** on December 10, 1991, (56 FR 64470). A proposed rule implementing the amended Order was published in the **Federal Register** on December 17, 1991, (56 FR 65450). Implementing rules were published on July 1 and 2, 1992, (57 FR 29181) and (57 FR 29431), respectively.

This direct final rule would amend the value assigned to imported cotton in the Cotton Board Rules and Regulations (7 CFR 1205.510(b)(2)) that is used to determine the Cotton Research and Promotion assessment on imported cotton and cotton products. The total value of assessment levied on cotton imports is the sum of two parts. The first part of the assessment is based on the weight of cotton imported—levied at a rate of $1 per bale of cotton, which is equivalent to 500 pounds, or $1 per 226.8 kilograms of cotton. The second part of the import assessment (referred to as the supplemental assessment) is based on the value of imported cotton lint or the cotton contained in imported cotton products—levied at a rate of five-tenths of one percent of the value of domestically produced cotton.

Section 1205.510(b)(2) of the Cotton Research and Promotion Rules and Regulations provides for assigning the calendar year weighted average price received by U.S. farmers for Upland cotton to represent the value of imported cotton. This is so that the assessment on domestically produced cotton and the assessment on imported cotton and the cotton content of imported products is the same. The source for the average price statistic is *Agricultural Prices,* a publication of the National Agricultural Statistics Service (NASS) of the Department of Agriculture. Use of the weighted average price figure in the calculation of supplemental assessments on imported cotton and the cotton content of imported products will yield an assessment that is the same as assessments paid on domestically produced cotton.

The current value of imported cotton as published in 2017 in the **Federal Register** (82 FR 41829) for the purpose of calculating assessments on imported cotton is $0.011510 per kilogram. Using the average weighted price received by U.S. farmers for Upland cotton for the calendar year 2017, this direct final rule would amend the new value of imported cotton to $0.011905 per kilogram to reflect the price paid by U.S. farmers for Upland cotton during 2017.

An example of the complete assessment formula and how the figures are obtained is as follows:

One bale is equal to 500 pounds.

One kilogram equals 2.2046 pounds. One pound equals 0.453597 kilograms.

One Dollar per Bale Assessment Converted to Kilograms

A 500-pound bale equals 226.8 kg. (500 × 0.453597).
$1 per bale assessment equals $0.002000 per pound or $0.2000 cents per pound (1/500) or $0.004409 per kg or $0.4409 cents per kg. (1/226.8).

Supplemental Assessment of 5/10 of One Percent of the Value of the Cotton Converted to Kilograms

The 2017 calendar year weighted average price received by producers for Upland cotton is $0.68 per pound or $1.499128 per kg. (0.68 × 2.2046).
Five tenths of one percent of the average price equals $0.007496 per kg. (1.499128 × 0.005).

Total Assessment

The total assessment per kilogram of raw cotton is obtained by adding the $1 per bale equivalent assessment of $0.004409 per kg. and the supplemental assessment $0.007496 per kg., which equals $0.011905 per kg.

The current assessment on imported cotton is $0.011510 per kilogram of imported cotton. The revised assessment in this direct final rule is $0.011905, an increase of $0.000395 per kilogram. This increase reflects the increase in the average weighted price of Upland cotton received by U.S. farmers during the period January through December 2017.

Import Assessment Table in section 1205.510(b)(3) indicates the total assessment rate ($ per kilogram) due for each Harmonized Tariff Schedule (HTS) number that is subject to assessment. This table must be revised each year to reflect changes in supplemental assessment rates and any changes to the HTS numbers. In this direct final rule, AMS is amending the Import Assessment Table.

AMS believes that these amendments are necessary to ensure that assessments collected on imported cotton and the cotton content of imported products are the same as those paid on domestically produced cotton. Accordingly, changes reflected in this rule should be adopted and implemented as soon as possible since it is required by regulation.

As described in this **Federal Register** document, the amendment to the value used to determine the Cotton Research and Promotion Program importer assessment will be updated to reflect the assessment already paid by U.S. farmers. For the reasons mentioned above, AMS finds that publishing a proposed rule and seeking public comment is unnecessary because the change is required annually by regulation in 7 CFR 1205.510.

Also, this direct-final rulemaking furthers the objectives of Executive Order 13563, which requires that the regulatory process ''promote predictability and reduce uncertainty'' and ''identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends.''

AMS has used the direct rule rulemaking process since 2013 and has not received any adverse comments; however, if AMS does receives significant adverse comment during the comment period, it will publish, in a timely manner, a document in the **Federal Register** withdrawing this direct final rule. AMS will then address public comments in a subsequent proposed rule and final rule based on the proposed rule.

B. Regulatory Impact Analysis

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 12 of the Act, any person subject to an order may file with the Secretary of Agriculture (Secretary) a petition stating that the order, any provision of the plan, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the District Court of the United States in any district in which the person is an inhabitant, or has his principal place of business, has jurisdiction to review the Secretary's ruling, provided a complaint is filed within 20 days from the date of the entry of the Secretary's ruling.

Regulatory Flexibility Act and Paperwork Reduction Act

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has examined the economic impact of this rule on small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such action so that small businesses will not be unduly or disproportionately burdened. The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (importers) as having receipts of no more than $7,500,000. In 2017, an estimated 20,000 importers are subject to the rules and regulations issued pursuant to the Cotton Research and Promotion Order. Most are considered small entities as defined by the Small Business Administration.

This rule would only affect importers of cotton and cotton-containing products and would increase the assessments paid by the importers under the Cotton Research and Promotion Order. The current assessment on imported cotton is $0.011510 per kilogram of imported cotton. The amended assessment would be $0.011905, which was calculated based on the 12-month weighted average of price received by U.S. cotton farmers. Section 1205.510, ''Levy of assessments'', provides ''The rate of the supplemental assessment on imported cotton will be the same as that levied on cotton produced within the United States.'' In addition, section 1205.510 provides that the 12-month weighted average of prices received by U.S.

farmers will be used as the value of imported cotton for the purpose of levying the supplemental assessment on imported cotton.

Under the Cotton Research and Promotion Program, assessments are used by the Cotton Board to finance research and promotion programs designed to increase consumer demand for Upland cotton in the United States and international markets. In 2016 (the last audited year), producer assessments totaled $36.5 million and importer assessments totaled $36.51 million. According to the Cotton Board, should the volume of cotton products imported into the U.S. remain at the same level in 2018, one could expect an increase of assessments by approximately $1,278,951.

Imported organic cotton and products may be exempt from assessment if eligible under section 1205.519 of the Order.

There are no Federal rules that duplicate, overlap, or conflict with this rule.

In compliance with Office of Management and Budget (OMB) regulations (5 CFR part 1320) which implement the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35) the information collection requirements contained in the regulation to be amended have been previously approved by OMB and were assigned control number 0581–0093, National Research, Promotion, and Consumer Information Programs. This rule does not result in a change to the information collection and recordkeeping requirements previously approved.

A 30-day comment period is provided to comment on the changes to the Cotton Board Rules and Regulations proposed herein. This period is deemed appropriate because an amendment is required to adjust the assessments collected on imported cotton and the cotton content of imported products to be the same as those paid on domestically produced cotton. Accordingly, the change in this rule, if adopted, should be implemented as soon as possible.

List of Subjects in 7 CFR Part 1205

Advertising, Agricultural research, Cotton, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS amends 7 CFR part 1205 as follows:

PART 1205—COTTON RESEARCH AND PROMOTION

■ 1. The authority citation for part 1205 continues to read as follows:

Authority: 7 U.S.C. 2101–2118; 7 U.S.C 7401.

■ 2. In § 1205.510, paragraph (b)(2) and the table in paragraph (b)(3) are revised to read as follows:

§ 1205.510 Levy of assessments.

* * * * *

(b) * * *

(2) The 12-month average of monthly weighted average prices received by U.S. farmers will be calculated annually. Such weighted average will be used as the value of imported cotton for the purpose of levying the supplemental assessment on imported cotton and will be expressed in kilograms. The value of imported cotton for the purpose of levying this supplemental assessment is $1.1905 cents per kilogram.

(3) * * *

IMPORT ASSESSMENT TABLE

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5007106010	0.2713	0.3229827
5007106020	0.2713	0.3229827
5007906010	0.2713	0.3229827
5007906020	0.2713	0.3229827
5112904000	0.1085	0.1291693
5112905000	0.1085	0.1291693
5112909010	0.1085	0.1291693
5112909090	0.1085	0.1291693
5201000500	1	1.1905000
5201001200	1	1.1905000
5201001400	1	1.1905000
5201001800	1	1.1905000
5201002200	1	1.1905000
5201002400	1	1.1905000
5201002800	1	1.1905000
5201003400	1	1.1905000
5201003800	1	1.1905000
5204110000	1.0526	1.2531203
5204190000	0.6316	0.7519198
5204200000	1.0526	1.2531203
5205111000	1	1.1905000
5205112000	1	1.1905000
5205121000	1	1.1905000
5205122000	1	1.1905000
5205131000	1	1.1905000
5205132000	1	1.1905000
5205141000	1	1.1905000
5205142000	1	1.1905000
5205151000	1	1.1905000
5205152000	1	1.1905000
5205210020	1.044	1.2428820
5205210090	1.044	1.2428820
5205220020	1.044	1.2428820
5205220090	1.044	1.2428820
5205230020	1.044	1.2428820
5205230090	1.044	1.2428820
5205240020	1.044	1.2428820
5205240090	1.044	1.2428820
5205260020	1.044	1.2428820
5205260090	1.044	1.2428820

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5205270020	1.044	1.2428820
5205270090	1.044	1.2428820
5205280020	1.044	1.2428820
5205280090	1.044	1.2428820
5205310000	1	1.1905000
5205320000	1	1.1905000
5205330000	1	1.1905000
5205340000	1	1.1905000
5205350000	1	1.1905000
5205410020	1.044	1.2428820
5205410090	1.044	1.2428820
5205420021	1.044	1.2428820
5205420029	1.044	1.2428820
5205420090	1.044	1.2428820
5205430021	1.044	1.2428820
5205430029	1.044	1.2428820
5205430090	1.044	1.2428820
5205440021	1.044	1.2428820
5205440029	1.044	1.2428820
5205440090	1.044	1.2428820
5205460021	1.044	1.2428820
5205460029	1.044	1.2428820
5205460090	1.044	1.2428820
5205470021	1.044	1.2428820
5205470029	1.044	1.2428820
5205470090	1.044	1.2428820
5205480020	1.044	1.2428820
5205480090	1.044	1.2428820
5206110000	0.7368	0.8771604
5206120000	0.7368	0.8771604
5206130000	0.7368	0.8771604
5206140000	0.7368	0.8771604
5206150000	0.7368	0.8771604
5206210000	0.7692	0.9157326
5206220000	0.7692	0.9157326
5206230000	0.7692	0.9157326
5206240000	0.7692	0.9157326
5206250000	0.7692	0.9157326
5206310000	0.7368	0.8771604
5206320000	0.7368	0.8771604
5206330000	0.7368	0.8771604
5206340000	0.7368	0.8771604
5206350000	0.7368	0.8771604
5206410000	0.7692	0.9157326
5206420000	0.7692	0.9157326
5206430000	0.7692	0.9157326
5206440000	0.7692	0.9157326
5206450000	0.7692	0.9157326
5207100000	0.9474	1.1278797
5207900000	0.6316	0.7519198
5208112020	1.0852	1.2919306
5208112040	1.0852	1.2919306
5208112090	1.0852	1.2919306
5208114020	1.0852	1.2919306
5208114040	1.0852	1.2919306
5208114060	1.0852	1.2919306
5208114090	1.0852	1.2919306
5208116000	1.0852	1.2919306
5208118020	1.0852	1.2919306
5208118090	1.0852	1.2919306
5208124020	1.0852	1.2919306
5208124040	1.0852	1.2919306
5208124090	1.0852	1.2919306
5208126020	1.0852	1.2919306
5208126040	1.0852	1.2919306
5208126060	1.0852	1.2919306
5208126090	1.0852	1.2919306
5208128020	1.0852	1.2919306
5208128090	1.0852	1.2919306

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5208130000	1.0852	1.2919306
5208192020	1.0852	1.2919306
5208192090	1.0852	1.2919306
5208194020	1.0852	1.2919306
5208194090	1.0852	1.2919306
5208196020	1.0852	1.2919306
5208196090	1.0852	1.2919306
5208198020	1.0852	1.2919306
5208198090	1.0852	1.2919306
5208212020	1.0852	1.2919306
5208212040	1.0852	1.2919306
5208212090	1.0852	1.2919306
5208214020	1.0852	1.2919306
5208214040	1.0852	1.2919306
5208214060	1.0852	1.2919306
5208214090	1.0852	1.2919306
5208216020	1.0852	1.2919306
5208216090	1.0852	1.2919306
5208224020	1.0852	1.2919306
5208224040	1.0852	1.2919306
5208224090	1.0852	1.2919306
5208226020	1.0852	1.2919306
5208226040	1.0852	1.2919306
5208226060	1.0852	1.2919306
5208226090	1.0852	1.2919306
5208228020	1.0852	1.2919306
5208228090	1.0852	1.2919306
5208230000	1.0852	1.2919306
5208292020	1.0852	1.2919306
5208292090	1.0852	1.2919306
5208294020	1.0852	1.2919306
5208294090	1.0852	1.2919306
5208296020	1.0852	1.2919306
5208296090	1.0852	1.2919306
5208298020	1.0852	1.2919306
5208298090	1.0852	1.2919306
5208312000	1.0852	1.2919306
5208314020	1.0852	1.2919306
5208314040	1.0852	1.2919306
5208314090	1.0852	1.2919306
5208316020	1.0852	1.2919306
5208316040	1.0852	1.2919306
5208316060	1.0852	1.2919306
5208316090	1.0852	1.2919306
5208318020	1.0852	1.2919306
5208318090	1.0852	1.2919306
5208321000	1.0852	1.2919306
5208323020	1.0852	1.2919306
5208323040	1.0852	1.2919306
5208323090	1.0852	1.2919306
5208324020	1.0852	1.2919306
5208324040	1.0852	1.2919306
5208324060	1.0852	1.2919306
5208324090	1.0852	1.2919306
5208325020	1.0852	1.2919306
5208325090	1.0852	1.2919306
5208330000	1.0852	1.2919306
5208392020	1.0852	1.2919306
5208392090	1.0852	1.2919306
5208394020	1.0852	1.2919306
5208394090	1.0852	1.2919306
5208396020	1.0852	1.2919306
5208396090	1.0852	1.2919306
5208398020	1.0852	1.2919306
5208398090	1.0852	1.2919306
5208412000	1.0852	1.2919306
5208414000	1.0852	1.2919306
5208416000	1.0852	1.2919306
5208418000	1.0852	1.2919306
5208421000	1.0852	1.2919306
5208423000	1.0852	1.2919306
5208424000	1.0852	1.2919306
5208425000	1.0852	1.2919306
5208430000	1.0852	1.2919306
5208492000	1.0852	1.2919306
5208494010	1.0852	1.2919306
5208494020	1.0852	1.2919306
5208494090	1.0852	1.2919306
5208496010	1.0852	1.2919306
5208496020	1.0852	1.2919306
5208496030	1.0852	1.2919306
5208496090	1.0852	1.2919306
5208498020	1.0852	1.2919306
5208498090	1.0852	1.2919306
5208512000	1.0852	1.2919306
5208514020	1.0852	1.2919306
5208514040	1.0852	1.2919306
5208514090	1.0852	1.2919306
5208516020	1.0852	1.2919306
5208516040	1.0852	1.2919306
5208516060	1.0852	1.2919306
5208516090	1.0852	1.2919306
5208518020	1.0852	1.2919306
5208518090	1.0852	1.2919306
5208521000	1.0852	1.2919306
5208523020	1.0852	1.2919306
5208523035	1.0852	1.2919306
5208523045	1.0852	1.2919306
5208523090	1.0852	1.2919306
5208524020	1.0852	1.2919306
5208524035	1.0852	1.2919306
5208524045	1.0852	1.2919306
5208524055	1.0852	1.2919306
5208524065	1.0852	1.2919306
5208524090	1.0852	1.2919306
5208525020	1.0852	1.2919306
5208525090	1.0852	1.2919306
5208591000	1.0852	1.2919306
5208592015	1.0852	1.2919306
5208592025	1.0852	1.2919306
5208592085	1.0852	1.2919306
5208592095	1.0852	1.2919306
5208594020	1.0852	1.2919306
5208594090	1.0852	1.2919306
5208596020	1.0852	1.2919306
5208596090	1.0852	1.2919306
5208598020	1.0852	1.2919306
5208598090	1.0852	1.2919306
5209110020	1.0309	1.2272865
5209110025	1.0309	1.2272865
5209110035	1.0309	1.2272865
5209110050	1.0309	1.2272865
5209110090	1.0309	1.2272865
5209120020	1.0309	1.2272865
5209120040	1.0309	1.2272865
5209190020	1.0309	1.2272865
5209190040	1.0309	1.2272865
5209190060	1.0309	1.2272865
5209190090	1.0309	1.2272865
5209210020	1.0309	1.2272865
5209210025	1.0309	1.2272865
5209210035	1.0309	1.2272865
5209210050	1.0309	1.2272865
5209210090	1.0309	1.2272865
5209220020	1.0309	1.2272865
5209220040	1.0309	1.2272865
5209290020	1.0309	1.2272865
5209290040	1.0309	1.2272865
5209290060	1.0309	1.2272865
5209290090	1.0309	1.2272865
5209313000	1.0309	1.2272865
5209316020	1.0309	1.2272865
5209316025	1.0309	1.2272865
5209316035	1.0309	1.2272865
5209316050	1.0309	1.2272865
5209316090	1.0309	1.2272865
5209320020	1.0309	1.2272865
5209320040	1.0309	1.2272865
5209390020	1.0309	1.2272865
5209390040	1.0309	1.2272865
5209390060	1.0309	1.2272865
5209390080	1.0309	1.2272865
5209390090	1.0309	1.2272865
5209413000	1.0309	1.2272865
5209416020	1.0309	1.2272865
5209416040	1.0309	1.2272865
5209420020	0.9767	1.1627614
5209420040	0.9767	1.1627614
5209420060	0.9767	1.1627614
5209420080	0.9767	1.1627614
5209430030	1.0309	1.2272865
5209430050	1.0309	1.2272865
5209490020	1.0309	1.2272865
5209490040	1.0309	1.2272865
5209490090	1.0309	1.2272865
5209513000	1.0309	1.2272865
5209516015	1.0852	1.2919306
5209516025	1.0852	1.2919306
5209516032	1.0852	1.2919306
5209516035	1.0852	1.2919306
5209516050	1.0852	1.2919306
5209516090	1.0852	1.2919306
5209520020	1.0852	1.2919306
5209520040	1.0852	1.2919306
5209590015	1.0852	1.2919306
5209590025	1.0852	1.2919306
5209590040	1.0852	1.2919306
5209590060	1.0852	1.2919306
5209590090	1.0852	1.2919306
5210114020	0.6511	0.7751346
5210114040	0.6511	0.7751346
5210114090	0.6511	0.7751346
5210116020	0.6511	0.7751346
5210116040	0.6511	0.7751346
5210116060	0.6511	0.7751346
5210116090	0.6511	0.7751346
5210118020	0.6511	0.7751346
5210118090	0.6511	0.7751346
5210191000	0.6511	0.7751346
5210192020	0.6511	0.7751346
5210192090	0.6511	0.7751346
5210194020	0.6511	0.7751346
5210194090	0.6511	0.7751346
5210196020	0.6511	0.7751346
5210196090	0.6511	0.7751346
5210198020	0.6511	0.7751346
5210198090	0.6511	0.7751346
5210214020	0.6511	0.7751346
5210214040	0.6511	0.7751346
5210214090	0.6511	0.7751346
5210216020	0.6511	0.7751346
5210216040	0.6511	0.7751346
5210216060	0.6511	0.7751346
5210216090	0.6511	0.7751346
5210218020	0.6511	0.7751346
5210218090	0.6511	0.7751346
5210291000	0.6511	0.7751346

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5210292020	0.6511	0.7751346
5210292090	0.6511	0.7751346
5210294020	0.6511	0.7751346
5210294090	0.6511	0.7751346
5210296020	0.6511	0.7751346
5210296090	0.6511	0.7751346
5210298020	0.6511	0.7751346
5210298090	0.6511	0.7751346
5210314020	0.6511	0.7751346
5210314040	0.6511	0.7751346
5210314090	0.6511	0.7751346
5210316020	0.6511	0.7751346
5210316040	0.6511	0.7751346
5210316060	0.6511	0.7751346
5210316090	0.6511	0.7751346
5210318020	0.6511	0.7751346
5210318090	0.6511	0.7751346
5210320000	0.6511	0.7751346
5210392020	0.6511	0.7751346
5210392090	0.6511	0.7751346
5210394020	0.6511	0.7751346
5210394090	0.6511	0.7751346
5210396020	0.6511	0.7751346
5210396090	0.6511	0.7751346
5210398020	0.6511	0.7751346
5210398090	0.6511	0.7751346
5210414000	0.6511	0.7751346
5210416000	0.6511	0.7751346
5210418000	0.6511	0.7751346
5210491000	0.6511	0.7751346
5210492000	0.6511	0.7751346
5210494010	0.6511	0.7751346
5210494020	0.6511	0.7751346
5210494090	0.6511	0.7751346
5210496010	0.6511	0.7751346
5210496020	0.6511	0.7751346
5210496090	0.6511	0.7751346
5210498020	0.6511	0.7751346
5210498090	0.6511	0.7751346
5210514020	0.6511	0.7751346
5210514040	0.6511	0.7751346
5210514090	0.6511	0.7751346
5210516020	0.6511	0.7751346
5210516040	0.6511	0.7751346
5210516060	0.6511	0.7751346
5210516090	0.6511	0.7751346
5210518020	0.6511	0.7751346
5210518090	0.6511	0.7751346
5210591000	0.6511	0.7751346
5210592020	0.6511	0.7751346
5210592090	0.6511	0.7751346
5210594020	0.6511	0.7751346
5210594090	0.6511	0.7751346
5210596020	0.6511	0.7751346
5210596090	0.6511	0.7751346
5210598020	0.6511	0.7751346
5210598090	0.6511	0.7751346
5211110020	0.6511	0.7751346
5211110025	0.6511	0.7751346
5211110035	0.6511	0.7751346
5211110050	0.6511	0.7751346
5211110090	0.6511	0.7751346
5211120020	0.6511	0.7751346
5211120040	0.6511	0.7751346
5211190020	0.6511	0.7751346
5211190040	0.6511	0.7751346
5211190060	0.6511	0.7751346
5211190090	0.6511	0.7751346
5211202120	0.6511	0.7751346

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5211202125	0.6511	0.7751346
5211202135	0.6511	0.7751346
5211202150	0.6511	0.7751346
5211202190	0.6511	0.7751346
5211202220	0.6511	0.7751346
5211202240	0.6511	0.7751346
5211202920	0.6511	0.7751346
5211202940	0.6511	0.7751346
5211202960	0.6511	0.7751346
5211202990	0.6511	0.7751346
5211310020	0.6511	0.7751346
5211310025	0.6511	0.7751346
5211310035	0.6511	0.7751346
5211310050	0.6511	0.7751346
5211310090	0.6511	0.7751346
5211320020	0.6511	0.7751346
5211320040	0.6511	0.7751346
5211390020	0.6511	0.7751346
5211390040	0.6511	0.7751346
5211390060	0.6511	0.7751346
5211390090	0.6511	0.7751346
5211410020	0.6511	0.7751346
5211410040	0.6511	0.7751346
5211420020	0.7054	0.8397787
5211420040	0.7054	0.8397787
5211420060	0.6511	0.7751346
5211420080	0.6511	0.7751346
5211430030	0.6511	0.7751346
5211430050	0.6511	0.7751346
5211490020	0.6511	0.7751346
5211490090	0.6511	0.7751346
5211510020	0.6511	0.7751346
5211510030	0.6511	0.7751346
5211510050	0.6511	0.7751346
5211510090	0.6511	0.7751346
5211520020	0.6511	0.7751346
5211520040	0.6511	0.7751346
5211590015	0.6511	0.7751346
5211590025	0.6511	0.7751346
5211590040	0.6511	0.7751346
5211590060	0.6511	0.7751346
5211590090	0.6511	0.7751346
5212111010	0.5845	0.6958473
5212111020	0.6231	0.7418006
5212116010	0.8681	1.0334731
5212116020	0.8681	1.0334731
5212116030	0.8681	1.0334731
5212116040	0.8681	1.0334731
5212116050	0.8681	1.0334731
5212116060	0.8681	1.0334731
5212116070	0.8681	1.0334731
5212116080	0.8681	1.0334731
5212116090	0.8681	1.0334731
5212121010	0.5845	0.6958473
5212121020	0.6231	0.7418006
5212126010	0.8681	1.0334731
5212126020	0.8681	1.0334731
5212126030	0.8681	1.0334731
5212126040	0.8681	1.0334731
5212126050	0.8681	1.0334731
5212126060	0.8681	1.0334731
5212126070	0.8681	1.0334731
5212126080	0.8681	1.0334731
5212126090	0.8681	1.0334731
5212131010	0.5845	0.6958473
5212131020	0.6231	0.7418006
5212136010	0.8681	1.0334731
5212136020	0.8681	1.0334731
5212136030	0.8681	1.0334731

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5212136040	0.8681	1.0334731
5212136050	0.8681	1.0334731
5212136060	0.8681	1.0334731
5212136070	0.8681	1.0334731
5212136080	0.8681	1.0334731
5212136090	0.8681	1.0334731
5212141010	0.5845	0.6958473
5212141020	0.6231	0.7418006
5212146010	0.8681	1.0334731
5212146020	0.8681	1.0334731
5212146030	0.8681	1.0334731
5212146090	0.8681	1.0334731
5212151010	0.5845	0.6958473
5212151020	0.6231	0.7418006
5212156010	0.8681	1.0334731
5212156020	0.8681	1.0334731
5212156030	0.8681	1.0334731
5212156040	0.8681	1.0334731
5212156050	0.8681	1.0334731
5212156060	0.8681	1.0334731
5212156070	0.8681	1.0334731
5212156080	0.8681	1.0334731
5212156090	0.8681	1.0334731
5212211010	0.5845	0.6958473
5212211020	0.6231	0.7418006
5212216010	0.8681	1.0334731
5212216020	0.8681	1.0334731
5212216030	0.8681	1.0334731
5212216040	0.8681	1.0334731
5212216050	0.8681	1.0334731
5212216060	0.8681	1.0334731
5212216090	0.8681	1.0334731
5212221010	0.5845	0.6958473
5212221020	0.6231	0.7418006
5212226010	0.8681	1.0334731
5212226020	0.8681	1.0334731
5212226030	0.8681	1.0334731
5212226040	0.8681	1.0334731
5212226050	0.8681	1.0334731
5212226060	0.8681	1.0334731
5212226090	0.8681	1.0334731
5212231010	0.5845	0.6958473
5212231020	0.6231	0.7418006
5212236010	0.8681	1.0334731
5212236020	0.8681	1.0334731
5212236030	0.8681	1.0334731
5212236040	0.8681	1.0334731
5212236050	0.8681	1.0334731
5212236060	0.8681	1.0334731
5212236090	0.8681	1.0334731
5212241010	0.5845	0.6958473
5212241020	0.6231	0.7418006
5212246010	0.8681	1.0334731
5212246020	0.7054	0.8397787
5212246030	0.8681	1.0334731
5212246040	0.8681	1.0334731
5212246090	0.8681	1.0334731
5212251010	0.5845	0.6958473
5212251020	0.6231	0.7418006
5212256010	0.8681	1.0334731
5212256020	0.8681	1.0334731
5212256030	0.8681	1.0334731
5212256040	0.8681	1.0334731
5212256050	0.8681	1.0334731
5212256060	0.8681	1.0334731
5212256090	0.8681	1.0334731
5309213005	0.5426	0.6459653
5309213010	0.5426	0.6459653
5309213015	0.5426	0.6459653

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5309213020	0.5426	0.6459653
5309214010	0.2713	0.3229827
5309214090	0.2713	0.3229827
5309293005	0.5426	0.6459653
5309293010	0.5426	0.6459653
5309293015	0.5426	0.6459653
5309293020	0.5426	0.6459653
5309294010	0.2713	0.3229827
5309294090	0.2713	0.3229827
5311003005	0.5426	0.6459653
5311003010	0.5426	0.6459653
5311003015	0.5426	0.6459653
5311003020	0.5426	0.6459653
5311004010	0.8681	1.0334731
5311004020	0.8681	1.0334731
5407810010	0.5426	0.6459653
5407810020	0.5426	0.6459653
5407810030	0.5426	0.6459653
5407810040	0.5426	0.6459653
5407810090	0.5426	0.6459653
5407820010	0.5426	0.6459653
5407820020	0.5426	0.6459653
5407820030	0.5426	0.6459653
5407820040	0.5426	0.6459653
5407820090	0.5426	0.6459653
5407830010	0.5426	0.6459653
5407830020	0.5426	0.6459653
5407830030	0.5426	0.6459653
5407830040	0.5426	0.6459653
5407830090	0.5426	0.6459653
5407840010	0.5426	0.6459653
5407840020	0.5426	0.6459653
5407840030	0.5426	0.6459653
5407840040	0.5426	0.6459653
5407840090	0.5426	0.6459653
5509210000	0.1053	0.1253597
5509220010	0.1053	0.1253597
5509220090	0.1053	0.1253597
5509530030	0.3158	0.3759599
5509530060	0.3158	0.3759599
5509620000	0.5263	0.6265602
5509920000	0.5263	0.6265602
5510300000	0.3684	0.4385802
5511200000	0.3158	0.3759599
5512110010	0.1085	0.1291693
5512110022	0.1085	0.1291693
5512110027	0.1085	0.1291693
5512110030	0.1085	0.1291693
5512110040	0.1085	0.1291693
5512110050	0.1085	0.1291693
5512110060	0.1085	0.1291693
5512110070	0.1085	0.1291693
5512110090	0.1085	0.1291693
5512190005	0.1085	0.1291693
5512190010	0.1085	0.1291693
5512190015	0.1085	0.1291693
5512190022	0.1085	0.1291693
5512190027	0.1085	0.1291693
5512190030	0.1085	0.1291693
5512190035	0.1085	0.1291693
5512190040	0.1085	0.1291693
5512190045	0.1085	0.1291693
5512190050	0.1085	0.1291693
5512190090	0.1085	0.1291693
5512210010	0.0326	0.0388103
5512210020	0.0326	0.0388103
5512210030	0.0326	0.0388103
5512210040	0.0326	0.0388103
5512210060	0.0326	0.0388103

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5512210070	0.0326	0.0388103
5512210090	0.0326	0.0388103
5512290010	0.217	0.2583385
5512910010	0.0543	0.0646442
5512990005	0.0543	0.0646442
5512990010	0.0543	0.0646442
5512990015	0.0543	0.0646442
5512990020	0.0543	0.0646442
5512990025	0.0543	0.0646442
5512990030	0.0543	0.0646442
5512990035	0.0543	0.0646442
5512990040	0.0543	0.0646442
5512990045	0.0543	0.0646442
5512990090	0.0543	0.0646442
5513110020	0.3581	0.4263181
5513110040	0.3581	0.4263181
5513110060	0.3581	0.4263181
5513110090	0.3581	0.4263181
5513120000	0.3581	0.4263181
5513130020	0.3581	0.4263181
5513130040	0.3581	0.4263181
5513130090	0.3581	0.4263181
5513190010	0.3581	0.4263181
5513190020	0.3581	0.4263181
5513190030	0.3581	0.4263181
5513190040	0.3581	0.4263181
5513190050	0.3581	0.4263181
5513190060	0.3581	0.4263181
5513190090	0.3581	0.4263181
5513210020	0.3581	0.4263181
5513210040	0.3581	0.4263181
5513210060	0.3581	0.4263181
5513210090	0.3581	0.4263181
5513230121	0.3581	0.4263181
5513230141	0.3581	0.4263181
5513230191	0.3581	0.4263181
5513290010	0.3581	0.4263181
5513290020	0.3581	0.4263181
5513290030	0.3581	0.4263181
5513290040	0.3581	0.4263181
5513290050	0.3581	0.4263181
5513290060	0.3581	0.4263181
5513290090	0.3581	0.4263181
5513310000	0.3581	0.4263181
5513390111	0.3581	0.4263181
5513390115	0.3581	0.4263181
5513390191	0.3581	0.4263181
5513410020	0.3581	0.4263181
5513410040	0.3581	0.4263181
5513410060	0.3581	0.4263181
5513410090	0.3581	0.4263181
5513491000	0.3581	0.4263181
5513492020	0.3581	0.4263181
5513492040	0.3581	0.4263181
5513492090	0.3581	0.4263181
5513499010	0.3581	0.4263181
5513499020	0.3581	0.4263181
5513499030	0.3581	0.4263181
5513499040	0.3581	0.4263181
5513499050	0.3581	0.4263181
5513499060	0.3581	0.4263181
5513499090	0.3581	0.4263181
5514110020	0.4341	0.5167961
5514110030	0.4341	0.5167961
5514110050	0.4341	0.5167961
5514110090	0.4341	0.5167961
5514120020	0.4341	0.5167961
5514120040	0.4341	0.5167961
5514191020	0.4341	0.5167961

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5514191040	0.4341	0.5167961
5514191090	0.4341	0.5167961
5514199010	0.4341	0.5167961
5514199020	0.4341	0.5167961
5514199030	0.4341	0.5167961
5514199040	0.4341	0.5167961
5514199090	0.4341	0.5167961
5514210020	0.4341	0.5167961
5514210030	0.4341	0.5167961
5514210050	0.4341	0.5167961
5514210090	0.4341	0.5167961
5514220020	0.4341	0.5167961
5514220040	0.4341	0.5167961
5514230020	0.4341	0.5167961
5514230040	0.4341	0.5167961
5514230090	0.4341	0.5167961
5514290010	0.4341	0.5167961
5514290020	0.4341	0.5167961
5514290030	0.4341	0.5167961
5514290040	0.4341	0.5167961
5514290090	0.4341	0.5167961
5514303100	0.4341	0.5167961
5514303210	0.4341	0.5167961
5514303215	0.4341	0.5167961
5514303280	0.4341	0.5167961
5514303310	0.4341	0.5167961
5514303390	0.4341	0.5167961
5514303910	0.4341	0.5167961
5514303920	0.4341	0.5167961
5514303990	0.4341	0.5167961
5514410020	0.4341	0.5167961
5514410030	0.4341	0.5167961
5514410050	0.4341	0.5167961
5514410090	0.4341	0.5167961
5514420020	0.4341	0.5167961
5514420040	0.4341	0.5167961
5514430020	0.4341	0.5167961
5514430040	0.4341	0.5167961
5514430090	0.4341	0.5167961
5514490010	0.4341	0.5167961
5514490020	0.4341	0.5167961
5514490030	0.4341	0.5167961
5514490040	0.4341	0.5167961
5514490090	0.4341	0.5167961
5515110005	0.1085	0.1291693
5515110010	0.1085	0.1291693
5515110015	0.1085	0.1291693
5515110020	0.1085	0.1291693
5515110025	0.1085	0.1291693
5515110030	0.1085	0.1291693
5515110035	0.1085	0.1291693
5515110040	0.1085	0.1291693
5515110045	0.1085	0.1291693
5515110090	0.1085	0.1291693
5515120010	0.1085	0.1291693
5515120022	0.1085	0.1291693
5515120027	0.1085	0.1291693
5515120030	0.1085	0.1291693
5515120040	0.1085	0.1291693
5515120090	0.1085	0.1291693
5515190005	0.1085	0.1291693
5515190010	0.1085	0.1291693
5515190015	0.1085	0.1291693
5515190020	0.1085	0.1291693
5515190025	0.1085	0.1291693
5515190030	0.1085	0.1291693
5515190035	0.1085	0.1291693
5515190040	0.1085	0.1291693
5515190045	0.1085	0.1291693

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5515190090	0.1085	0.1291693
5515290005	0.1085	0.1291693
5515290010	0.1085	0.1291693
5515290015	0.1085	0.1291693
5515290020	0.1085	0.1291693
5515290025	0.1085	0.1291693
5515290030	0.1085	0.1291693
5515290035	0.1085	0.1291693
5515290040	0.1085	0.1291693
5515290045	0.1085	0.1291693
5515290090	0.1085	0.1291693
5515999005	0.1085	0.1291693
5515999010	0.1085	0.1291693
5515999015	0.1085	0.1291693
5515999020	0.1085	0.1291693
5515999025	0.1085	0.1291693
5515999030	0.1085	0.1291693
5515999035	0.1085	0.1291693
5515999040	0.1085	0.1291693
5515999045	0.1085	0.1291693
5515999090	0.1085	0.1291693
5516210010	0.1085	0.1291693
5516210020	0.1085	0.1291693
5516210030	0.1085	0.1291693
5516210040	0.1085	0.1291693
5516210090	0.1085	0.1291693
5516220010	0.1085	0.1291693
5516220020	0.1085	0.1291693
5516220030	0.1085	0.1291693
5516220040	0.1085	0.1291693
5516220090	0.1085	0.1291693
5516230010	0.1085	0.1291693
5516230020	0.1085	0.1291693
5516230030	0.1085	0.1291693
5516230040	0.1085	0.1291693
5516230090	0.1085	0.1291693
5516240010	0.1085	0.1291693
5516240020	0.1085	0.1291693
5516240030	0.1085	0.1291693
5516240040	0.1085	0.1291693
5516240085	0.1085	0.1291693
5516240095	0.1085	0.1291693
5516410010	0.3798	0.4521519
5516410022	0.3798	0.4521519
5516410027	0.3798	0.4521519
5516410030	0.3798	0.4521519
5516410040	0.3798	0.4521519
5516410050	0.3798	0.4521519
5516410060	0.3798	0.4521519
5516410070	0.3798	0.4521519
5516410090	0.3798	0.4521519
5516420010	0.3798	0.4521519
5516420022	0.3798	0.4521519
5516420027	0.3798	0.4521519
5516420030	0.3798	0.4521519
5516420040	0.3798	0.4521519
5516420050	0.3798	0.4521519
5516420060	0.3798	0.4521519
5516420070	0.3798	0.4521519
5516420090	0.3798	0.4521519
5516430010	0.217	0.2583385
5516430015	0.3798	0.4521519
5516430020	0.3798	0.4521519
5516430035	0.3798	0.4521519
5516430080	0.3798	0.4521519
5516440010	0.3798	0.4521519
5516440022	0.3798	0.4521519
5516440027	0.3798	0.4521519
5516440030	0.3798	0.4521519

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5516440040	0.3798	0.4521519
5516440050	0.3798	0.4521519
5516440060	0.3798	0.4521519
5516440070	0.3798	0.4521519
5516440090	0.3798	0.4521519
5516910010	0.0543	0.0646442
5516910020	0.0543	0.0646442
5516910030	0.0543	0.0646442
5516910040	0.0543	0.0646442
5516910050	0.0543	0.0646442
5516910060	0.0543	0.0646442
5516910070	0.0543	0.0646442
5516910090	0.0543	0.0646442
5516920010	0.0543	0.0646442
5516920020	0.0543	0.0646442
5516920030	0.0543	0.0646442
5516920040	0.0543	0.0646442
5516920050	0.0543	0.0646442
5516920060	0.0543	0.0646442
5516920070	0.0543	0.0646442
5516920090	0.0543	0.0646442
5516930010	0.0543	0.0646442
5516930020	0.0543	0.0646442
5516930090	0.0543	0.0646442
5516940010	0.0543	0.0646442
5516940020	0.0543	0.0646442
5516940030	0.0543	0.0646442
5516940040	0.0543	0.0646442
5516940050	0.0543	0.0646442
5516940060	0.0543	0.0646442
5516940070	0.0543	0.0646442
5516940090	0.0543	0.0646442
5601210010	0.9767	1.1627614
5601210090	0.9767	1.1627614
5601220010	0.9767	1.1627614
5601220090	0.9767	1.1627614
5601300000	0.3256	0.3876268
5602101000	0.0543	0.0646442
5602109090	0.4341	0.5167961
5602290000	0.4341	0.5167961
5602909000	0.3256	0.3876268
5603143000	0.2713	0.3229827
5603910010	0.0217	0.0258339
5603910090	0.0651	0.0775016
5603920010	0.0217	0.0258339
5603920090	0.0651	0.0775016
5603930010	0.0217	0.0258339
5603930090	0.0651	0.0775016
5603941090	0.3256	0.3876268
5603943000	0.1628	0.1938134
5603949010	0.0326	0.0388103
5604100000	0.2632	0.3133396
5604909000	0.2105	0.2506003
5605009000	0.1579	0.1879800
5606000010	0.1263	0.1503602
5606000090	0.1263	0.1503602
5607502500	0.1684	0.2004802
5607909000	0.8421	1.0025201
5608901000	1.0526	1.2531203
5608902300	0.6316	0.7519198
5608902700	0.6316	0.7519198
5608903000	0.3158	0.3759599
5609001000	0.8421	1.0025201
5609004000	0.2105	0.2506003
5701101300	0.0526	0.0626203
5701101600	0.0526	0.0626203
5701104000	0.0526	0.0626203
5701109000	0.0526	0.0626203
5701901010	1	1.1905000

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5701901020	1	1.1905000
5701901030	0.0526	0.0626203
5701901090	0.0526	0.0626203
5701902010	0.9474	1.1278797
5701902020	0.9474	1.1278797
5701902030	0.0526	0.0626203
5701902090	0.0526	0.0626203
5702101000	0.0447	0.0532154
5702109010	0.0447	0.0532154
5702109020	0.85	1.0119250
5702109030	0.0447	0.0532154
5702109090	0.0447	0.0532154
5702201000	0.0447	0.0532154
5702311000	0.0447	0.0532154
5702312000	0.0895	0.1065498
5702322000	0.0895	0.1065498
5702391000	0.0895	0.1065498
5702392010	0.8053	0.9587097
5702392090	0.0447	0.0532154
5702411000	0.0447	0.0532154
5702412000	0.0447	0.0532154
5702421000	0.0895	0.1065498
5702422020	0.0895	0.1065498
5702422080	0.0895	0.1065498
5702491020	0.8947	1.0651404
5702491080	0.8947	1.0651404
5702492000	0.0895	0.1065498
5702502000	0.0895	0.1065498
5702504000	0.0447	0.0532154
5702505200	0.0895	0.1065498
5702505600	0.85	1.0119250
5702912000	0.0447	0.0532154
5702913000	0.0447	0.0532154
5702914000	0.0447	0.0532154
5702921000	0.0447	0.0532154
5702929000	0.0447	0.0532154
5702990500	0.8947	1.0651404
5702991500	0.8947	1.0651404
5703201000	0.0452	0.0538106
5703202010	0.0452	0.0538106
5703302000	0.0452	0.0538106
5703900000	0.3615	0.4303658
5705001000	0.0452	0.0538106
5705002005	0.0452	0.0538106
5705002015	0.0452	0.0538106
5705002020	0.7682	0.9145421
5705002030	0.0452	0.0538106
5705002090	0.1808	0.2152424
5801210000	0.9767	1.1627614
5801221000	0.9767	1.1627614
5801229000	0.9767	1.1627614
5801230000	0.9767	1.1627614
5801260010	0.7596	0.9043038
5801260020	0.7596	0.9043038
5801271000	0.9767	1.1627614
5801275010	1.0852	1.2919306
5801275020	0.9767	1.1627614
5801310000	0.217	0.2583385
5801320000	0.217	0.2583385
5801330000	0.217	0.2583385
5801360010	0.217	0.2583385
5801360020	0.217	0.2583385
5802110000	1.0309	1.2272865
5802190000	1.0309	1.2272865
5802200020	0.1085	0.1291693
5802200090	0.3256	0.3876268
5802300030	0.4341	0.5167961
5802300090	0.1085	0.1291693
5803001000	1.0852	1.2919306

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
5803002000	0.8681	1.0334731
5803003000	0.8681	1.0334731
5803005000	0.3256	0.3876268
5804101000	0.4341	0.5167961
5804109090	0.2193	0.2610767
5804291000	0.8772	1.0443066
5804300020	0.3256	0.3876268
5805001000	0.1085	0.1291693
5805003000	1.0852	1.2919306
5806101000	0.8681	1.0334731
5806103090	0.217	0.2583385
5806200010	0.2577	0.3067919
5806200090	0.2577	0.3067919
5806310000	0.8681	1.0334731
5806393080	0.217	0.2583385
5806400000	0.0814	0.0969067
5807100510	0.8681	1.0334731
5807102010	0.8681	1.0334731
5807900510	0.8681	1.0334731
5807902010	0.8681	1.0334731
5808104000	0.217	0.2583385
5808107000	0.217	0.2583385
5808900010	0.4341	0.5167961
5810100000	0.3256	0.3876268
5810910010	0.7596	0.9043038
5810910020	0.7596	0.9043038
5810921000	0.217	0.2583385
5810929030	0.217	0.2583385
5810929050	0.217	0.2583385
5810929080	0.217	0.2583385
5811002000	0.8681	1.0334731
5901102000	0.5643	0.6717992
5901904000	0.8139	0.9689480
5903101000	0.4341	0.5167961
5903103000	0.1085	0.1291693
5903201000	0.4341	0.5167961
5903203090	0.1085	0.1291693
5903901000	0.4341	0.5167961
5903903090	0.1085	0.1291693
5904901000	0.0326	0.0388103
5905001000	0.1085	0.1291693
5905009000	0.1085	0.1291693
5906100000	0.4341	0.5167961
5906911000	0.4341	0.5167961
5906913000	0.1085	0.1291693
5906991000	0.4341	0.5167961
5906993000	0.1085	0.1291693
5907002500	0.3798	0.4521519
5907003500	0.3798	0.4521519
5907008090	0.3798	0.4521519
5908000000	0.7813	0.9301377
5909001000	0.6837	0.8139449
5909002000	0.4883	0.5813212
5910001010	0.3798	0.4521519
5910001020	0.3798	0.4521519
5910001030	0.3798	0.4521519
5910001060	0.3798	0.4521519
5910001070	0.3798	0.4521519
5910001090	0.6837	0.8139449
5910009000	0.5697	0.6782279
5911101000	0.1736	0.2066708
5911102000	0.0434	0.0516677
5911201000	0.4341	0.5167961
5911310010	0.4341	0.5167961
5911310020	0.4341	0.5167961
5911310030	0.4341	0.5167961
5911310080	0.4341	0.5167961
5911320010	0.4341	0.5167961
5911320020	0.4341	0.5167961
5911320030	0.4341	0.5167961
5911320080	0.4341	0.5167961
5911400000	0.5426	0.6459653
5911900040	0.3158	0.3759599
5911900080	0.2105	0.2506003
6001106000	0.1096	0.1304788
6001210000	0.9868	1.1747854
6001220000	0.1096	0.1304788
6001290000	0.1096	0.1304788
6001910010	0.8772	1.0443066
6001910020	0.8772	1.0443066
6001920010	0.0548	0.0652394
6001920020	0.0548	0.0652394
6001920030	0.0548	0.0652394
6001920040	0.0548	0.0652394
6001999000	0.1096	0.1304788
6002404000	0.7401	0.8810891
6002408020	0.1974	0.2350047
6002408080	0.1974	0.2350047
6002904000	0.7895	0.9398998
6002908020	0.1974	0.2350047
6002908080	0.1974	0.2350047
6003201000	0.8772	1.0443066
6003203000	0.8772	1.0443066
6003301000	0.1096	0.1304788
6003306000	0.1096	0.1304788
6003401000	0.1096	0.1304788
6003406000	0.1096	0.1304788
6003901000	0.1096	0.1304788
6003909000	0.1096	0.1304788
6004100010	0.2961	0.3525071
6004100025	0.2961	0.3525071
6004100085	0.2961	0.3525071
6004902010	0.2961	0.3525071
6004902025	0.2961	0.3525071
6004902085	0.2961	0.3525071
6004909000	0.2961	0.3525071
6005210000	0.7127	0.8484694
6005220000	0.7127	0.8484694
6005230000	0.7127	0.8484694
6005240000	0.7127	0.8484694
6005360010	0.1096	0.1304788
6005360080	0.1096	0.1304788
6005370010	0.1096	0.1304788
6005370080	0.1096	0.1304788
6005380010	0.1096	0.1304788
6005380080	0.1096	0.1304788
6005390010	0.1096	0.1304788
6005390080	0.1096	0.1304788
6005410010	0.1096	0.1304788
6005410080	0.1096	0.1304788
6005420010	0.1096	0.1304788
6005420080	0.1096	0.1304788
6005430010	0.1096	0.1304788
6005430080	0.1096	0.1304788
6005440010	0.1096	0.1304788
6005440080	0.1096	0.1304788
6005909000	0.1096	0.1304788
6006211000	1.0965	1.3053833
6006219020	0.7675	0.9137088
6006219080	0.7675	0.9137088
6006221000	1.0965	1.3053833
6006229020	0.7675	0.9137088
6006229080	0.7675	0.9137088
6006231000	1.0965	1.3053833
6006239020	0.7675	0.9137088
6006239080	0.7675	0.9137088
6006241000	1.0965	1.3053833
6006249020	0.7675	0.9137088
6006249080	0.7675	0.9137088
6006310020	0.3289	0.3915555
6006310040	0.3289	0.3915555
6006310060	0.3289	0.3915555
6006310080	0.3289	0.3915555
6006320020	0.3289	0.3915555
6006320040	0.3289	0.3915555
6006320060	0.3289	0.3915555
6006320080	0.3289	0.3915555
6006330020	0.3289	0.3915555
6006330040	0.3289	0.3915555
6006330060	0.3289	0.3915555
6006330080	0.3289	0.3915555
6006340020	0.3289	0.3915555
6006340040	0.3289	0.3915555
6006340060	0.3289	0.3915555
6006340080	0.3289	0.3915555
6006410025	0.3289	0.3915555
6006410085	0.3289	0.3915555
6006420025	0.3289	0.3915555
6006420085	0.3289	0.3915555
6006430025	0.3289	0.3915555
6006430085	0.3289	0.3915555
6006440025	0.3289	0.3915555
6006440085	0.3289	0.3915555
6006909000	0.1096	0.1304788
6101200010	1.02	1.2143100
6101200020	1.02	1.2143100
6101301000	0.2072	0.2466716
6101900500	0.1912	0.2276236
6101909010	0.5737	0.6829899
6101909030	0.51	0.6071550
6101909060	0.255	0.3035775
6102100000	0.255	0.3035775
6102200010	0.9562	1.1383561
6102200020	0.9562	1.1383561
6102300500	0.1785	0.2125043
6102909005	0.5737	0.6829899
6102909015	0.4462	0.5312011
6102909030	0.255	0.3035775
6103101000	0.0637	0.0758349
6103104000	0.1218	0.1450029
6103105000	0.1218	0.1450029
6103106010	0.8528	1.0152584
6103106015	0.8528	1.0152584
6103106030	0.8528	1.0152584
6103109010	0.5482	0.6526321
6103109020	0.5482	0.6526321
6103109030	0.5482	0.6526321
6103109040	0.1218	0.1450029
6103109050	0.1218	0.1450029
6103109080	0.1827	0.2175044
6103320000	0.8722	1.0383541
6103398010	0.7476	0.8900178
6103398030	0.3738	0.4450089
6103398060	0.2492	0.2966726
6103411010	0.3576	0.4257228
6103411020	0.3576	0.4257228
6103412000	0.3576	0.4257228
6103421020	0.8343	0.9932342
6103421035	0.8343	0.9932342
6103421040	0.8343	0.9932342
6103421050	0.8343	0.9932342
6103421065	0.8343	0.9932342
6103421070	0.8343	0.9932342
6103422010	0.8343	0.9932342
6103422015	0.8343	0.9932342
6103422025	0.8343	0.9932342
6103431520	0.2384	0.2838152

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6103431535	0.2384	0.2838152
6103431540	0.2384	0.2838152
6103431550	0.2384	0.2838152
6103431565	0.2384	0.2838152
6103431570	0.2384	0.2838152
6103432020	0.2384	0.2838152
6103432025	0.2384	0.2838152
6103491020	0.2437	0.2901249
6103491060	0.2437	0.2901249
6103492000	0.2437	0.2901249
6103498010	0.5482	0.6526321
6103498014	0.3655	0.4351278
6103498024	0.2437	0.2901249
6103498026	0.2437	0.2901249
6103498034	0.5482	0.6526321
6103498038	0.3655	0.4351278
6103498060	0.2437	0.2901249
6104196010	0.8722	1.0383541
6104196020	0.8722	1.0383541
6104196030	0.8722	1.0383541
6104196040	0.8722	1.0383541
6104198010	0.5607	0.6675134
6104198020	0.5607	0.6675134
6104198030	0.5607	0.6675134
6104198040	0.5607	0.6675134
6104198060	0.3738	0.4450089
6104198090	0.2492	0.2966726
6104320000	0.8722	1.0383541
6104392010	0.5607	0.6675134
6104392030	0.3738	0.4450089
6104392090	0.2492	0.2966726
6104420010	0.8528	1.0152584
6104420020	0.8528	1.0152584
6104499010	0.5482	0.6526321
6104499030	0.3655	0.4351278
6104499060	0.2437	0.2901249
6104520010	0.8822	1.0502591
6104520020	0.8822	1.0502591
6104598010	0.5672	0.6752516
6104598030	0.3781	0.4501281
6104598090	0.2521	0.3001251
6104610010	0.2384	0.2838152
6104610020	0.2384	0.2838152
6104610030	0.2384	0.2838152
6104621010	0.7509	0.8939465
6104621020	0.8343	0.9932342
6104621030	0.8343	0.9932342
6104622006	0.7151	0.8513266
6104622011	0.8343	0.9932342
6104622016	0.7151	0.8513266
6104622021	0.8343	0.9932342
6104622026	0.7151	0.8513266
6104622028	0.8343	0.9932342
6104622030	0.8343	0.9932342
6104622050	0.8343	0.9932342
6104622060	0.8343	0.9932342
6104631020	0.2384	0.2838152
6104631030	0.2384	0.2838152
6104632006	0.8343	0.9932342
6104632011	0.8343	0.9932342
6104632016	0.7151	0.8513266
6104632021	0.8343	0.9932342
6104632026	0.3576	0.4257228
6104632028	0.3576	0.4257228
6104632030	0.3576	0.4257228
6104632050	0.7151	0.8513266
6104632060	0.3576	0.4257228
6104691000	0.3655	0.4351278
6104692030	0.3655	0.4351278
6104692060	0.3655	0.4351278
6104698010	0.5482	0.6526321
6104698014	0.3655	0.4351278
6104698020	0.2437	0.2901249
6104698022	0.5482	0.6526321
6104698026	0.3655	0.4351278
6104698038	0.2437	0.2901249
6104698040	0.2437	0.2901249
6105100010	0.9332	1.1109746
6105100020	0.9332	1.1109746
6105100030	0.9332	1.1109746
6105202010	0.2916	0.3471498
6105202020	0.2916	0.3471498
6105202030	0.2916	0.3471498
6105908010	0.5249	0.6248935
6105908030	0.3499	0.4165560
6105908060	0.2333	0.2777437
6106100010	0.9332	1.1109746
6106100020	0.9332	1.1109746
6106100030	0.9332	1.1109746
6106202010	0.2916	0.3471498
6106202020	0.4666	0.5554873
6106202030	0.2916	0.3471498
6106901500	0.0583	0.0694062
6106902510	0.5249	0.6248935
6106902530	0.3499	0.4165560
6106902550	0.2916	0.3471498
6106903010	0.5249	0.6248935
6106903030	0.3499	0.4165560
6106903040	0.2916	0.3471498
6107110010	1.0727	1.2770494
6107110020	1.0727	1.2770494
6107120010	0.4767	0.5675114
6107120020	0.4767	0.5675114
6107191000	0.1192	0.1419076
6107210010	0.8343	0.9932342
6107210020	0.7151	0.8513266
6107220010	0.3576	0.4257228
6107220015	0.1192	0.1419076
6107220025	0.2384	0.2838152
6107299000	0.1788	0.2128614
6107910030	1.1918	1.4188379
6107910040	1.1918	1.4188379
6107910090	0.9535	1.1351418
6107991030	0.3576	0.4257228
6107991040	0.3576	0.4257228
6107991090	0.3576	0.4257228
6107999000	0.1192	0.1419076
6108199010	1.0611	1.2632396
6108199030	0.2358	0.2807199
6108210010	1.179	1.4035995
6108210020	1.179	1.4035995
6108299000	0.3537	0.4210799
6108310010	1.0611	1.2632396
6108310020	1.0611	1.2632396
6108320010	0.2358	0.2807199
6108320015	0.2358	0.2807199
6108320025	0.2358	0.2807199
6108398000	0.3537	0.4210799
6108910005	1.179	1.4035995
6108910015	1.179	1.4035995
6108910025	1.179	1.4035995
6108910030	1.179	1.4035995
6108910040	1.179	1.4035995
6108920005	0.2358	0.2807199
6108920015	0.2358	0.2807199
6108920025	0.2358	0.2807199
6108920030	0.2358	0.2807199
6108920040	0.2358	0.2807199
6108999000	0.3537	0.4210799
6109100004	1.0022	1.1931191
6109100007	1.0022	1.1931191
6109100011	1.0022	1.1931191
6109100012	1.0022	1.1931191
6109100014	1.0022	1.1931191
6109100018	1.0022	1.1931191
6109100023	1.0022	1.1931191
6109100027	1.0022	1.1931191
6109100037	1.0022	1.1931191
6109100040	1.0022	1.1931191
6109100045	1.0022	1.1931191
6109100060	1.0022	1.1931191
6109100065	1.0022	1.1931191
6109100070	1.0022	1.1931191
6109901007	0.2948	0.3509594
6109901009	0.2948	0.3509594
6109901013	0.2948	0.3509594
6109901025	0.2948	0.3509594
6109901047	0.2948	0.3509594
6109901049	0.2948	0.3509594
6109901050	0.2948	0.3509594
6109901060	0.2948	0.3509594
6109901065	0.2948	0.3509594
6109901070	0.2948	0.3509594
6109901075	0.2948	0.3509594
6109901090	0.2948	0.3509594
6109908010	0.3499	0.4165560
6109908030	0.2333	0.2777437
6110201010	0.7476	0.8900178
6110201020	0.7476	0.8900178
6110201022	0.7476	0.8900178
6110201024	0.7476	0.8900178
6110201026	0.7476	0.8900178
6110201029	0.7476	0.8900178
6110201031	0.7476	0.8900178
6110201033	0.7476	0.8900178
6110202005	1.1214	1.3350267
6110202010	1.1214	1.3350267
6110202015	1.1214	1.3350267
6110202020	1.1214	1.3350267
6110202025	1.1214	1.3350267
6110202030	1.1214	1.3350267
6110202035	1.1214	1.3350267
6110202041	1.0965	1.3053833
6110202044	1.0965	1.3053833
6110202046	1.0965	1.3053833
6110202049	1.0965	1.3053833
6110202067	1.0965	1.3053833
6110202069	1.0965	1.3053833
6110202077	1.0965	1.3053833
6110202079	1.0965	1.3053833
6110909010	0.5607	0.6675134
6110909012	0.1246	0.1483363
6110909014	0.3738	0.4450089
6110909026	0.5607	0.6675134
6110909028	0.1869	0.2225045
6110909030	0.3738	0.4450089
6110909044	0.5607	0.6675134
6110909046	0.5607	0.6675134
6110909052	0.3738	0.4450089
6110909054	0.3738	0.4450089
6110909064	0.2492	0.2966726
6110909066	0.2492	0.2966726
6110909067	0.5607	0.6675134
6110909069	0.5607	0.6675134
6110909071	0.5607	0.6675134
6110909073	0.5607	0.6675134
6110909079	0.3738	0.4450089

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6110909080	0.3738	0.4450089
6110909081	0.3738	0.4450089
6110909082	0.3738	0.4450089
6110909088	0.2492	0.2966726
6110909090	0.2492	0.2966726
6111201000	1.1918	1.4188379
6111202000	1.1918	1.4188379
6111203000	0.9535	1.1351418
6111204000	0.9535	1.1351418
6111205000	0.9535	1.1351418
6111206010	0.9535	1.1351418
6111206020	0.9535	1.1351418
6111206030	0.9535	1.1351418
6111206050	0.9535	1.1351418
6111206070	0.9535	1.1351418
6111301000	0.2384	0.2838152
6111302000	0.2384	0.2838152
6111303000	0.2384	0.2838152
6111304000	0.2384	0.2838152
6111305010	0.2384	0.2838152
6111305015	0.2384	0.2838152
6111305020	0.2384	0.2838152
6111305030	0.2384	0.2838152
6111305050	0.2384	0.2838152
6111305070	0.2384	0.2838152
6111901000	0.2384	0.2838152
6111902000	0.2384	0.2838152
6111903000	0.2384	0.2838152
6111904000	0.2384	0.2838152
6111905010	0.2384	0.2838152
6111905020	0.2384	0.2838152
6111905030	0.2384	0.2838152
6111905050	0.2384	0.2838152
6111905070	0.2384	0.2838152
6112110010	0.9535	1.1351418
6112110020	0.9535	1.1351418
6112110030	0.9535	1.1351418
6112110040	0.9535	1.1351418
6112110050	0.9535	1.1351418
6112110060	0.9535	1.1351418
6112120010	0.2384	0.2838152
6112120020	0.2384	0.2838152
6112120030	0.2384	0.2838152
6112120040	0.2384	0.2838152
6112120050	0.2384	0.2838152
6112120060	0.2384	0.2838152
6112191010	0.2492	0.2966726
6112191020	0.2492	0.2966726
6112191030	0.2492	0.2966726
6112191040	0.2492	0.2966726
6112191050	0.2492	0.2966726
6112191060	0.2492	0.2966726
6112201060	0.2492	0.2966726
6112201070	0.2492	0.2966726
6112201080	0.2492	0.2966726
6112201090	0.2492	0.2966726
6112202010	0.8722	1.0383541
6112202020	0.3738	0.4450089
6112202030	0.2492	0.2966726
6112310010	0.1192	0.1419076
6112310020	0.1192	0.1419076
6112390010	1.0727	1.2770494
6112410010	0.1192	0.1419076
6112410020	0.1192	0.1419076
6112410030	0.1192	0.1419076
6112410040	0.1192	0.1419076
6112490010	0.8939	1.0641880
6113001005	0.1246	0.1483363
6113001010	0.1246	0.1483363

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6113001012	0.1246	0.1483363
6113009015	0.3489	0.4153655
6113009020	0.3489	0.4153655
6113009038	0.3489	0.4153655
6113009042	0.3489	0.4153655
6113009055	0.3489	0.4153655
6113009060	0.3489	0.4153655
6113009074	0.3489	0.4153655
6113009082	0.3489	0.4153655
6114200005	0.9747	1.1603804
6114200010	0.9747	1.1603804
6114200015	0.8528	1.0152584
6114200020	0.8528	1.0152584
6114200035	0.8528	1.0152584
6114200040	0.8528	1.0152584
6114200042	0.3655	0.4351278
6114200044	0.8528	1.0152584
6114200046	0.8528	1.0152584
6114200048	0.8528	1.0152584
6114200052	0.8528	1.0152584
6114200055	0.8528	1.0152584
6114200060	0.8528	1.0152584
6114301010	0.2437	0.2901249
6114301020	0.2437	0.2901249
6114302060	0.1218	0.1450029
6114303014	0.2437	0.2901249
6114303020	0.2437	0.2901249
6114303030	0.2437	0.2901249
6114303042	0.2437	0.2901249
6114303044	0.2437	0.2901249
6114303052	0.2437	0.2901249
6114303054	0.2437	0.2901249
6114303060	0.2437	0.2901249
6114303070	0.2437	0.2901249
6114909045	0.5482	0.6526321
6114909055	0.3655	0.4351278
6114909070	0.3655	0.4351278
6115100500	0.4386	0.5221533
6115101510	1.0965	1.3053833
6115103000	0.9868	1.1747854
6115106000	0.1096	0.1304788
6115298010	1.0965	1.3053833
6115309030	0.7675	0.9137088
6115956000	0.9868	1.1747854
6115959000	0.9868	1.1747854
6115966020	0.2193	0.2610767
6115991420	0.2193	0.2610767
6115991920	0.2193	0.2610767
6115999000	0.1096	0.1304788
6116101300	0.3463	0.4122702
6116101720	0.8079	0.9618050
6116104810	0.4444	0.5290582
6116105510	0.6464	0.7695392
6116107510	0.6464	0.7695392
6116109500	0.1616	0.1923848
6116920500	0.8079	0.9618050
6116920800	0.8079	0.9618050
6116926410	1.0388	1.2366914
6116926420	1.0388	1.2366914
6116926430	1.1542	1.3740751
6116926440	1.0388	1.2366914
6116927450	1.0388	1.2366914
6116927460	1.1542	1.3740751
6116927470	1.0388	1.2366914
6116928800	1.0388	1.2366914
6116929400	1.0388	1.2366914
6116938800	0.1154	0.1373837
6116939400	0.1154	0.1373837
6116994800	0.1154	0.1373837

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6116995400	0.1154	0.1373837
6116999510	0.4617	0.5496539
6116999530	0.3463	0.4122702
6117106010	0.9234	1.0993077
6117106020	0.2308	0.2747674
6117808500	0.9234	1.0993077
6117808710	1.1542	1.3740751
6117808770	0.1731	0.2060756
6117809510	0.9234	1.0993077
6117809540	0.3463	0.4122702
6117809570	0.1731	0.2060756
6117909003	1.1542	1.3740751
6117909015	0.2308	0.2747674
6117909020	1.1542	1.3740751
6117909040	1.1542	1.3740751
6117909060	1.1542	1.3740751
6117909080	1.1542	1.3740751
6201121000	0.8981	1.0691881
6201122010	0.8482	1.0097821
6201122020	0.8482	1.0097821
6201122025	0.9979	1.1880000
6201122035	0.9979	1.1880000
6201122050	0.6486	0.7721583
6201122060	0.6486	0.7721583
6201134015	0.1996	0.2376238
6201134020	0.1996	0.2376238
6201134030	0.2495	0.2970298
6201134040	0.2495	0.2970298
6201199010	0.5613	0.6682277
6201199030	0.3742	0.4454851
6201199060	0.3742	0.4454851
6201920500	0.8779	1.0451400
6201921700	1.0974	1.3064547
6201921905	0.9754	1.1612137
6201921910	0.9754	1.1612137
6201921921	1.2193	1.4515767
6201921931	1.2193	1.4515767
6201921941	1.2193	1.4515767
6201921951	0.9754	1.1612137
6201921961	0.9754	1.1612137
6201923000	0.8779	1.0451400
6201923500	1.0974	1.3064547
6201924505	0.9754	1.1612137
6201924510	0.9754	1.1612137
6201924521	1.2193	1.4515767
6201924531	1.2193	1.4515767
6201924541	1.2193	1.4515767
6201924551	0.9754	1.1612137
6201924561	0.9754	1.1612137
6201931500	0.2926	0.3483403
6201931810	0.2439	0.2903630
6201931820	0.2439	0.2903630
6201934911	0.2439	0.2903630
6201934921	0.2439	0.2903630
6201935000	0.2926	0.3483403
6201935210	0.2439	0.2903630
6201935220	0.2439	0.2903630
6201936511	0.2439	0.2903630
6201936521	0.2439	0.2903630
6201991510	0.5487	0.6532274
6201991530	0.3658	0.4354849
6201991560	0.2439	0.2903630
6201998010	0.5487	0.6532274
6201998030	0.3658	0.4354849
6201998060	0.2439	0.2903630
6202121000	0.8879	1.0570450
6202122010	1.0482	1.2478821
6202122020	1.0482	1.2478821
6202122025	1.2332	1.4681246

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6202122035	1.2332	1.4681246
6202122050	0.8016	0.9543048
6202122060	0.8016	0.9543048
6202134005	0.2524	0.3004822
6202134010	0.2524	0.3004822
6202134020	0.3155	0.3756028
6202134030	0.3155	0.3756028
6202199010	0.5678	0.6759659
6202199030	0.3786	0.4507233
6202199060	0.2524	0.3004822
6202920300	0.9865	1.1744283
6202920500	0.9865	1.1744283
6202921210	0.9865	1.1744283
6202921220	0.9865	1.1744283
6202921226	1.2332	1.4681246
6202921231	1.2332	1.4681246
6202921261	0.9865	1.1744283
6202921271	0.9865	1.1744283
6202922500	0.9865	1.1744283
6202923000	0.9865	1.1744283
6202929010	0.9865	1.1744283
6202929020	0.9865	1.1744283
6202929026	1.2332	1.4681246
6202929031	1.2332	1.4681246
6202929061	0.9865	1.1744283
6202929071	0.9865	1.1744283
6202930100	0.296	0.3523880
6202930310	0.2466	0.2935773
6202930320	0.2466	0.2935773
6202930911	0.2466	0.2935773
6202930921	0.2466	0.2935773
6202931500	0.296	0.3523880
6202932510	0.2466	0.2935773
6202932520	0.2466	0.2935773
6202935511	0.2466	0.2935773
6202935521	0.2466	0.2935773
6202991511	0.5549	0.6606085
6202991531	0.37	0.4404850
6202991561	0.2466	0.2935773
6202998011	0.5549	0.6606085
6202998031	0.37	0.4404850
6202998061	0.2466	0.2935773
6203122010	0.1233	0.1467887
6203122020	0.1233	0.1467887
6203191010	0.9865	1.1744283
6203191020	0.9865	1.1744283
6203191030	0.9865	1.1744283
6203199010	0.5549	0.6606085
6203199020	0.5549	0.6606085
6203199030	0.5549	0.6606085
6203199050	0.37	0.4404850
6203199080	0.2466	0.2935773
6203221000	1.2332	1.4681246
6203321000	0.6782	0.8073971
6203322010	1.1715	1.3946708
6203322020	1.1715	1.3946708
6203322030	1.1715	1.3946708
6203322040	1.1715	1.3946708
6203322050	1.1715	1.3946708
6203332010	0.1233	0.1467887
6203332020	0.1233	0.1467887
6203392010	0.1233	0.1467887
6203392020	0.1233	0.1467887
6203399010	0.5549	0.6606085
6203399030	0.37	0.4404850
6203399060	0.2466	0.2935773
6203420300	1.0616	1.2638348
6203420505	0.7077	0.8425169
6203420510	0.9436	1.1233558

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6203420525	0.9436	1.1233558
6203420550	0.9436	1.1233558
6203420590	0.9436	1.1233558
6203420703	1.0616	1.2638348
6203420706	1.1796	1.4043138
6203420711	1.1796	1.4043138
6203420716	0.9436	1.1233558
6203420721	1.1796	1.4043138
6203420726	1.1796	1.4043138
6203420731	1.1796	1.4043138
6203420736	1.1796	1.4043138
6203420741	0.9436	1.1233558
6203420746	0.9436	1.1233558
6203420751	0.8752	1.0419256
6203420756	0.8752	1.0419256
6203420761	0.8752	1.0419256
6203421700	1.0616	1.2638348
6203422505	0.7077	0.8425169
6203422510	0.9436	1.1233558
6203422525	0.9436	1.1233558
6203422550	0.9436	1.1233558
6203422590	0.9436	1.1233558
6203424503	1.0616	1.2638348
6203424506	1.1796	1.4043138
6203424511	1.1796	1.4043138
6203424516	0.9436	1.1233558
6203424521	1.1796	1.4043138
6203424526	1.1796	1.4043138
6203424531	1.1796	1.4043138
6203424536	1.1796	1.4043138
6203424541	0.9436	1.1233558
6203424546	0.9436	1.1233558
6203424551	0.8752	1.0419256
6203424556	0.8752	1.0419256
6203424561	0.8752	1.0419256
6203430100	0.1887	0.2246474
6203430300	0.118	0.1404790
6203430505	0.118	0.1404790
6203430510	0.2359	0.2808390
6203430525	0.2359	0.2808390
6203430550	0.2359	0.2808390
6203430590	0.2359	0.2808390
6203431110	0.059	0.0702395
6203431190	0.059	0.0702395
6203431310	0.1167	0.1389314
6203431315	0.1167	0.1389314
6203431320	0.1167	0.1389314
6203431330	0.1167	0.1389314
6203431335	0.1167	0.1389314
6203431340	0.1167	0.1389314
6203434500	0.1887	0.2246474
6203435500	0.118	0.1404790
6203436005	0.118	0.1404790
6203436010	0.2359	0.2808390
6203436025	0.2359	0.2808390
6203436050	0.2359	0.2808390
6203436090	0.2359	0.2808390
6203436500	0.4128	0.4914384
6203437510	0.059	0.0702395
6203437590	0.059	0.0702395
6203439010	0.1167	0.1389314
6203439015	0.1167	0.1389314
6203439020	0.1167	0.1389314
6203439030	0.1167	0.1389314
6203439035	0.1167	0.1389314
6203439040	0.1167	0.1389314
6203490105	0.118	0.1404790
6203490110	0.2359	0.2808390
6203490125	0.2359	0.2808390

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6203490150	0.2359	0.2808390
6203490190	0.2359	0.2808390
6203490515	0.2359	0.2808390
6203490520	0.2359	0.2808390
6203490530	0.118	0.1404790
6203490545	0.118	0.1404790
6203490550	0.118	0.1404790
6203490560	0.118	0.1404790
6203490920	0.5308	0.6319174
6203490930	0.3539	0.4213180
6203490945	0.2359	0.2808390
6203492505	0.118	0.1404790
6203492510	0.2359	0.2808390
6203492525	0.2359	0.2808390
6203492550	0.2359	0.2808390
6203492590	0.2359	0.2808390
6203493500	0.4128	0.4914384
6203495015	0.2359	0.2808390
6203495020	0.2359	0.2808390
6203495030	0.118	0.1404790
6203495045	0.118	0.1404790
6203495050	0.118	0.1404790
6203495060	0.118	0.1404790
6203499020	0.5308	0.6319174
6203499030	0.3539	0.4213180
6203499045	0.2359	0.2808390
6204110000	0.0617	0.0734539
6204120010	0.9865	1.1744283
6204120020	0.9865	1.1744283
6204120030	0.9865	1.1744283
6204120040	0.9865	1.1744283
6204132010	0.1233	0.1467887
6204132020	0.1233	0.1467887
6204192000	0.1233	0.1467887
6204198010	0.5549	0.6606085
6204198020	0.5549	0.6606085
6204198030	0.5549	0.6606085
6204198040	0.5549	0.6606085
6204198060	0.3083	0.3670312
6204198090	0.2466	0.2935773
6204221000	1.2332	1.4681246
6204321000	0.6782	0.8073971
6204322010	1.1715	1.3946708
6204322020	1.1715	1.3946708
6204322030	0.9865	1.1744283
6204322040	0.9865	1.1744283
6204398010	0.5549	0.6606085
6204398030	0.3083	0.3670312
6204412010	0.0603	0.0717872
6204412020	0.0603	0.0717872
6204421000	1.2058	1.4355049
6204422000	0.6632	0.7895396
6204423010	1.2058	1.4355049
6204423020	1.2058	1.4355049
6204423030	0.9043	1.0765692
6204423040	0.9043	1.0765692
6204423050	0.9043	1.0765692
6204423060	0.9043	1.0765692
6204431000	0.4823	0.5741782
6204432000	0.0603	0.0717872
6204442000	0.4316	0.5138198
6204495010	0.5549	0.6606085
6204495030	0.2466	0.2935773
6204510010	0.0631	0.0751206
6204510020	0.0631	0.0751206
6204521000	1.2618	1.5021729
6204522010	1.1988	1.4271714
6204522020	1.1988	1.4271714
6204522030	1.1988	1.4271714

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6204522040	1.1988	1.4271714
6204522070	1.0095	1.2018098
6204522080	1.0095	1.2018098
6204531000	0.4416	0.5257248
6204532010	0.0631	0.0751206
6204532020	0.0631	0.0751206
6204533010	0.2524	0.3004822
6204533020	0.2524	0.3004822
6204591000	0.4416	0.5257248
6204594010	0.5678	0.6759659
6204594030	0.2524	0.3004822
6204594060	0.2524	0.3004822
6204610510	0.059	0.0702395
6204610520	0.059	0.0702395
6204611510	0.059	0.0702395
6204611520	0.059	0.0702395
6204611530	0.059	0.0702395
6204611540	0.118	0.1404790
6204616010	0.059	0.0702395
6204616020	0.059	0.0702395
6204618010	0.059	0.0702395
6204618020	0.059	0.0702395
6204618030	0.059	0.0702395
6204618040	0.118	0.1404790
6204620300	0.8681	1.0334731
6204620505	0.7077	0.8425169
6204620510	0.9436	1.1233558
6204620525	0.9436	1.1233558
6204620550	0.9436	1.1233558
6204621503	1.0616	1.2638348
6204621506	1.1796	1.4043138
6204621511	1.1796	1.4043138
6204621521	0.9436	1.1233558
6204621526	1.1796	1.4043138
6204621531	1.1796	1.4043138
6204621536	1.1796	1.4043138
6204621541	1.1796	1.4043138
6204621546	0.9436	1.1233558
6204621551	0.9436	1.1233558
6204621556	0.9335	1.1113318
6204621561	0.9335	1.1113318
6204621566	0.9335	1.1113318
6204625000	0.8681	1.0334731
6204626005	0.7077	0.8425169
6204626010	0.9436	1.1233558
6204626025	0.9436	1.1233558
6204626050	0.9436	1.1233558
6204627000	1.1796	1.4043138
6204628003	1.0616	1.2638348
6204628006	1.1796	1.4043138
6204628011	1.1796	1.4043138
6204628021	0.9436	1.1233558
6204628026	1.1796	1.4043138
6204628031	1.1796	1.4043138
6204628036	1.1796	1.4043138
6204628041	1.1796	1.4043138
6204628046	0.9436	1.1233558
6204628051	0.9436	1.1233558
6204628056	0.9335	1.1113318
6204628061	0.9335	1.1113318
6204628066	0.9335	1.1113318
6204630100	0.2019	0.2403620
6204630200	0.118	0.1404790
6204630305	0.118	0.1404790
6204630310	0.2359	0.2808390
6204630325	0.2359	0.2808390
6204630350	0.2359	0.2808390
6204630810	0.059	0.0702395
6204630820	0.059	0.0702395

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6204630910	0.0603	0.0717872
6204630990	0.0603	0.0717872
6204631110	0.2412	0.2871486
6204631125	0.2412	0.2871486
6204631130	0.2412	0.2871486
6204631132	0.2309	0.2748865
6204631135	0.2309	0.2748865
6204631140	0.2309	0.2748865
6204635000	0.2019	0.2403620
6204635500	0.118	0.1404790
6204636005	0.118	0.1404790
6204636010	0.2359	0.2808390
6204636025	0.2359	0.2808390
6204636050	0.2359	0.2808390
6204636500	0.4718	0.5616779
6204637010	0.059	0.0702395
6204637020	0.059	0.0702395
6204637510	0.0603	0.0717872
6204637590	0.0603	0.0717872
6204639010	0.2412	0.2871486
6204639025	0.2412	0.2871486
6204639030	0.2412	0.2871486
6204639032	0.2309	0.2748865
6204639035	0.2309	0.2748865
6204639040	0.2309	0.2748865
6204690105	0.118	0.1404790
6204690110	0.2359	0.2808390
6204690110	0.2359	0.2808390
6204690125	0.2359	0.2808390
6204690150	0.2359	0.2808390
6204690210	0.059	0.0702395
6204690220	0.059	0.0702395
6204690230	0.059	0.0702395
6204690310	0.2359	0.2808390
6204690320	0.2359	0.2808390
6204690330	0.2359	0.2808390
6204690340	0.2309	0.2748865
6204690350	0.2309	0.2748865
6204690360	0.2309	0.2748865
6204690510	0.5308	0.6319174
6204690530	0.2359	0.2808390
6204690570	0.3539	0.4213180
6204690610	0.5308	0.6319174
6204690630	0.2359	0.2808390
6204690644	0.2359	0.2808390
6204690646	0.2359	0.2808390
6204690650	0.3539	0.4213180
6204691505	0.118	0.1404790
6204691510	0.2359	0.2808390
6204691525	0.2359	0.2808390
6204691525	0.2359	0.2808390
6204691550	0.2359	0.2808390
6204692210	0.059	0.0702395
6204692220	0.059	0.0702395
6204692230	0.059	0.0702395
6204692810	0.2359	0.2808390
6204692820	0.2359	0.2808390
6204692830	0.2359	0.2808390
6204692840	0.2309	0.2748865
6204692850	0.2309	0.2748865
6204692860	0.2309	0.2748865
6204696510	0.5308	0.6319174
6204696530	0.2359	0.2808390
6204696570	0.3539	0.4213180
6204698010	0.5308	0.6319174
6204698030	0.2359	0.2808390
6204698044	0.2359	0.2808390
6204698046	0.2359	0.2808390
6204698050	0.3539	0.4213180

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6205201000	1.1796	1.4043138
6205202003	0.9436	1.1233558
6205202016	0.9436	1.1233558
6205202021	0.9436	1.1233558
6205202026	0.9436	1.1233558
6205202031	0.9436	1.1233558
6205202036	1.0616	1.2638348
6205202041	1.0616	1.2638348
6205202044	1.0616	1.2638348
6205202047	0.9436	1.1233558
6205202051	0.9436	1.1233558
6205202056	0.9436	1.1233558
6205202061	0.9436	1.1233558
6205202066	0.9436	1.1233558
6205202071	0.9436	1.1233558
6205202076	0.9436	1.1233558
6205301000	0.4128	0.4914384
6205302010	0.2949	0.3510785
6205302020	0.2949	0.3510785
6205302030	0.2949	0.3510785
6205302040	0.2949	0.3510785
6205302050	0.2949	0.3510785
6205302055	0.2949	0.3510785
6205302060	0.2949	0.3510785
6205302070	0.2949	0.3510785
6205302075	0.2949	0.3510785
6205302080	0.2949	0.3510785
6205900710	0.118	0.1404790
6205900720	0.118	0.1404790
6205901000	0.2359	0.2808390
6205903010	0.5308	0.6319174
6205903030	0.2359	0.2808390
6205903050	0.1769	0.2105995
6205904010	0.5308	0.6319174
6205904030	0.2359	0.2808390
6205904040	0.2359	0.2808390
6206100010	0.5308	0.6319174
6206100030	0.2359	0.2808390
6206100040	0.118	0.1404790
6206100050	0.2359	0.2808390
6206203010	0.059	0.0702395
6206203020	0.059	0.0702395
6206301000	1.1796	1.4043138
6206302000	0.6488	0.7723964
6206303003	0.9436	1.1233558
6206303011	0.9436	1.1233558
6206303021	0.9436	1.1233558
6206303031	0.9436	1.1233558
6206303041	0.9436	1.1233558
6206303051	0.9436	1.1233558
6206303061	0.9436	1.1233558
6206401000	0.4128	0.4914384
6206403010	0.2949	0.3510785
6206403020	0.2949	0.3510785
6206403025	0.2949	0.3510785
6206403030	0.2949	0.3510785
6206403040	0.2949	0.3510785
6206403050	0.2949	0.3510785
6206900010	0.5308	0.6319174
6206900030	0.2359	0.2808390
6206900040	0.1769	0.2105995
6207110000	1.0281	1.2239531
6207199010	0.3427	0.4079844
6207199030	0.4569	0.5439395
6207210010	1.0502	1.2502631
6207210020	1.0502	1.2502631
6207210030	1.0502	1.2502631
6207210040	1.0502	1.2502631
6207220000	0.3501	0.4167941

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6207291000	0.1167	0.1389314
6207299030	0.1167	0.1389314
6207911000	1.0852	1.2919306
6207913010	1.0852	1.2919306
6207913020	1.0852	1.2919306
6207997520	0.2412	0.2871486
6207998510	0.2412	0.2871486
6207998520	0.2412	0.2871486
6208110000	0.2412	0.2871486
6208192000	1.0852	1.2919306
6208195000	0.1206	0.1435743
6208199000	0.2412	0.2871486
6208210010	1.0026	1.1935953
6208210020	1.0026	1.1935953
6208210030	1.0026	1.1935953
6208220000	0.118	0.1404790
6208299030	0.2359	0.2808390
6208911010	1.0852	1.2919306
6208911020	1.0852	1.2919306
6208913010	1.0852	1.2919306
6208913020	1.0852	1.2919306
6208920010	0.1206	0.1435743
6208920020	0.1206	0.1435743
6208920030	0.1206	0.1435743
6208920040	0.1206	0.1435743
6208992010	0.0603	0.0717872
6208992020	0.0603	0.0717872
6208995010	0.2412	0.2871486
6208995020	0.2412	0.2871486
6208998010	0.2412	0.2871486
6208998020	0.2412	0.2871486
6209201000	1.0967	1.3056214
6209202000	1.039	1.2369295
6209203000	0.9236	1.0995458
6209205030	0.9236	1.0995458
6209205035	0.9236	1.0995458
6209205045	0.9236	1.0995458
6209205050	0.9236	1.0995458
6209301000	0.2917	0.3472689
6209302000	0.2917	0.3472689
6209303010	0.2334	0.2778627
6209303020	0.2334	0.2778627
6209303030	0.2334	0.2778627
6209303040	0.2334	0.2778627
6209900500	0.1154	0.1373837
6209901000	0.2917	0.3472689
6209902000	0.2917	0.3472689
6209903010	0.2917	0.3472689
6209903015	0.2917	0.3472689
6209903020	0.2917	0.3472689
6209903030	0.2917	0.3472689
6209903040	0.2917	0.3472689
6210109010	0.217	0.2583385
6210109040	0.217	0.2583385
6210203000	0.0362	0.0430961
6210205000	0.0844	0.1004782
6210207000	0.1809	0.2153615
6210303000	0.0362	0.0430961
6210305000	0.0844	0.1004782
6210307000	0.0362	0.0430961
6210309020	0.422	0.5023910
6210401500	0.037	0.0440485
6210402520	0.4316	0.5138198
6210402531	0.0863	0.1027402
6210402539	0.0863	0.1027402
6210402540	0.4316	0.5138198
6210402550	0.4316	0.5138198
6210402800	0.111	0.1321455
6210402925	0.111	0.1321455

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6210402933	0.111	0.1321455
6210402945	0.111	0.1321455
6210402960	0.111	0.1321455
6210403500	0.037	0.0440485
6210405520	0.4316	0.5138198
6210405531	0.0863	0.1027402
6210405539	0.0863	0.1027402
6210405540	0.4316	0.5138198
6210405550	0.4316	0.5138198
6210407500	0.111	0.1321455
6210408025	0.111	0.1321455
6210408033	0.111	0.1321455
6210408045	0.111	0.1321455
6210408060	0.111	0.1321455
6210500300	0.037	0.0440485
6210500520	0.0863	0.1027402
6210500531	0.0863	0.1027402
6210500539	0.0863	0.1027402
6210500540	0.0863	0.1027402
6210500555	0.0863	0.1027402
6210501200	0.4316	0.5138198
6210502250	0.148	0.1761940
6210502260	0.148	0.1761940
6210502270	0.148	0.1761940
6210502290	0.148	0.1761940
6210503500	0.037	0.0440485
6210505520	0.0863	0.1027402
6210505531	0.0863	0.1027402
6210505539	0.0863	0.1027402
6210505540	0.0863	0.1027402
6210505555	0.0863	0.1027402
6210507500	0.4316	0.5138198
6210508050	0.148	0.1761940
6210508060	0.148	0.1761940
6210508070	0.148	0.1761940
6210508090	0.148	0.1761940
6211111010	0.1206	0.1435743
6211111020	0.1206	0.1435743
6211118010	1.0852	1.2919306
6211118020	1.0852	1.2919306
6211118040	0.2412	0.2871486
6211121010	0.0603	0.0717872
6211121020	0.0603	0.0717872
6211128010	1.0852	1.2919306
6211128020	1.0852	1.2919306
6211128030	0.6029	0.7177525
6211200410	0.7717	0.9187089
6211200420	0.0965	0.1148833
6211200430	0.7717	0.9187089
6211200440	0.0965	0.1148833
6211200810	0.3858	0.4592949
6211200820	0.3858	0.4592949
6211201510	0.7615	0.9065658
6211201515	0.2343	0.2789342
6211201520	0.6443	0.7670392
6211201525	0.2929	0.3486975
6211201530	0.7615	0.9065658
6211201535	0.3515	0.4184608
6211201540	0.7615	0.9065658
6211201545	0.2929	0.3486975
6211201550	0.7615	0.9065658
6211201555	0.41	0.4881050
6211201560	0.7615	0.9065658
6211201565	0.2343	0.2789342
6211202400	0.1233	0.1467887
6211202810	0.8016	0.9543048
6211202820	0.2466	0.2935773
6211202830	0.3083	0.3670312
6211203400	0.1233	0.1467887

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6211203810	0.8016	0.9543048
6211203820	0.2466	0.2935773
6211203830	0.3083	0.3670312
6211204400	0.1233	0.1467887
6211204815	0.8016	0.9543048
6211204835	0.2466	0.2935773
6211204860	0.3083	0.3670312
6211205400	0.1233	0.1467887
6211205810	0.8016	0.9543048
6211205820	0.2466	0.2935773
6211205830	0.3083	0.3670312
6211206400	0.1233	0.1467887
6211206810	0.8016	0.9543048
6211206820	0.2466	0.2935773
6211206830	0.3083	0.3670312
6211207400	0.1233	0.1467887
6211207810	0.9249	1.1010935
6211207820	0.2466	0.2935773
6211207830	0.3083	0.3670312
6211325003	0.6412	0.7633486
6211325007	0.8016	0.9543048
6211325010	0.9865	1.1744283
6211325015	0.9865	1.1744283
6211325025	0.9865	1.1744283
6211325030	0.9249	1.1010935
6211325040	0.9249	1.1010935
6211325050	0.9249	1.1010935
6211325060	0.9249	1.1010935
6211325070	0.9249	1.1010935
6211325075	0.9249	1.1010935
6211325081	0.9249	1.1010935
6211329003	0.6412	0.7633486
6211329007	0.8016	0.9543048
6211329010	0.9865	1.1744283
6211329015	0.9865	1.1744283
6211329025	0.9865	1.1744283
6211329030	0.9249	1.1010935
6211329040	0.9249	1.1010935
6211329050	0.9249	1.1010935
6211329060	0.9249	1.1010935
6211329070	0.9249	1.1010935
6211329075	0.9249	1.1010935
6211329081	0.9249	1.1010935
6211335003	0.0987	0.1175024
6211335007	0.1233	0.1467887
6211335010	0.3083	0.3670312
6211335015	0.3083	0.3670312
6211335017	0.3083	0.3670312
6211335025	0.37	0.4404850
6211335030	0.37	0.4404850
6211335035	0.37	0.4404850
6211335040	0.37	0.4404850
6211335054	0.37	0.4404850
6211335058	0.37	0.4404850
6211335061	0.37	0.4404850
6211339003	0.0987	0.1175024
6211339007	0.1233	0.1467887
6211339010	0.3083	0.3670312
6211339015	0.3083	0.3670312
6211339017	0.3083	0.3670312
6211339025	0.37	0.4404850
6211339030	0.37	0.4404850
6211339035	0.37	0.4404850
6211339040	0.37	0.4404850
6211339054	0.37	0.4404850
6211339058	0.37	0.4404850
6211339061	0.37	0.4404850
6211390310	0.1233	0.1467887
6211390320	0.1233	0.1467887

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6211390330	0.1233	0.1467887
6211390340	0.1233	0.1467887
6211390345	0.1233	0.1467887
6211390351	0.1233	0.1467887
6211391510	0.2466	0.2935773
6211391520	0.2466	0.2935773
6211391530	0.2466	0.2935773
6211391540	0.2466	0.2935773
6211391550	0.2466	0.2935773
6211391560	0.2466	0.2935773
6211391570	0.2466	0.2935773
6211391590	0.2466	0.2935773
6211393010	0.1233	0.1467887
6211393020	0.1233	0.1467887
6211393030	0.1233	0.1467887
6211393040	0.1233	0.1467887
6211393045	0.1233	0.1467887
6211393051	0.1233	0.1467887
6211398010	0.2466	0.2935773
6211398020	0.2466	0.2935773
6211398030	0.2466	0.2935773
6211398040	0.2466	0.2935773
6211398050	0.2466	0.2935773
6211398060	0.2466	0.2935773
6211398070	0.2466	0.2935773
6211398090	0.2466	0.2935773
6211420503	0.6412	0.7633486
6211420507	0.8016	0.9543048
6211420510	0.9865	1.1744283
6211420520	0.9865	1.1744283
6211420525	1.1099	1.3213360
6211420530	0.8632	1.0276396
6211420540	0.9865	1.1744283
6211420554	1.1099	1.3213360
6211420556	1.1099	1.3213360
6211420560	0.9865	1.1744283
6211420570	1.1099	1.3213360
6211420575	1.1099	1.3213360
6211420581	1.1099	1.3213360
6211421003	0.6412	0.7633486
6211421007	0.8016	0.9543048
6211421010	0.9865	1.1744283
6211421020	0.9865	1.1744283
6211421025	1.1099	1.3213360
6211421030	0.8632	1.0276396
6211421040	0.9865	1.1744283
6211421054	1.1099	1.3213360
6211421056	1.1099	1.3213360
6211421060	0.9865	1.1744283
6211421070	1.1099	1.3213360
6211421075	1.1099	1.3213360
6211421081	1.1099	1.3213360
6211430503	0.0987	0.1175024
6211430507	0.1233	0.1467887
6211430510	0.2466	0.2935773
6211430520	0.2466	0.2935773
6211430530	0.2466	0.2935773
6211430540	0.2466	0.2935773
6211430550	0.2466	0.2935773
6211430560	0.2466	0.2935773
6211430564	0.3083	0.3670312
6211430566	0.2466	0.2935773
6211430574	0.3083	0.3670312
6211430576	0.37	0.4404850
6211430578	0.37	0.4404850
6211430591	0.2466	0.2935773
6211431003	0.0987	0.1175024
6211431007	0.1233	0.1467887
6211431010	0.2466	0.2935773

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6211431020	0.2466	0.2935773
6211431030	0.2466	0.2935773
6211431040	0.2466	0.2935773
6211431050	0.2466	0.2935773
6211431060	0.2466	0.2935773
6211431064	0.3083	0.3670312
6211431066	0.2466	0.2935773
6211431074	0.3083	0.3670312
6211431076	0.37	0.4404850
6211431078	0.37	0.4404850
6211431091	0.2466	0.2935773
6211492510	0.2466	0.2935773
6211492520	0.2466	0.2935773
6211492530	0.2466	0.2935773
6211492540	0.2466	0.2935773
6211492550	0.2466	0.2935773
6211492560	0.2466	0.2935773
6211492570	0.2466	0.2935773
6211492580	0.2466	0.2935773
6211492590	0.2466	0.2935773
6211498010	0.2466	0.2935773
6211498020	0.2466	0.2935773
6211498030	0.2466	0.2935773
6211498040	0.2466	0.2935773
6211498050	0.2466	0.2935773
6211498060	0.2466	0.2935773
6211498070	0.2466	0.2935773
6211498080	0.2466	0.2935773
6211498090	0.2466	0.2935773
6212105010	0.9138	1.0878789
6212105020	0.2285	0.2720293
6212105030	0.2285	0.2720293
6212109010	0.9138	1.0878789
6212109020	0.2285	0.2720293
6212109040	0.2285	0.2720293
6212200010	0.6854	0.8159687
6212200020	0.2856	0.3400068
6212200030	0.1142	0.1359551
6212300010	0.6854	0.8159687
6212300020	0.2856	0.3400068
6212300030	0.1142	0.1359551
6212900010	0.1828	0.2176234
6212900020	0.1828	0.2176234
6212900030	0.1828	0.2176234
6212900050	0.0914	0.1088117
6212900090	0.4112	0.4895336
6213201000	1.1187	1.3318124
6213202000	1.0069	1.1987145
6213900700	0.4475	0.5327488
6213901000	0.4475	0.5327488
6213902000	0.3356	0.3995318
6214300000	0.1142	0.1359551
6214400000	0.1142	0.1359551
6214900010	0.8567	1.0199014
6214900090	0.2285	0.2720293
6215100025	0.1142	0.1359551
6215200000	0.1142	0.1359551
6215900015	1.0281	1.2239531
6216000800	0.0685	0.0815493
6216001300	0.3427	0.4079844
6216001720	0.6397	0.7615629
6216001730	0.1599	0.1903610
6216001900	0.3427	0.4079844
6216002110	0.578	0.6881090
6216002120	0.2477	0.2948869
6216002410	0.6605	0.7863253
6216002425	0.1651	0.1965516
6216002600	0.1651	0.1965516
6216002910	0.6605	0.7863253

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6216002925	0.1651	0.1965516
6216003100	0.1651	0.1965516
6216003300	0.5898	0.7021569
6216003500	0.5898	0.7021569
6216003800	1.1796	1.4043138
6216004100	1.1796	1.4043138
6217109510	0.9646	1.1483563
6217109520	0.1809	0.2153615
6217109530	0.2412	0.2871486
6217909003	0.9646	1.1483563
6217909005	0.1809	0.2153615
6217909010	0.2412	0.2871486
6217909025	0.9646	1.1483563
6217909030	0.1809	0.2153615
6217909035	0.2412	0.2871486
6217909050	0.9646	1.1483563
6217909055	0.1809	0.2153615
6217909060	0.2412	0.2871486
6217909075	0.9646	1.1483563
6217909080	0.1809	0.2153615
6217909085	0.2412	0.2871486
6301300010	0.8305	0.9887103
6301300020	0.8305	0.9887103
6301900030	0.2215	0.2636958
6302100005	1.1073	1.3182407
6302100008	1.1073	1.3182407
6302100015	1.1073	1.3182407
6302213010	1.1073	1.3182407
6302213020	1.1073	1.3182407
6302213030	1.1073	1.3182407
6302213040	1.1073	1.3182407
6302213050	1.1073	1.3182407
6302215010	0.7751	0.9227566
6302215020	0.7751	0.9227566
6302215030	0.7751	0.9227566
6302215040	0.7751	0.9227566
6302215050	0.7751	0.9227566
6302217010	1.1073	1.3182407
6302217020	1.1073	1.3182407
6302217030	1.1073	1.3182407
6302217040	1.1073	1.3182407
6302217050	1.1073	1.3182407
6302219010	0.7751	0.9227566
6302219020	0.7751	0.9227566
6302219030	0.7751	0.9227566
6302219040	0.7751	0.9227566
6302219050	0.7751	0.9227566
6302221010	0.5537	0.6591799
6302221020	0.3876	0.4614378
6302221030	0.5537	0.6591799
6302221040	0.3876	0.4614378
6302221050	0.3876	0.4614378
6302221060	0.3876	0.4614378
6302222010	0.3876	0.4614378
6302222020	0.3876	0.4614378
6302222030	0.3876	0.4614378
6302290020	0.2215	0.2636958
6302313010	1.1073	1.3182407
6302313020	1.1073	1.3182407
6302313030	1.1073	1.3182407
6302313040	1.1073	1.3182407
6302313050	1.1073	1.3182407
6302315010	0.7751	0.9227566
6302315020	0.7751	0.9227566
6302315030	0.7751	0.9227566
6302315040	0.7751	0.9227566
6302315050	0.7751	0.9227566
6302317010	1.1073	1.3182407
6302317020	1.1073	1.3182407

IMPORT ASSESSMENT TABLE—Continued

[Raw cotton fiber]

HTS No.	Conv. factor	Cents/kg.
6302317030	1.1073	1.3182407
6302317040	1.1073	1.3182407
6302317050	1.1073	1.3182407
6302319010	0.7751	0.9227566
6302319020	0.7751	0.9227566
6302319030	0.7751	0.9227566
6302319040	0.7751	0.9227566
6302319050	0.7751	0.9227566
6302321010	0.5537	0.6591799
6302321020	0.3876	0.4614378
6302321030	0.5537	0.6591799
6302321040	0.3876	0.4614378
6302321050	0.3876	0.4614378
6302321060	0.3876	0.4614378
6302322010	0.5537	0.6591799
6302322020	0.3876	0.4614378
6302322030	0.5537	0.6591799
6302322040	0.3876	0.4614378
6302322050	0.3876	0.4614378
6302322060	0.3876	0.4614378
6302390030	0.2215	0.2636958
6302402010	0.9412	1.1204986
6302511000	0.5537	0.6591799
6302512000	0.8305	0.9887103
6302513000	0.5537	0.6591799
6302514000	0.7751	0.9227566
6302593020	0.5537	0.6591799
6302600010	1.1073	1.3182407
6302600020	0.9966	1.1864523
6302600030	0.9966	1.1864523
6302910005	0.9966	1.1864523
6302910015	1.1073	1.3182407
6302910025	0.9966	1.1864523
6302910035	0.9966	1.1864523
6302910045	0.9966	1.1864523
6302910050	0.9966	1.1864523
6302910060	0.9966	1.1864523
6302931000	0.4429	0.5272725
6302932000	0.4429	0.5272725
6302992000	0.2215	0.2636958
6303191100	0.8859	1.0546640
6303910010	0.609	0.7250145
6303910020	0.609	0.7250145
6303921000	0.2768	0.3295304
6303922010	0.2768	0.3295304
6303922030	0.2768	0.3295304
6303922050	0.2768	0.3295304
6303990010	0.2768	0.3295304
6304111000	0.9966	1.1864523
6304113000	0.1107	0.1317884
6304190500	0.9966	1.1864523
6304191000	1.1073	1.3182407
6304191500	0.3876	0.4614378
6304192000	0.3876	0.4614378
6304193060	0.2215	0.2636958
6304910020	0.8859	1.0546640
6304910070	0.2215	0.2636958
6304920000	0.8859	1.0546640
6304996040	0.2215	0.2636958
6505001515	1.1189	1.3320505
6505001525	0.5594	0.6659657
6505001540	1.1189	1.3320505
6505002030	0.9412	1.1204986
6505002060	0.9412	1.1204986
6505002545	0.5537	0.6591799
6507000000	0.3986	0.4745333
9404901000	0.2104	0.2504812
9404908020	0.9966	1.1864523
9404908040	0.9966	1.1864523
9404908505	0.6644	0.7909682
9404908536	0.0997	0.1186929
9404909505	0.6644	0.7909682
9404909570	0.2658	0.3164349
9619002100	0.8681	1.0334731
9619002500	0.1085	0.1291693
9619003100	0.9535	1.1351418
9619003300	1.1545	1.3744323
9619004100	0.2384	0.2838152
9619004300	0.2384	0.2838152
9619006100	0.8528	1.0152584
9619006400	0.2437	0.2901249
9619006800	0.3655	0.4351278
9619007100	1.1099	1.3213360
9619007400	0.2466	0.2935773
9619007800	0.2466	0.2935773
9619007900	0.2466	0.2935773

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(Authority: 7 U.S.C. 2101–2118)

Dated: August 13, 2018

Bruce Summers,

Administrator.

[FR Doc. 2018–17723 Filed 8–16–18; 8:45 am]

BILLING CODE 3410–02–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1016

[Docket No. CFPB–2016–0032]

RIN 3170–AA60

Amendment to the Annual Privacy Notice Requirement Under the Gramm-Leach-Bliley Act (Regulation P)

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is amending Regulation P, which requires, among other things, that financial institutions provide an annual notice describing their privacy policies and practices to their customers. The amendment implements a December 2015 statutory amendment to the Gramm-Leach-Bliley Act providing an exception to this annual notice requirement for financial institutions that meet certain conditions.

DATES: The amendments to Regulation P in this final rule will become effective on September 17, 2018.

FOR FURTHER INFORMATION CONTACT: Monique Chenault, Paralegal Specialist; Joseph Devlin, Senior Counsel; Office of Regulations, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Summary of the Final Rule

Title V, Subtitle A of the Gramm-Leach-Bliley Act (GLBA) [1] and Regulation P, which implements the GLBA, mandate that financial institutions provide their customers with annual notices regarding those institutions' privacy policies. If financial institutions share certain consumer information with particular types of third parties, the annual notices must also provide customers with an opportunity to opt out of the sharing. Regulation P sets forth requirements for how financial institutions must deliver these annual privacy notices. In certain circumstances, Regulation P permits financial institutions to use an alternative delivery method to provide annual notices. This method requires, among other things, that the annual notice be posted on a financial institution's website.

On December 4, 2015, Congress amended the GLBA as part of the Fixing America's Surface Transportation Act (FAST Act). This amendment, titled Eliminate Privacy Notice Confusion,[2] added new GLBA section 503(f). This subsection provides an exception under which financial institutions that meet certain conditions are not required to provide annual privacy notices to customers. Section 503(f)(1) requires that to qualify for this exception, a financial institution must not share nonpublic personal information about customers except as described in certain statutory exceptions. (Sharing as described in these specified statutory exceptions does not trigger the customer's statutory right to opt out of the financial institution's sharing.) In addition, section 503(f)(2) requires that the financial institution must not have changed its policies and practices with regard to disclosing nonpublic personal information from those that the institution disclosed in the most recent privacy notice it sent.

Section 503(f) took effect upon enactment in December 2015. In July 2016 the Bureau proposed to update Regulation P to reflect the change in the underlying law. As part of its implementation, the Bureau is also amending Regulation P to provide timing requirements for delivery of annual privacy notices in the event that a financial institution that qualified for this annual notice exception later changes its policies or practices in such a way that it no longer qualifies for the exception. The Bureau is further

[1] 15 U.S.C. 6801 through 6809.

[2] FAST Act, Public Law 114–94, section 75001.

removing the Regulation P provision that allows for use of the alternative delivery method for annual privacy notices because the Bureau believes the alternative delivery method will no longer be used in light of the annual notice exception. Finally, the Bureau is amending Regulation P to make a technical correction to one of its definitions.

II. Background

A. The Statute and Regulation

The GLBA was enacted into law in 1999 and governs the privacy practices of a broad range of financial institutions.[3] Rulemaking authority to implement the GLBA privacy provisions was initially spread among many agencies. The Federal Reserve Board (Board), the Office of Comptroller of the Currency (OCC), the Federal Deposit Insurance Corporation (FDIC), and the Office of Thrift Supervision (OTS) jointly adopted final rules in 2000 to implement the notice requirements of the GLBA.[4] The National Credit Union Administration (NCUA), Federal Trade Commission (FTC), Securities and Exchange Commission (SEC), and Commodity Futures Trading Commission (CFTC) were part of the same interagency process, but each of these agencies issued separate rules.[5] In 2009, all of the agencies with the authority to issue rules to implement the GLBA privacy notice provisions issued a joint final rule with a model form that financial institutions could use, at their option, to provide required initial and annual disclosures.[6]

In 2011, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act)[7] transferred GLBA privacy notice rulemaking authority from the Board, NCUA, OCC, OTS, the FDIC, and the FTC (in part) to the Bureau.[8] The Bureau then restated the implementing regulations in Regulation P, 12 CFR part 1016, in late 2011 through an interim final rule.[9] In April 2016, the Bureau finalized that interim final rule as amended by 79 FR 64057 (Oct. 28, 2014).[10]

The Bureau has the authority to promulgate GLBA privacy rules for depository institutions and many non-depository institutions. However, rulewriting authority with regard to securities and futures-related companies is vested in the SEC and CFTC, respectively, and rulewriting authority with respect to certain motor vehicle dealers is vested in the FTC.[11] The four agencies are required to consult with each other and with representatives of State insurance authorities to assure, to the extent possible, consistency and comparability among implementing rules.[12] Toward that end, the Bureau has consulted and coordinated with these agencies and with the National Association of Insurance Commissioners (NAIC) concerning this final rule and the proposal that preceded it. The Bureau has also consulted with prudential regulators and other appropriate Federal agencies, as required under Section 1022 of the Dodd-Frank Act as part of its general rulewriting process.[13]

The GLBA and Regulation P require that financial institutions provide consumers with certain notices describing their privacy policies.[14] Financial institutions are generally required to provide an initial notice of these policies when a customer relationship is established and to provide an annual notice to customers every year that the customer relationship continues.[15] Except as otherwise authorized in the regulation, if a financial institution chooses to disclose nonpublic personal information about a consumer to a nonaffiliated third party other than as described in its initial notice, the institution is also required to deliver a revised privacy notice.[16] The types of information required to be included in the initial, annual, and revised notices are identical. Each notice must describe whether and how the financial institution shares consumers' nonpublic personal information with other entities.[17] The notices must also briefly describe how financial institutions protect the nonpublic personal information they collect and maintain.[18]

GLBA Section 502 and Regulation P also require that initial, annual, and revised notices provide information about the right to opt out of certain financial institution sharing of nonpublic personal information with some types of nonaffiliated third parties. For example, a mortgage customer has the right to opt out of a financial institution disclosing his or her name and address to an unaffiliated home insurance company. On the other hand, a financial institution is not required to allow a consumer to opt out of the institution's disclosure of his or her nonpublic personal information to third party service providers and pursuant to joint marketing arrangements subject to certain requirements; disclosures relating to maintaining and servicing accounts, securitization, law enforcement and compliance, and consumer reporting; and certain other disclosures described in the GLBA and Regulation P as exceptions to the opt-out requirement.[19]

In addition to opt-out rights under the GLBA, annual privacy notices also may include information about certain consumer opt-out rights under the Fair Credit Reporting Act (FCRA). The privacy notices under the GLBA/Regulation P and affiliate disclosures under the FCRA/Regulation V interact in two ways. First, section 603(d)(2)(A)(iii) of the FCRA excludes from that statute's definition of a consumer report[20] the sharing of certain information about a consumer with the institution's affiliates if the consumer is notified of such sharing and is given an opportunity to opt out.[21] Section 503(c)(4) of the GLBA and Regulation P require financial institutions to incorporate into any required Regulation P notices the notification and opt-out disclosures provided pursuant to section 603(d)(2)(A)(iii) of the FCRA, if the institution provides such disclosures.[22]

Second, section 624 of the FCRA and Regulation V's Affiliate Marketing Rule provide that an affiliate of a financial institution that receives certain information (*e.g.,* transaction history)[23]

[3] Public Law 106–102, 113 Stat. 1338 (1999).

[4] 65 FR 35162 (June 1, 2000).

[5] 65 FR 31722 (May 18, 2000) (NCUA final rule); 65 FR 33646 (May 24, 2000) (FTC final rule); 65 FR 40334 (June 29, 2000) (SEC final rule); 66 FR 21236 (Apr. 27, 2001) (CFTC final rule).

[6] 74 FR 62890 (Dec. 1, 2009).

[7] Public Law 111–203, 124 Stat. 1376 (2010).

[8] Public Law 111–203, section 1093. The FTC retained rulewriting authority over any financial institution that is a person described in 12 U.S.C. 5519 (*i.e.,* motor vehicle dealers predominantly engaged in the sale and servicing of motor vehicles, the leasing and servicing of motor vehicles, or both).

[9] 76 FR 79025 (Dec. 21, 2011).

[10] 81 FR 25323 (Apr. 28, 2016).

[11] 15 U.S.C. 6804; 12 CFR 1016.1(b).

[12] 15 U.S.C. 6804(a)(2).

[13] 12 U.S.C. 5512(b)(2)(B).

[14] When a financial institution has a continuing relationship with the consumer, an annual privacy notice is required and the consumer is then referred to as a ''customer.'' 12 CFR 1016.3(i), 1016.3(j)(1).

[15] 12 CFR 1016.4(a)(1), 1016.5(a)(1). Financial institutions are also required to provide initial notices to consumers before disclosing any nonpublic personal information to a nonaffiliated third party outside of certain exceptions. 12 CFR 1016.4(a)(2).

[16] 12 CFR 1016.8.

[17] 12 CFR 1016.6(a)(1)–(5), (9).

[18] 12 CFR 1016.6(a)(8).

[19] 15 U.S.C. 6802(b)(2), (e); 12 CFR 1016.13, 1016.14, 1016.15.

[20] 15 U.S.C. 1681a(d).

[21] 15 U.S.C. 1681a(d)(2)(A)(iii).

[22] 15 U.S.C. 6803(c)(4); 12 CFR 1016.6(a)(7).

[23] The type of information to which section 624 applies is information that would be a consumer

from the institution about a consumer may not use the information to make solicitations for marketing purposes unless the consumer is notified of such use and provided with an opportunity to opt out of that use.[24] Section 624 of the FCRA and Regulation V also permit (but do not require) financial institutions to incorporate any opt-out disclosures provided under section 624 of the FCRA and subpart C of Regulation V into privacy notices provided pursuant to the GLBA and Regulation P.[25]

B. The Alternative Delivery Method for Annual Privacy Notices

In pursuit of the Bureau's goal of reducing unnecessary or unduly burdensome regulations, the Bureau in December 2011 issued a Request for Information (RFI) seeking specific suggestions from the public for streamlining regulations the Bureau had inherited from other Federal agencies. In that RFI, the Bureau specifically identified the annual privacy notice as a potential opportunity for streamlining and solicited comment on possible alternatives to delivering the annual privacy notice.[26] Numerous industry commenters responded to the RFI by advocating for the elimination or limitation of the annual notice requirement.

Financial institutions historically have provided annual notices generally by U.S. postal mail.[27] In 2014, the Bureau adopted a rule to allow financial institutions to use an alternative delivery method to provide annual privacy notices through posting the notices on their websites if they meet certain conditions.[28] Specifically, financial institutions were allowed to use the alternative delivery method for annual notices if: (1) No opt-out rights were triggered by the financial institution's information sharing practices under the GLBA; (2) no FCRA section 603 opt-out notices were required to appear on the annual notice and any opt-outs required by FCRA section 624 had previously been provided, if applicable, or the annual notice was not the only notice provided to satisfy those requirements; (3) the information included in the annual notice had not changed since the customer received the previous notice; and (4) the financial institution used the model form provided in Regulation P for its annual notice.

In addition, to assist customers with limited or no access to the internet, an institution using the alternative delivery method was required to mail annual notices to customers who requested them by telephone. To make customers aware that its annual privacy notice was available through the website or by phone, the institution was required to include a clear and conspicuous statement of availability at least once per year on an account statement, coupon book, or a notice or disclosure the institution issued under any provision of law.

C. Statutory Amendment and Proposed Rule

On December 4, 2015, Congress amended the GLBA as part of the FAST Act. This amendment, titled Eliminate Privacy Notice Confusion,[29] added new GLBA section 503(f), which provides an exception under which financial institutions that meet two conditions are not required to provide annual notices to customers.[30] New GLBA section 503(f)(1) states the first condition for the annual notice exception: That a financial institution must provide nonpublic personal information only in accordance with certain exceptions in the GLBA; providing nonpublic personal information under these exceptions does not trigger consumer opt-out rights.[31] New GLBA section 503(f)(2) states the second condition for the annual notice exception: That a financial institution must not have changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed in the most recent disclosure sent to consumers in accordance with GLBA section 503. The statutory amendment became effective upon enactment in December 2015.

On July 15, 2016, the Bureau published a proposed rule to implement the FAST Act statutory amendment to the GLBA. The Bureau has considered the comments received on that proposed rule, and now issues this final rule based on it.

D. Effective Date

As discussed above, the statutory exception to the annual notice requirement is already effective. The amendments to Regulation P in this final rule will be effective 30 days from the date of publication in the **Federal Register**.

E. Privacy Considerations

In developing this final rule, the Bureau considered its potential impact on consumer privacy. The rule will not affect the collection or use of consumers' nonpublic personal information by financial institutions. The rule implements a new statutory exception to limit the circumstances under which financial institutions subject to Regulation P will be required to deliver annual privacy notices to their customers. Delivery of annual privacy notices is required under the rule if financial institutions make certain types of changes to their privacy policies or if the statute and Regulation P afford customers the right to opt out of financial institutions' sharing of customers' nonpublic personal information with nonaffiliated third parties. The statutory exception and this final rule do not affect the requirement to deliver an initial privacy notice, and all consumers will continue to receive such notices describing the privacy policies of any financial institutions with which they do business to the extent currently required.

III. Legal Authority

The Bureau is issuing this final rule pursuant to its authority under section 504 of the GLBA, as amended by section 1093 of the Dodd-Frank Act.[32] The Bureau is also issuing this rule pursuant to its authority under sections 1022 and 1061 of the Dodd-Frank Act.[33]

IV. Section-by-Section Analysis

Section 1016.3 Definitions

3(s)(1)

Regulation P's substantive requirements, including the requirement to deliver privacy notices, are generally

report, but for the exclusions provided by section 603(d)(2)(A)(i), (ii), or (iii) of the FCRA.

[24] 15 U.S.C. 1681s–3 and 12 CFR pt. 1022, subpart C.

[25] 15 U.S.C. 1681s–3(b); 12 CFR 1022.23(b).

[26] 76 FR 75825, 75828 (Dec. 5, 2011).

[27] Regulation P, however, does allow financial institutions to provide notices electronically (*e.g.,* by email) with consent. 12 CFR 1016.9(a) (stating that a financial institution may deliver the notice electronically if the consumer agrees). The Bureau believes that most consumers do not receive privacy notices electronically.

[28] 79 FR 64057 (revising 12 CFR 1016.9(c)). The Bureau's alternative delivery method became effective on October 28, 2014. *Id.*

[29] FAST Act, Public Law 114–94, section 75001.

[30] In order to avoid confusion and facilitate responsiveness to consumer requests, the Bureau notes that a financial institution that qualifies for the annual notice exception could provide a privacy notice to a customer without jeopardizing the availability of the exception, such as in response to a customer specifically requesting a copy of the notice.

[31] These provisions are in GLBA section 502(b)(2) or (e) and are incorporated into existing Regulation P at § 1016.13, § 1016.14, and § 1016.15. They provide exceptions from the requirement that a financial institution provide notice and an opportunity to opt out of sharing nonpublic personal information with a nonaffiliated third party.

[32] 15 U.S.C. 6804.

[33] 12 U.S.C. 5512, 5581.

imposed upon entities that meet the definition of ''You'' in § 1016.3(s)(1). That provision defines ''You'' as a ''financial institution or other person for which the Bureau has rulemaking authority under section 504(a)(1)(A) of the GLBA.'' In order to coordinate this definition more correctly with the term's usage in the regulation, the Bureau proposed to limit ''You'' to financial institutions.

The Bureau received no comments on this technical amendment, and adopts it now as proposed.

As explained above, Regulation P's substantive requirements, including the requirement to deliver privacy notices, are generally imposed upon entities that meet the definition of ''You'' in § 1016.3(s)(1). The Bureau has rulemaking authority over entities other than financial institutions pursuant to GLBA section 504(a)(1)(A).[34] The statute's privacy notice requirements, however, specifically apply only to financial institutions.[35] The Bureau therefore believes that it is appropriate to limit the definition of ''You'' in § 1016.3(s)(1) to financial institutions. For this reason, the Bureau is amending § 1016.3(s)(1) to remove the phrase ''or other persons.'' The Bureau does not believe this technical amendment to § 1016.3(s)(1) will change the settled understanding of the scope of Regulation P's privacy notice requirements. Instead, the Bureau believes it will clarify that the scope of Regulation P's privacy notice requirements is consistent with the understanding of stakeholders.

Section 1016.5 Annual Privacy Notice to Customers Required

5(a) General Rule

The Bureau proposed to amend the general requirement in § 1016.5(a)(1) that financial institutions provide annual notices, to clarify that the Bureau has added an exception to this requirement in § 1016.5(e) to incorporate the amendment to GLBA section 503.

No commenters specifically discussed the conforming change to the general rule in § 1016.5(a). One commenter suggested that the Bureau remove any GLBA privacy notice requirement and instead require financial institutions to post their privacy notices online, allow all consumers to choose whether to receive any privacy notices, make electronic notices the default for any consumers who opt to receive any privacy notices, and allow financial institutions to charge fees for any paper privacy notices they provide.

The Bureau now adopts the conforming amendment to the general requirement in § 1016.5(a)(1) that financial institutions provide annual notices, to clarify that the Bureau has added an exception to this requirement in § 1016.5(e) to incorporate the amendment to GLBA section 503. The Bureau does not believe that the comment is relevant to the proposal and it does not provide a basis to change the approach proposed by the Bureau. Congress did not include revisions along the lines the commenter suggested in the statutory provision that the Bureau is implementing in this rulemaking.

5(e) Exception to Annual Notice Requirement

New GLBA § 503(f) provides that a financial institution is excepted from providing an annual notice if it meets the two conditions described below. The Bureau proposed to add new § 1016.5(e) to incorporate into Regulation P the exception created by new § 503(f). Under proposed § 1016.5(e), as in section 503(f), a financial institution would be excepted from providing an annual notice if it meets the two conditions discussed below.

The commenters overwhelmingly supported proposed § 1016.5(e). Although some commenters asked that the exception be broadened, no commenters who discussed the proposed exception objected to it. The commenters stated that the exception would reduce burden and would not harm consumers, and was less complicated and burdensome than the previous alternative delivery method. Some suggested that the provision would benefit consumers. The comments that specifically discussed either of the two requirements for the exception, in § 1016.5(e)(1)(i) and (ii), are discussed below in relation to those provisions.

A trade association representing credit unions requested that to eliminate confusion and protect institutions from citations, the rule should be effective retroactive to December 4, 2015, the date the statutory GLBA amendments took effect. In addition, an attorney suggested that the Bureau preempt State privacy statutes that might require institutions to continue providing annual privacy notices in spite of the Federal exception. The attorney recommended the Bureau modify § 1016.17 to expressly preempt contrary State law, and instead require that an institution make its privacy notice continually available online.

After considering the comments and for the reasons discussed below, the Bureau now adopts the exception to the annual notice requirement largely as proposed, with certain changes to the timing provisions in § 1016.5(e)(2), as discussed below.

In regard to the comment recommending that § 1016.17 be modified, § 1016.17 implements GLBA § 507,[36] which provides specific standards regarding preemption of State law. The Bureau does not believe that the comment is relevant to the proposal and it does not provide a basis to change the approach proposed by the Bureau. Congress did not include revisions along the lines the commenter suggested in the statute that the Bureau is implementing in this rulemaking.

In regard to the comment on retroactivity, the Bureau has made clear in the proposed rule and this final rule that new GLBA § 503(f) became effective upon enactment in December 2015.[37] As the central elements of this rule are already in effect, the Bureau believes that there is no need to make this rule retroactive. To the extent that this rule changes applicable law, the Bureau notes that retroactive rulemaking is disfavored by the courts, and the commenter has not established why it would be appropriate here. This rule takes effect 30 days after its publication in the **Federal Register**.

5(e)(1) When Exception Available

5(e)(1)(i)

New GLBA section 503(f)(1) states the first condition for the annual privacy notice exception: that a financial institution provide nonpublic personal information only in accordance with the provisions of subsection (b)(2) or (e) of section 502 of the GLBA. The Bureau proposed § 1016.5(e)(1)(i) to incorporate this condition by requiring that to qualify for the annual notice exception, any nonpublic personal information that financial institutions provide to nonaffiliated third parties must be provided only in accordance with § 1016.13, § 1016.14 or § 1016.15 of Regulation P.

Almost no commenters specifically discussed the first of the two requirements of the new statutory exception. One credit union explained that it does not share nonpublic personal information beyond the exceptions provided in § 1016.13,

[34] Such rulemaking authority has been exercised with respect to nonaffiliated third parties to which a financial institution discloses nonpublic personal information and that third party's affiliates for purposes of GLBA section 502(c)'s limits on reuse of information. *See* 12 CFR 1016.11(c)–(d).

[35] *See* GLBA sections 502(a)–(b) and 503(a).

[36] 15 U.S.C. 6807.

[37] See above, Part II.C.

§ 1016.14 or § 1016.15 of Regulation P, and that it believes the § 1016.5(e)(1)(i) requirement will work well. Another commenter discussed voluntary opt-outs that a financial institution may offer, asking whether the inclusion on the privacy notice of opt-outs that allow consumers to opt out of sharing that is described in § 1016.13, § 1016.14 or § 1016.15 of Regulation P would interfere with meeting the requirement in § 1016.5(e)(1)(i).

The Bureau now adopts § 1016.5(e)(1)(i) as proposed. Section 1016.5(e)(1)(i) will incorporate the first requirement of GLBA § 503(f) by requiring that to qualify for the annual notice exception, any nonpublic personal information that financial institutions provide to nonaffiliated third parties must be provided only in accordance with § 1016.13, § 1016.14 or § 1016.15 of Regulation P; these regulatory sections implement subsections (b)(2) and (e) of section 502.[38] A financial institution sharing information only pursuant to these exceptions is not required to provide customers with a right to opt out of that sharing. In addition, because they would only involve information sharing within the exceptions of § 1016.13, § 1016.14 or § 1016.15, voluntary opt-outs included on privacy notices would not affect compliance with the § 1016.5(e)(1)(i) requirement or the annual notice exception.

The Bureau notes that § 1016.6(a)(7) requires that annual privacy notices incorporate any disclosures made under FCRA section 603(d)(2)(A)(iii) regarding the consumer's ability to opt out of sharing of information among affiliates. Further, the notices may incorporate any opt-out disclosures provided under FCRA section 624.[39] GLBA section 503(f)(1) does not mention information sharing that would trigger an opt-out notice under FCRA sections 603(d)(2)(A)(iii) or 624.

Given the structure of the statute, the Bureau does not interpret GLBA section 503(f)(1) to preclude financial institutions that provide nonpublic personal information in accordance with FCRA sections 603(d)(2)(A)(iii) or 624 from qualifying for the exception. Thus, as the Bureau stated in its proposal, the presence or absence of these FCRA disclosures on a financial institution's privacy notice will not affect whether the institution satisfies GLBA section 503(f)(1) and § 1016.5(e)(1)(i). As the Bureau noted, however, financial institutions that choose to take advantage of the annual notice exception must still provide any opt-out disclosures required under FCRA sections 603(d)(2)(A)(iii) and 624, if applicable. Under the FCRA, neither of these opt-outs is required to be provided annually.[40] Accordingly, institutions can provide these disclosures through other methods, for example, through their initial privacy notices in most circumstances.

5(e)(1)(ii)

New GLBA section 503(f)(2) states the second condition for the annual notice exception: that a financial institution not have changed its ''policies and practices with regard to disclosing nonpublic personal information'' from the policies and practices that were disclosed in the most recent notice sent to consumers in accordance with GLBA section 503. Because the Bureau determined that the statutory language was ambiguous as to the exact types of sharing intended, the Bureau proposed § 1016.5(e)(1)(ii) to resolve this ambiguity by requiring that, to qualify for the annual notice exception, a financial institution must not have changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 1016.6(a)(2) through (5) and (9) in the most recent privacy notice the financial institution provided.

As with the first requirement for the annual notice exception at § 1016.5(e)(1)(i), few commenters specifically discussed the second requirement at § 1016.5(e)(1)(ii). However, the commenters overwhelmingly signaled their support for these provisions by supporting the Bureau's implementation of the statutory exception. Two trade associations representing credit unions did specifically express support for the proposed interpretation of the statutory language as referring only to a change to a disclosure under § 1016.6(a)(2) through (5) and (9).

The Bureau now adopts § 1016.5(e)(1)(ii) as proposed, providing that, to qualify for the annual notice exception, a financial institution must not have changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 1016.6(a)(2) through (5) and (9) in the most recent privacy notice the financial institution provided.

Paragraphs (1) through (9) of § 1016.6(a) list the specific information that must be included in privacy notices. Section 1016.6(a)(2) through (5) and (9) require a financial institution to include information related to its policies and practices with regard to disclosing nonpublic personal information, but § 1016.6(a)(1) (information collection) and § 1016.6(a)(8) (confidentiality and security) do not.[41] Accordingly, the Bureau believes that only changes to an institution's policies and practices that would require changes to any of the disclosures required by § 1016.6(a)(2) through (5) and (9) would cause a financial institution to be unable to use the exception in § 1016.5(e)(1)(ii).[42]

Section 1016.6(a)(7) requires that any disclosure an institution makes under FCRA section 603(d)(2)(A)(iii), which describes a consumer's ability to opt out of disclosures of information among affiliates, be included on the privacy notice. The Bureau believes that the statute is ambiguous as to whether a financial institution that changes the disclosure required under § 1016.6(a)(7) from the most recent notice sent to consumers would satisfy GLBA section 503(f)(2). In the proposed rule, the Bureau sought comment on whether proposed § 1016.5(e)(1)(ii) should include changes to disclosures required by § 1016.6(a)(7) and on how frequently institutions change that disclosure. The Bureau further sought comment on whether institutions would prefer to inform customers of these changes

[38] The sharing described in these provisions includes, among other things, sharing involving third party service providers, joint marketing arrangements, maintaining and servicing accounts, securitization, law enforcement and compliance, and reporting to consumer reporting agencies.

[39] 15 U.S.C. 1681s–3(b); 12 CFR 1022.23(b).

[40] *See* 15 U.S.C. 1681a(d)(2)(A)(iii); 12 CFR 1022.21, 1022.27; 72 FR 62910, 62930 (Nov. 7, 2007).

[41] The information specified in § 1016.6(a)(6) describes the consumer's right pursuant to Regulation P to opt out of an institution's disclosure of information and would be inapplicable where a financial institution qualifies for the annual notice exception.

[42] To have used the Bureau's former alternative delivery method, the information a financial institution was required to convey on its annual privacy notice pursuant to § 1016.6(a)(1) through (5), (8), and (9) was required not to have changed from the information disclosed in the most recent privacy notice provided to the consumer. See removed 12 CFR 1016.9(c)(2)(D). Thus, changes to the information a financial institution was required to convey pursuant to § 1016.6(a)(1) and (8) would have prevented a financial institution from using the alternative delivery method but such changes will not prevent a financial institution from satisfying § 1016.5(e)(1)(ii) for the annual notice exception. Because institutions that include information on their privacy notice pursuant to § 1016.6(a)(7) (which relates to opt-out notices provided pursuant to the FCRA) were not permitted to use the alternative delivery method in any case, § 1016.6(a)(7) was not listed as a type of information that if changed would have prevented a financial institution from using the alternative delivery method.

through sending an annual privacy notice or through sending a disclosure describing only the FCRA section 603(d)(2)(A)(iii) opt-outs, if applicable, and also sought comment on the impact on consumers of these two methods.

All the commenters who addressed these issues stated that changes to the disclosures required by FCRA section 603(d)(2)(A)(iii) should not affect the availability of the annual notice exception. A State-wide trade association representing credit unions indicated that the presence or absence of FCRA disclosures on a credit union's privacy notice, and subsequent changes to those FCRA sharing practices, should not impact whether an institution qualifies for the annual notice exception. This trade association stated, without providing data, that it believed that changes by credit unions in its State to FCRA section 603(d)(2)(A)(iii) information disclosures are infrequent, and that few such credit unions share data in a way that trigger a FCRA opt-out in the first place. Other commenters who discussed the 603(d)(2)(A)(iii) information disclosures stated that allowing changes to disqualify financial institutions from the annual notice exception would interfere with the burden reduction intended, and that FCRA has its own disclosure requirements.

Given the structure of the statute, the Bureau does not interpret GLBA section 503(f)(2) to preclude financial institutions that make changes to disclosures required by § 1016.6(a)(7) from qualifying for the exception. The Bureau also notes that a change in the 603(d)(2)(A)(iii) information disclosures only requires a one-time notice and opt out. The Bureau does not believe that consumers would be materially benefited by requiring this one-time notice to be included in a privacy notice under Regulation P, especially where it is required in a separate notice required by the FCRA.

In addition to the discussion of 603(d)(2)(A)(iii) information disclosures, the Bureau noted in the proposed rule that a financial institution would satisfy § 1016.5(e)(1)(ii) if it changes its disclosures describing policies and practices with regard to disclosing nonpublic personal information that are included in the institution's privacy notice without being required by the GLBA or § 1016.6 (*e.g.,* disclosures describing sharing with affiliates under FCRA section 624 or voluntary disclosures and opt-outs). The Bureau sought comment on whether changes to disclosures that are not required to be included in privacy notices by the GLBA or § 1016.6 should cause an institution not to satisfy § 1016.5(e)(1)(ii).

The Bureau received few comments on this issue. A trade association representing credit unions stated that later changes to initial voluntary disclosures should not trigger the need to send annual privacy notices. The commenter suggested that imposing such a requirement would dissuade institutions from making voluntary disclosures. A banking and insurance trade association stated that affiliate marketing policy changes should not impact the availability of the exception. A trade association representing banks stated that changes to disclosures that are not required to be included in privacy notices should not trigger non-compliance. The trade association believed it would be costly and burdensome to add additional disclosures.

As indicated in the preamble to the proposed rule, the Bureau has determined that disclosures describing sharing with affiliates under FCRA section 624 or voluntary disclosures and opt-outs will not affect a financial institution's eligibility for the annual privacy notice exception under GLBA § 503(f). The Bureau believes that the alternative interpretation could discourage the use of voluntary disclosures while adding unnecessary burden.

5(e)(2) Delivery of Annual Privacy Notice After Financial Institution No Longer Meets Requirements for Exception

New GLBA section 503(f) states that a financial institution that meets the requirements for the annual notice exception will not be required to provide annual notices ''until such time'' as the financial institution fails to comply with the criteria described in section 503(f)(1) and 503(f)(2), which are now implemented in § 1016.5(e)(1)(i) and (ii). A financial institution will no longer meet the requirements for the exception either by beginning to share nonpublic personal information in ways that trigger rights to opt-out notices under the GLBA and Regulation P, or by otherwise changing its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 1016.6(a)(2) through (5) and (9) in the most recent privacy notice the financial institution provided.

Financial institutions that no longer meet the conditions for the exception must provide customers with annual privacy notices. However, the GLBA, including new GLBA section 503(f), does not clearly specify when institutions must provide these notices. Thus, the statute is ambiguous on the point. It could be read to require the financial institution to provide an annual privacy notice by the time it changes its policies or practices in such a way that it no longer qualifies for the exception. Alternatively, it could be read to subject the financial institution, at the time it changes its policies or practices in such a way that it no longer qualifies for the exception, to the requirement to provide an annual privacy notice while being silent as to the timing for providing that notice.

Pursuant to its authority in GLBA section 504 to issue rules to implement the GLBA, the Bureau proposed to resolve this ambiguity by adopting this second reading and issuing standards for when institutions must provide these notices. Specifically, in proposed § 1016.5(e)(2)(i) and (ii), the Bureau proposed to use its rulemaking authority under GLBA section 504(a) to establish timing requirements for providing an annual notice in these circumstances. The Bureau proposed to establish these requirements to ensure that delivery of the annual privacy notice in these circumstances is consistent with the existing timing requirements for privacy notices in the regulation, where applicable, and to provide clarity to financial institutions regarding these requirements.

In developing the proposed framework, the Bureau looked to existing requirements under the statute and regulation because they already address circumstances in which a financial institution might change its policies and procedures in a way that affects the content of the notices. Specifically, § 1016.8 requires that the financial institution provide a revised notice to consumers *before* implementing certain types of changes; in other cases, the statute and regulation currently contemplate that a change in policy and procedure that affects the content of the notices would simply be reflected on the next regular annual notice provided to the customer. The Bureau is therefore proposing different timing requirements for the resumption of the annual notice requirement depending on whether the change at issue would trigger the requirement for a revised notice under § 1016.8 prior to the change taking effect.

Accordingly, the timing requirements in proposed § 1016.5(e)(2)(i) and (ii) would differ depending on whether the change that causes the financial institution to no longer satisfy the conditions for the annual notice

exception also triggers a requirement under existing Regulation P to deliver a revised notice. Section 1016.8 currently requires that financial institutions provide revised notices to consumers before the institutions share nonpublic personal information with a nonaffiliated third party if their sharing would be different from what the institution described in the initial notice it delivered. After delivering the revised notice, the financial institution must also give the consumer a reasonable opportunity to opt out of any new information sharing beyond the Regulation P exceptions before the new sharing occurs.

Three-fifths of all industry commenters on the proposed rule specifically addressed the proposed timing requirements. The comments on the timing requirements viewed the requirement in § 1016.5(e)(2)(i) and that in § 1016.5(e)(2)(ii) very differently, as will be discussed below in regard to those sections. In regard to the overall timing requirements, one trade association representing credit unions expressed appreciation for the Bureau's proposal, stating that such clarification will eliminate confusion surrounding delivery requirements after a financial institution no longer meets the requirements for the exception. A trade association representing banks supported the proposed timing requirements, asserting that institutions will not find it difficult to comply with the suggested conditions. This commenter also requested clarification that once notices are sent and there are no further privacy changes, an institution will be able to again qualify for the exception, thus excepting them from having to send further annual notices.

The Bureau is adopting the timing provisions largely as proposed, with a change to the duration of the timing requirement in § 1016.5(e)(2)(ii), as discussed below. The Bureau is also adding another example to § 1016.5(e)(2)(iii) to clarify whether a financial institution again qualifies for the annual notice exception after delivering an annual notice under § 1016.5(e)(2).

5(e)(2)(i) Changes Preceded by a Revised Privacy Notice

For changes to a financial institution's policies or practices that cause it to no longer satisfy the conditions for the exception and also trigger an obligation to send a revised notice prior to the change, the Bureau proposed in § 1016.5(e)(2)(i) that financial institutions would be required to resume delivery of their subsequent regular annual notices pursuant to the existing timing requirements that govern delivery of annual notices generally. Because the revised notice would inform the customer of the institution's changed policies and practices before any new sharing occurs, the Bureau believed that there is no clear urgency regarding delivery of the first annual notice subsequent to implementation of the new policies and procedures.

Specifically, § 1016.4(a)(1) generally requires a financial institution to provide an initial notice to an individual who becomes the institution's customer no later than when it establishes a customer relationship. Section 1016.5(a) requires a financial institution to provide a privacy notice to its customers ''not less than annually'' during the continuation of any customer relationship. Section 1016.5(a)(1) defines annually to mean ''at least once in any period of 12 consecutive months.'' It further provides that a financial institution ''may define the 12-consecutive-month period, but [] must apply it to the customer on a consistent basis.'' Section 1016.5(a)(2) provides an example of the meaning of ''annually'' in relation to the delivery of the first annual notice after the initial notice:

> You provide a notice annually if you define the 12-consecutive-month period as a calendar year and provide the annual notice to the customer once in each calendar year following the calendar year in which you provided the initial notice. For example, if a customer opens an account on any day of year 1, you must provide an annual notice to that customer by December 31 of year 2.

The example in § 1016.5(a)(2) provides financial institutions with the flexibility to select a specific date during the year to provide annual notices to all customers, regardless of when a particular customer relationship began. This flexibility avoids burdening institutions with either having to provide annual notices on the anniversary of initial notices, or alternatively providing two notices in the first year of the customer relationship to get all accounts originated in a given calendar year on the same cycle for delivering subsequent annual notices.

The Bureau proposed that the approach to timing of the annual notice in § 1016.5(a)(2) be applied if a financial institution makes a change that causes it to lose the exception and triggers the requirement to deliver a revised notice prior to the change. Under the proposed approach, if a financial institution provides a revised notice on any day of year 1 in advance of changing its policies or practices such that it loses the exception, that revised notice would be treated as analogous to an initial notice in § 1016.5(a)(2). Assuming that the financial institution defines the 12-month period as the calendar year, the financial institution would have to provide the first annual notice after losing the exception by December 31 of year 2.

The Bureau invited comment on the timing conditions proposed in § 1016.5(e)(2)(i). Few commenters separately discussed § 1016.5(e)(2)(i). All commenters who explicitly addressed the proposed timing requirements under § 1016.5(e)(2)(i) agreed with the Bureau's proposed approach. No industry commenters suggested alternative timing conditions. One credit union asserted that the proposed timing condition would incentivize credit unions to plan and notify their members in advance of making changes to privacy policies. Two trade associations representing banks and credit unions supported the timing requirement because it would prevent institutions from having to send out multiple notices within the same year. The trade association representing credit unions asserted that redundant notices provide no benefit to consumers and pose a burden and expense on credit unions.

The Bureau now adopts § 1016.5(e)(2)(i) as proposed. The Bureau believes that using the same approach in § 1016.5(e)(2)(i) as in existing § 1016.5(a)(2) is appropriate for two reasons. First, customers will receive a revised notice informing them of the change in the financial institution's policies or practices before the change occurs, and thus customers will not be harmed by the financial institution taking a longer period of time in which to deliver the first annual notice after the annual notice exception has been lost. Second, this approach will preserve flexibility for financial institutions and avoid requiring them to deliver a revised notice and an annual notice in the same year, and allowing them to use a convenient delivery date for annual notices for all customers. The Bureau believes this flexibility is justified because a financial institution that is required to deliver a revised privacy notice pursuant to § 1016.8 may have continuing annual notice obligations after the exception is lost. Such an institution could be sharing other than as described in the Regulation P exceptions and thus fail to satisfy § 1016.5(e)(1)(i), making the annual notice exception unavailable in future years.

5(e)(2)(ii) Changes Not Preceded by a Revised Privacy Notice

For financial institutions that change their policies and practices in such a way as to lose the § 503(f) exception, but do not share information in a way that triggers the requirement under § 1016.8 to deliver a revised notice prior to the change, the Bureau proposed that a financial institution must deliver the annual notice within 60 days after the change that caused the institution to lose the exception. The Bureau proposed this 60-day period for providing the annual notice in this situation because customers would not receive a revised notice from the financial institution prior to the institution's change in policies or practices.

The Bureau requested comment on whether 60 days is an appropriate period for delivering annual notices in these circumstances or if another period would be more appropriate. Approximately half of all commenters specifically addressed the timing conditions proposed under § 1016.5(e)(2)(ii). These commenters generally opposed the 60-day requirement, advocating instead for an increased amount of time for institutions to deliver the revised notice. The majority of these commenters requested at least 90 days to deliver the notice.

Trade associations representing credit unions cited cost concerns with the 60-day requirement, asserting that because they send quarterly statements to many consumers, the timing requirement would require institutions to send out an additional notice. Some of these commenters suggested that 90 days was a more appropriate timeframe, as it would allow institutions to minimize costs by sending the revised notice with the next quarterly statement. One of these trade associations representing credit unions also asserted that 60 days was too brief, particularly for small credit unions addressing inadvertent changes. This commenter suggested 90 to 120 days to allow credit unions the opportunity to include the notice with the quarterly periodic statement, and noted that while all members may not receive monthly statements, most receive account statements quarterly.

Other industry commenters suggested 120 days as an appropriate time to deliver the annual notice. A few of these commenters cited the same above-mentioned cost concerns that are associated with separate mailers. These commenters asserted that 120 days would allow the notice to be included with regularly scheduled member statements, therefore eliminating the need for an additional mailer. One industry commenter representing credit unions noted that a separate mailer would be especially costly for smaller credit unions with fewer resources.

Industry commenters who suggested 120 days also stated, without specific explanation, that the proposed 60-day requirement did not provide institutions enough time to perform. A few of these industry commenters asserted that smaller credit unions, particularly those with fewer resources, would find the 60-day time frame too short. Some of those same commenters thought that larger credit unions with numerous departments working to consolidate information would also struggle to meet the 60-day requirement. Several trade associations representing credit unions stated that a longer time frame would allow credit unions time to organize logistics, educate staff, and command the resources necessary to draft and send the required notice. One industry commenter stated that an extension would not negatively impact consumers because prior notice is still required when changes allow sharing with third parties of non-public personal information and the option to opt out in advance.

One trade association commenter representing credit unions suggested at least 180 days, citing the fact that § 1016.8 does not require a revised privacy notice under the circumstances described in § 1016.5(e)(2)(ii). This commenter also suggested that to combat costs, financial institutions should have the option to include a message on periodic statements or mailers that there has been a change to the privacy notice, and direct the recipient to the financial institution's website to view and download an electronic copy of the revised notice.

The Bureau now adopts the timing provision in § 1016.5(e)(2)(ii) with a 100 calendar day period during which the financial institution must provide the annual privacy notice. The unanimous industry objection to the 60-day period suggests that the proposal likely would have imposed costs that the Bureau had not anticipated. The 100-day period will accommodate the inclusion of the notice with quarterly statements. The Bureau believes that providing 10 days in addition to the 90 days many commenters requested is appropriate because most calendar quarters are slightly longer than 90 days, and a short additional period should be allowed for administrative activities and to provide flexibility if the end date falls on a weekend or holiday. The Bureau does not believe that consumers will be harmed by this extension of the time period from the proposal.

However, the Bureau notes that the commenters requesting 120 or 180 days provided no specific reason why allowing such additional time would contribute to cost savings beyond allowing the notice to be included in quarterly statements. The Bureau is not aware of any other reason, and therefore declines to adopt a longer period.

The Bureau believes that the 100-day deadline will not impose undue or unreasonable costs on financial institutions, particularly since the delivery requirement is effectively a one-time burden absent additional changes to a financial institution's policies and practices. Specifically, after providing the one annual notice, the financial institution will likely once again meet both of the conditions for the exception—it will not be sharing nonpublic personal information with nonaffiliates other than as described in a Regulation P exception to the opt-out requirements and its policies and practices will not have changed since it provided the annual notice. Because the financial institution likely will once again meet the conditions for the exception, it likely will not be required to provide future annual notices. In other words, these financial institutions will likely lose the exception for only a single year. The Bureau is including an additional example in § 1016.5(e)(2)(iii)(B) for clarity. Given that financial institutions delivering notices pursuant to § 1016.5(e)(2)(ii) will likely have no continuing obligation to send annual notices, they likely will not need flexibility in choosing a convenient delivery date for future annual notices, beyond the 100 days of flexibility being provided for a single privacy notice.[43]

In regard to the comment that the regulation should allow financial institutions to include a message on periodic statements or mailers directing customers to an electronic copy of the annual notice, the Bureau believes that any reduction in costs would be minimal because the financial institution is likely not required to provide more than one notice. In addition, the Bureau did not propose or request comment on such an option.

The Bureau also notes that financial institutions have substantial flexibility in managing the burden involved in sending the one annual notice because institutions can generally choose when

[43] If the financial institution were to make changes in the future to its practices and policies, these changes could trigger a new obligation to provide annual privacy notices.

they change their policies or practices. Accordingly, an institution can choose when to make the change triggering the commencement of the 100-day period for delivery of the annual notice, so that the date of delivery can be as convenient and low-cost as possible.

5(e)(2)(iii) Examples

In order to facilitate compliance with proposed § 1016.5(e)(2), the Bureau proposed § 1016.5(e)(2)(iii) to provide an example for when an institution must provide an annual notice after changing its policies or practices such that it no longer meets the requirements for the annual notice exception set forth in proposed § 1016.5(e)(1).

The Bureau did not receive any comments specifically discussing the example provided in § 1016.5(e)(2)(iii). Because the Bureau believes that the example will provide clarity and facilitate compliance, it is now being made final in § 1016.5(e)(2)(iii)(A), with a minor change due to the alteration of the time frame in § 1016.5(e)(2)(ii). In addition, the Bureau is providing a second example, in § 1016.5(e)(2)(iii)(B), to facilitate compliance when a financial institution must only provide one annual notice before it again qualifies for the § 1016.5(e)(1) exception.

Section 1016.5(e)(2)(iii)(A) provides an example for when an institution must provide an annual notice after changing its policies or practices such that it no longer meets the requirements for the annual notice exception in § 1016.5(e)(1). The Bureau believes this example will facilitate compliance with § 1016.5(e)(2). The example assumes that an institution changes its policies or practices effective April 1 of year 1 and defines the 12-consecutive-month period pursuant to § 1016.5(a)(1) as a calendar year. Section 1016.5(e)(2)(iii)(A) states that the institution must provide an annual notice by December 31 of year 2 if the institution was required to provide a revised notice prior to the change and provided that revised notice on March 1 of year 1 in advance of the change. Section 1016.5(e)(2)(iii)(A) further states that the institution must provide an annual notice by July 9 of year 1 if the institution was not required to provide a revised notice prior to the change.

The Bureau is also providing a second example, in § 1016.5(e)(2)(iii)(B), to facilitate compliance when a financial institution must provide only one annual notice before it again qualifies for the § 1016.5(e)(1) exception, as discussed above in relation to § 1016.5(e)(2)(ii). The example assumes that a financial institution changes its policies and practices in such a way that it no longer meets the requirements of § 1016.5(e)(1), and so provides an annual notice to its customers. The example further assumes that after providing the annual notice to its customers, the financial institution once again meets the requirements of § 1016.5(e)(1) for an exception to the annual notice requirement. The example explains that the financial institution does not need to provide additional annual notices to its customers until such time as it no longer meets the requirements of § 1016.5(e)(1).

Section 1016.9 Delivering Privacy and Opt Out Notices

9(c)(2) Alternative Delivery Method for Providing Certain Annual Notices

As discussed in Part II, the Bureau amended Regulation P in October 2014 to allow financial institutions that met certain criteria to deliver annual notices pursuant to the ''alternative delivery method.'' Because financial institutions that met the conditions in Regulation P to use the alternative delivery method will also meet the conditions for the statutory exception in section 503(f), the Bureau proposed to remove the alternative delivery method from Regulation P by removing § 1016.9(c)(2) and renumbering existing § 1016.9(c)(1) as § 1016.9(c).

Commenters generally expressed support for the proposed removal of the alternative delivery method. Ten commenters addressed the issue, with eight supporting the proposal and two opposing it.

Some commenters welcomed elimination of the alternative delivery method, asserting that the conditions associated with the 2014 provision deterred institutions from taking advantage of the intended relief. A debt collector organization stated that the alternative delivery method did not provide a solution for many debt collectors and consumers. This commenter asserted that the alternative delivery required model form created a significant risk of class action litigation because of claims that the language conflicts with the Fair Debt Collection Practices Act's prohibitions on third-party disclosure. A commenter representing several trade associations stated that the alternative delivery method requirement to post the notice online eliminated any benefits from the 2014 rule.

Two trade associations agreed that the alternative delivery method would no longer be useful in light of the statutory exception to the annual notice requirement, and one of these trade associations stated that it was unlikely that financial institutions would continue to use a complex means of compliance when a simpler one was available.

Several commenters discussed benefits associated with eliminating the alternative delivery method. One trade association stated that removing the alternative delivery method would eliminate confusion between the rule and the statute. Another trade association representing banks expressed appreciation of the elimination of the alternative delivery method, arguing that it would remove the confusion of having both an exception from the annual privacy notice and an alternative to the delivery requirement. One trade association stated that consumers will benefit from the elimination of the method, as they will experience decreasing information overload.

One trade association representing banks requested clarification that institutions that qualify for the exception but still keep a copy of the privacy policy on their websites will not be criticized or penalized.

Two trade association commenters representing the consumer credit industry and credit unions did not support removal of the alternative delivery method. These commenters stated that their customers or members prefer to receive communications electronically. Both commenters cited cost burdens associated with mailing privacy notices.

The trade association representing the consumer credit industry stated that several of their member financial institutions, particularly those that provide indirect auto loans, do not qualify for the statutory exception to the annual notice requirement because the institutions share consumer information with nonaffiliated third parties other than as described in §§ 1016.13, 14 and 15. These institutions are required under § 1016.10 of Regulation P to inform consumers through the institution's annual privacy notice that the consumer has a right to opt out of that information sharing. The trade association representing the consumer credit industry encouraged expansion of the alternative delivery method, highlighting the cost effectiveness of electronic delivery and stating that many institutions upgraded systems to implement the alternative delivery method under the 2014 rule. This commenter also urged the Bureau to consider allowing institutions that share with nonaffiliated third parties to deliver their privacy notices electronically, such as via website

posting, similar to the method permitted by the alternative delivery method.

After considering the comments, the Bureau now adopts the proposed change, removing the alternative delivery method from Regulation P by removing § 1016.9(c)(2) and renumbering former § 1016.9(c)(1) as § 1016.9(c).

Any financial institution that met the conditions to use the alternative delivery method will also meet the conditions to be excepted from delivering an annual privacy notice pursuant to new GLBA section 503(f). First, new GLBA section 503(f)(1) is substantively identical to the first requirement for using the alternative delivery method: [44] That the financial institution share nonpublic personal information about customers with nonaffiliated third parties only in ways that do not give rise to the customer's right to opt out of that sharing.[45] Second, new GLBA section 503(f)(2) is similar to the fourth requirement for using the alternative delivery method: that the institution must not have changed its policies and practices with regard to disclosing nonpublic personal information from those that were disclosed to the customer in the most recent privacy notice.[46] Accordingly, any financial institution that would have met the requirements in former § 1016.9(c)(2) will also meet the requirements of section 503(f).

The Bureau believes that a financial institution that has both options available to it would choose not to send the annual privacy notice at all, rather than to deliver it pursuant to the alternative delivery method, so that it can eliminate rather than merely reduce the cost of providing annual notices. Given that any financial institution that qualifies to use the alternative delivery method for its annual notices also meets the qualifications for the new annual notice exception, the Bureau believes that including the alternative delivery method in Regulation P is no longer useful.

The Bureau notes that financial institutions that delivered annual notices using the alternative delivery method while it was in effect delivered those notices using a method that was in compliance with Regulation P, notwithstanding that the alternative delivery method provision is now being removed from the regulation. The Bureau further notes that financial institutions that qualify for the new annual notice exception may still choose to post privacy notices on their websites, deliver privacy notices to consumers who request them, and notify consumers of the notices' availability. Such activities will not affect a financial institution's eligibility for the new 503(f) exception.

The Bureau has considered the comments suggesting that it retain and expand the alternative delivery method for providing annual privacy notices. In this rulemaking, the Bureau is implementing the FAST Act amendments to the GLBA, which eliminate the requirement that financial institutions provide an annual privacy notice if certain conditions are met. In making these amendments to the GLBA, Congress did not address the delivery method financial institutions must or may use if they continue to be required to provide an annual privacy notice, including where financial institutions have not changed their privacy policies since their last privacy notice and they share information with nonaffiliated third parties other than as described in §§ 1016.13, .14, and .15. Because Congress did not address these issues in the FAST Act amendments to the GLBA, the Bureau declines to address them in this rulemaking to implement those amendments.

V. Dodd-Frank Act Section 1022(b)(2) Analysis

A. Overview

In developing the final rule, the Bureau has considered the potential benefits, costs, and impacts as required by section 1022(b)(2) of the Dodd-Frank Act.[47] The Bureau requested comment on the preliminary analysis as well as the submission of additional data that could inform the Bureau's analysis of the benefits, costs, and impacts of the rule. The Bureau received one comment on the preliminary analysis, which it has considered in developing this final analysis. In addition, the Bureau has consulted and coordinated with the SEC, CFTC, FTC, and NAIC, and consulted with or offered to consult with the OCC, Federal Reserve Board, FDIC, NCUA, and HUD, including regarding consistency with any prudential, market, or systemic objectives administered by such agencies.

This final rule implements the December 2015 amendment to the GLBA by amending § 1016.5 of Regulation P to provide that a financial institution is not required to deliver an annual privacy notice if it:

(1) Provides nonpublic personal information to nonaffiliated third parties only in accordance with the provisions of § 1016.13, § 1016.14, or § 1016.15; and

(2) Has not changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 1016.6(a)(2) through (5) and (9) in the most recent privacy notice provided.

In considering the potential benefits, costs, and impacts of the rule, the Bureau takes as the baseline for the analysis the legal regime that existed prior to the FAST Act's amendment of the GLBA.[48] This regime includes the current provisions of Regulation P. The Bureau assumes that all financial institutions that can use the alternative delivery method provided in § 1016.9(c)(2) are doing so.

B. Potential Benefits and Costs to Consumers and Covered Persons

The impact on consumers of § 1016.5(e) depends on whether the particular consumer prefers or would otherwise benefit from receiving an annual privacy notice that does not offer the consumer an opt-out under the GLBA and is largely unchanged[49] from previous notices. Under § 1016.5(e), financial institutions that meet the requirements for the annual notice exception would not be required to provide consumers with annual privacy notices, and the Bureau anticipates that most institutions would decide not to provide notices in these circumstances.

[44] See removed 12 CFR 1016.9(c)(2)(i)(A).

[45] This sharing is pursuant to GLBA section 503(b)(2) and (e), which correspond to Regulation P §§ 1016.13, 1016.14, and 1016.15.

[46] See removed 12 CFR 1016.9(c)(2)(i)(D). The requirement in former § 1016.9(c)(2)(i)(D) was somewhat more restrictive because it required a financial institution not to have changed its practices with respect to disclosing nonpublic personal information and protecting the confidentiality and security of nonpublic personal information whereas section 503(f)(2) requires that the institution not have changed its policies only with respect to disclosing nonpublic personal information. *See* the section-by-section analysis of § 1016.5(e)(1)(ii) for further discussion.

[47] Specifically, section 1022(b)(2)(A) of the Dodd-Frank Act calls for the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas.

[48] The proposal referred to this as the ''regulatory regime that currently exists.'' 81 FR at 44808. However, the baseline the Bureau is using did not and does not reflect that the FAST Act has taken effect. The Bureau has discretion in each rulemaking to choose the relevant provisions to discuss and to choose the most appropriate baseline for that particular rulemaking.

[49] As discussed in part IV in the section-by-section analysis of § 1016.5(e)(1)(ii), certain changes to an institution's policies or practices would not cause the institution to lose the annual notice exception.

While there is no data available on the number of consumers who are indifferent to (or dislike) receiving unchanged privacy notices every year, the limited use of opt-outs and anecdotal evidence suggest that there are such consumers.[50] For this group of consumers, § 1016.5(e) might provide a benefit because it would be available to some institutions that cannot use the alternative delivery method, so that more consumers would stop receiving mailed annual privacy notices.

For other consumers who would prefer or otherwise benefit from receiving the annual notices, there will be some cost because many institutions that previously delivered notices—whether through the standard delivery methods or through the alternative delivery method that includes posting on the institution's website—will no longer deliver annual notices. Consumers may be less informed about opportunities to limit a financial institution's information sharing practices if the financial institution meets the requirements for the annual notice exception and chooses not to provide annual notices. For example, some consumers will receive fewer notices in which a financial institution offers *voluntary* opt-outs, *i.e.,* opt-outs that the financial institution is not required by Regulation P to offer (because, for example, the type of sharing the financial institution does is covered by an exception) but that the institution decides to provide anyway via the annual privacy notice. Voluntary opt-outs do not appear to be common, however.[51] Further, institutions may continue to offer voluntary opt-outs and may offer them through other mechanisms even if they do not provide annual privacy notices.

If financial institutions choose not to provide notices pursuant to the annual notice exception, consumers may also be less informed of their opt-out rights under the FCRA. Section 503(c)(4) of the GLBA and Regulation P require financial institutions providing initial and annual privacy notices to incorporate into them any notification and opt-out disclosures provided pursuant to section 603(d)(2)(A)(iii) of the FCRA.[52] Section 624 of the FCRA and Regulation V also permit (but do not require) financial institutions providing initial and annual privacy notices under Regulation P to incorporate any opt-out disclosures provided under section 624 of the FCRA and subpart C of Regulation V into those notices.[53] Because financial institutions will likely decide not to provide annual notices pursuant to the exception in proposed § 1016.5(e), consumers may be less informed of their opt-out rights pursuant to these sections of the FCRA to the extent that institutions use less effective methods to convey information about these rights to consumers.[54] Consumers also may be less informed about a financial institution's data collection practices and its policies and practices with respect to protecting the confidentiality and security of nonpublic personal information.

Regarding benefits and costs to covered persons, the primary effect of the rule will be burden reduction achieved by lowering the costs to industry of providing annual privacy notices. Section 1016.5(e) imposes no new compliance requirements on any financial institution. Any institution that could use the alternative delivery method will meet the requirements for the annual notice exception pursuant to § 1016.5(e).[55] A financial institution that is in compliance with current law will not be required to take any different or additional action unless it chooses to take advantage of the annual notice exception and thus will be required to separately meet its opt-out obligations, if any, pursuant to the FCRA.[56] This analysis assumes that no financial institution will do so unless the net result of the choice is burden reducing.

The expected cost savings to financial institutions from the revisions to § 1016.5(e) depend on whether the financial institution uses the alternative delivery method under the baseline. Financial institutions that currently use the alternative delivery method will likely cease complying with the requirements in current § 1016.9(c)(2) since they necessarily meet the requirements of the exception to the annual notice requirement and thus will no longer be required to deliver an annual notice.[57] However, the Bureau expects that financial institutions that change from using the alternative delivery method to provide annual notices to not providing these notices at all will achieve little cost savings.[58] Financial institutions that currently do not use the alternative delivery method are expected to use the proposed annual notice exception if the expected costs of any changes required to use the exception and the costs of any consequences of not providing the annual disclosure will be lower than the costs of complying with current Regulation P. The Bureau believes that few such financial institutions will find it in their interests to change their information sharing practices in order to use the annual notice exception. Thus, the Bureau takes the information sharing practices of financial institutions as given and considers how many financial institutions that do not currently meet the requirements to use the alternative delivery method can use the annual notice exception.[59] As a practical matter, the Bureau identifies these institutions solely by their

[50] One early analysis of the use of the opt-outs reported at most 5% of consumers make use of them in any year, and likely fewer. *See* Jeffrey M. Lacker, *The Economics of Financial Privacy: To Opt Out or Opt In?,* 88/3 Fed. Res. Bank Rich. Econ. Q., at 11 (Summer 2002), *available at https://www.richmondfed.org/-/media/richmondfedorg/publications/research/economic_quarterly/2002/summer/pdf/lacker.pdf.* One commenter on the proposed rule also estimated that 5% of consumers use opt-outs. AFSA Comment letter, August 10, 2016.

[51] *See* Lorrie Faith Cranor et al., *Are They Actually Any Different? Comparing Thousands of Financial Institutions' Privacy Practices, available at http://www.econinfosec.org/archive/weis2013/papers/CranorWEIS2013.pdf* (submitted as part of The Twelfth Workshop on the Economics of Information Security (WEIS 2013), June 11–12, 2013, Georgetown University, Washington, DC). Their findings (Table 2) imply that at most 15% of the 3,422 FDIC insured depositories that post the model privacy form on their websites offer at least one voluntary opt-out. Data from a much larger group of financial institutions analyzed by Cranor et al. (undated) imply (Table 2) that at most 27% of the 6,191 financial institutions that post the model privacy form on their websites offer at least one voluntary opt-out.

[52] 15 U.S.C. 6803(c)(4); 12 CFR 1016.6(a)(7).

[53] 15 U.S.C. 1681s–3(b); 12 CFR 1022.23(b).

[54] As explained in the section-by-section analysis of § 1016.5(e)(1)(i) in part IV, the annual notice exception in § 1016.5(e) does not relieve financial institutions of the obligation to provide consumers with the information that is required under FCRA sections 603(d)(2)(A)(iii) or 624.

[55] Any financial institution that meets the conditions to use the alternative delivery method will also meet the conditions to be excepted from delivering an annual privacy notice pursuant to new GLBA section 503(f) because the two conditions for section 503(f) are closely related to conditions for using the alternative delivery method. See the section-by-section analysis of § 1016.9(c) for further explanation.

[56] See the section-by-section analysis to § 1016.5(e)(1)(i) in part IV for an explanation of the interaction between the annual notice exception and the opt-outs provided under FCRA sections 603(d)(2)(A)(iii) and 624.

[57] *See supra* note 52.

[58] The Bureau believes that the alternative delivery method imposes little ongoing cost to financial institutions that have adopted it. These costs derive from the additional text on an account statement, coupon book, notice or disclosure the institution already provides; maintaining a webpage dedicated to the annual privacy notice; responding to telephone calls from a very small number of consumers requesting that the model form be mailed; and mailing the forms prompted by these calls.

[59] Because the Bureau takes institutions' sharing practices as given and because the cost savings estimate is based on a single year, the expected cost savings for institutions does not account for a reduction or increase in aggregate cost savings that may occur if any institutions change their sharing practices in the future such that they no longer meet the requirements for the annual notice exception or they begin to meet those requirements.

information sharing practices: That is to say, the Bureau identifies the financial institutions whose current information sharing practices do not meet the standards in § 1016.9(c)(2) but will meet the standards in § 1016.5(e). The Bureau then estimates the ongoing savings in costs to these financial institutions from no longer sending the annual privacy notice.[60]

For the 2014 Annual Privacy Notice Rule, the Bureau collected a sample of privacy policies from banks and credit unions and estimated both the number of financial institutions that would adopt the alternative delivery method and the aggregate cost savings that would result.[61] Specifically, the Bureau examined the privacy policies of 19 banks with assets over $100 billion as well as the privacy policies of 106 additional banks selected through random sampling. The Bureau previously concluded that 80% of banks could use the alternative delivery method that was set forth in § 1016.9(c)(2). For the current rulemaking, the Bureau re-analyzed this sample to identify banks with information sharing practices that do not meet the standard in § 1016.9(c)(2) but will meet the standard in § 1016.5(e). In the re-analysis, the Bureau finds that 48% of banks that could not use the alternative delivery method can use the proposed exception to the annual notice requirement. Most of these banks were not able to use the alternative delivery method because they offered opt-outs to consumers pursuant to FCRA section 603(d)(2)(A)(iii); a financial institution can meet the requirements for the annual notice exception in § 1016.5(e) even if it offers such opt-outs. Specifically, the Bureau previously estimated that approximately 1,350 banks could not use the alternative delivery method and our re-analysis shows that 650 of these banks (48%) will be able to use the annual notice exception.[62] For banks with assets over $10 billion, 70% of those that could not use the alternative delivery method can use the annual notice exception. For banks with assets of $10 billion or less and banks with assets of $500 million or less, the respective figures are 47% and 40%.

The Bureau also previously examined the privacy policies of the four credit unions with assets over $10 billion as well as the privacy policies of 50 additional credit unions selected through random sampling. The Bureau previously concluded that 46% of credit unions could use the alternative delivery method. The information evaluated in the re-analysis shows that none of the credit unions that could not use the alternative delivery method will be able to use the exception to the annual notice requirement. Credit unions that clearly could not use the alternative delivery method generally shared information with nonaffiliated third parties other than as specified in the exceptions in §§ 1016.13, 1016.14, and 1016.15. However, there are a number of cases in which the Bureau could not readily evaluate the information sharing practices of the sampled credit union because it did not have a website, did not post the privacy notice on its website, or did not use the model form.[63] In the proposal, the Bureau requested data and other factual information on the use of the alternative delivery method by credit unions and the likely use of the proposed annual notice exception by credit unions that cannot use the alternative delivery method. No comments provided data in response to this request.[64]

Regarding the number of non-depository financial institutions that will benefit from the exception to the annual notice requirement, the Bureau uses the same basic methodology as in its prior analysis. Specifically, the Bureau assumes that the fraction of non-depository financial institutions that cannot use the alternative delivery method but can use the new annual notice exception is the same for non-depository institutions as for banks (9.5%).[65]

Having identified the financial institutions that will benefit from the exception to the annual notice requirement, the Bureau estimates the benefit using the same basic methodology as in its prior analysis.[66] For banks, the Bureau allocated the total burden of providing the annual privacy notices to asset-size groups in proportion to the share of assets in the group. The Bureau then estimated an amount of burden reduction specific to each asset-size group using the results from the privacy notice analysis described above. The total burden reduction is then the sum of the burden reductions in each asset-size group. The estimated reduction in burden for banks using this methodology is approximately $3.158 million annually. The estimated reduction in burden for non-depository financial institutions is an additional $231,000 annually.[67] Thus, the Bureau believes that the total reduction in burden is approximately $3.389 million dollars annually.[68] This represents about 28% of the total $12.162 million annual cost of providing the annual privacy notice under Regulation P.

The Bureau requested comment on the preliminary presentation of this analysis as well as the submission of additional data that could inform the Bureau's consideration of the cost savings to financial institutions. No comments addressed this request.

[60] The Bureau assumes that a financial institution used the alternative delivery method whenever the Bureau can obtain the annual privacy notice from the website of the financial institution and the Bureau concludes from the information on the privacy notice that the information sharing practices of the financial institution comply with removed § 1016.9(c)(2). If a financial institution did not use the model form, the Bureau assumes that the financial institution would have adopted the model form if the information sharing practices complied with § 1016.9(c)(2). This methodology overstates the number of these financial institutions that could have used the alternative delivery method, because some of these financial institutions might not have met all of the requirements of § 1016.9(c)(2), and therefore understates the benefits of the annual notice exception to these financial institutions. On the other hand, if a financial institution does not have a website, the Bureau cannot (as a practical matter) obtain and evaluate its information sharing practices. In this case, the Bureau assumes that the financial institution cannot use either the alternative delivery method or the annual notice exception. This also tends to understate the benefits of the annual notice exception to these financial institutions, since none of them could have used the alternative delivery method but some might be able to use the annual notice exception.

[61] *See* 79 FR 64057, 64076–64077 (Oct. 28, 2014). Note that the term ''banks'' as used throughout this rule includes savings associations.

[62] While these 650 banks are just 9.5% of all banks, this percentage does not take into account the fact that the majority of banks could not potentially benefit from the exception to the annual privacy notice requirement since (by our previous analysis) they already use the alternative delivery method.

[63] One or more of these conditions held for a number of credit unions with assets of $500 million or less. As explained above, if a financial institution did not have a website or did not post the privacy notice on their website, the Bureau made the conservative assumption that it did not benefit from the alternative delivery method and will not benefit from the new annual notice exception. *See also* 79 FR 64057, 64076 (Oct. 28, 2014).

[64] Although no credit unions or credit union advocates commented or provided data, one State trade association representing banks stated that many financial institutions will appreciate and take advantage of the exception, but it will not create additional costs or harm to consumers. That commenter did not provide data.

[65] For further discussion, *see id.* at 64077.

[66] *See id.* at 64076–64077.

[67] Note that this figure excludes auto dealers. Auto dealers are regulated by the FTC and will not be directly impacted by this amendment to Regulation P.

[68] Some of these banks and non-depository financial institutions that currently include on their annual privacy notice the opt-out notices pursuant to FCRA section 603(d)(2)(A)(iii) or FCRA section 624 and the Affiliate Marketing Rule may now be required to deliver these notices separately. The Bureau does not have the data necessary to estimate the frequency with which these opt-out notices will be delivered separately or to subtract the cost of delivering them separately from the savings from no longer providing the annual privacy notice.

The Regulation P exception to the annual notice requirement implements a December 2015 statutory amendment to the GLBA. The Bureau considered alternatives to the timeline for delivery of annual notices when a financial institution that qualified for the annual exception changes its policies or practices such that it no longer qualifies. Because the estimates of costs and benefits to consumers and covered persons take institutions' sharing policies and practices as given, the alternatives with respect to the timeline for delivery of annual notices do not impact those estimates. Further, even if the estimates allowed for changes in sharing policies and practices that can cause institutions to meet or fail to meet the requirements for the annual notice exception, the aggregate annual benefits and costs of delivery will not likely be significantly impacted by the timeline for delivery of annual notices. The Bureau does note, however, that changing from 60 to 100 days for delivery of the annual privacy notice under § 1016.5(e)(2)(ii) should result in a small burden reduction from the proposal, as financial institutions will be able to send the notice with quarterly statements as they requested.

C. Impact on Depository Institutions With No More Than $10 Billion in Assets

The Bureau currently estimates that approximately 600 banks with $10 billion or less in assets cannot use the alternative delivery method but can use the annual notice exception. This constitutes 47% of banks with $10 billion or less in assets that do not use the alternative delivery method and 8.8% of all banks with $10 billion or less in assets. As reported above, 70% of banks with more than $10 billion in assets that do not use the alternative delivery method can use the proposed exception to the annual notice requirement. This is 55% of all banks with more than $10 billion in assets. Thus, the rule may have different impacts on federally insured depository institutions with $10 billion or less in assets as described in section 1026 of the Dodd-Frank Act. The Bureau currently believes that no credit unions of any size that could not use the alternative delivery method will be able to use the exception to the annual notice requirement.

D. Impact on Access to Credit and on Consumers in Rural Areas

The Bureau does not believe that the rule will reduce consumers' access to consumer financial products or services or have a unique impact on rural consumers.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations. The RFA defines a ''small business'' as a business that meets the size standard developed by the Small Business Administration pursuant to the Small Business Act. The RFA generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.[69] The Bureau also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small business representatives prior to proposing a rule for which an IRFA is required.[70]

At the proposed rule stage, the Bureau determined that an IRFA was not required because the proposal, if adopted, would not have a significant economic impact on a substantial number of small entities. For this final rule, the Bureau continues to believe that that determination is accurate. The Bureau does not expect the rule to impose costs on small entities. All methods of compliance under current law will remain available to small entities when this rule is adopted. Thus, a small entity that is in compliance with current law need not take any different or additional action under the new rule. In addition, based on the data analysis described previously, the Bureau believes that the annual notice exception will allow some small institutions to stop sending the annual notice and to thereby reduce costs.

Accordingly, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA),[71] Federal agencies are generally required to seek Office of Management and Budget (OMB) approval for information collection requirements prior to implementation. This proposal would amend Regulation P, 12 CFR part 1016. The collections of information related to Regulation P have been previously reviewed and approved by OMB in accordance with the PRA and assigned OMB Control Number 3170–0010. Under the PRA, the Bureau may not conduct or sponsor, and, notwithstanding any other provision of law, a person is not required to respond to an information collection, unless the information collection displays a valid control number assigned by OMB.

As explained below, the Bureau has determined that this rule does not contain any new or substantively revised information collection requirements other than those previously approved by OMB. The rule will implement the December 2015 amendment to the GLBA and amend § 1016.5 of Regulation P to provide that a financial institution is not required to deliver an annual privacy notice if it:

(1) Provides nonpublic personal information to nonaffiliated third parties only in accordance with the provisions of § 1016.13, § 1016.14, or § 1016.15 and;

(2) Has not changed its policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 1016.6(a)(2) through (5) and (9) in the most recent privacy notice provided.

Under Regulation P, the Bureau generally accounts for the paperwork burden for the following respondents pursuant to its enforcement/supervisory authority: Federally insured depository institutions with more than $10 billion in total assets, their depository institution affiliates, and certain non-depository institutions. The Bureau and the FTC generally both have enforcement authority over non-depository institutions subject to Regulation P. Accordingly, the Bureau has allocated to itself half of the final rule's estimated reduction in burden on non-depository financial institutions subject to Regulation P. Other Federal agencies, including the FTC, are responsible for estimating and reporting to OMB the paperwork burden for the institutions for which they have enforcement and/or supervision authority. They may use the Bureau's burden estimation methodology, but need not do so.

The Bureau does not believe that this final rule will impose any new or substantively revised collections of information as defined by the PRA, and instead believes that it will have the overall effect of reducing the previously approved estimated burden on industry for the information collections

[69] 5 U.S.C. 603 through 605.

[70] 5 U.S.C. 609.

[71] 44 U.S.C. 3501 through 3558.

associated with the Regulation P annual privacy notice. Using the Bureau's burden estimation methodology, the reduction in the estimated ongoing burden will be approximately 62,197 hours annually for the roughly 13,500 banks and credit unions subject to the rule, including Bureau respondents, and the roughly 29,400 entities regulated by the FTC also subject to the rule (*i.e.,* entities over which the FTC has Regulation P administrative enforcement authority). The reduction in estimated ongoing costs from the reduction in ongoing burden will be approximately $3.389 million annually.[72]

The Bureau believes that the one-time cost of adopting the annual notice exception for financial institutions that adopt it will be *de minimis.* The Bureau's methodology for estimating the reduction in ongoing burden was discussed above. The method is similar to that described in the PRA analysis in the 2014 Annual Privacy Notice Rule. The only difference is that instead of estimating the fraction of institutions that will be able to use the alternative delivery method, the Bureau estimates the fraction of institutions that will be able to use the annual notice exception and are not already using the alternative delivery method, to compute the reduction in burden relative to the baseline.[73]

The Bureau takes all of the reduction in ongoing burden from banks and credit unions with assets $10 billion and above and half the reduction in ongoing burden from the non-depository institutions subject to the FTC enforcement authority that are subject to the Bureau's Regulation P. The total reduction in ongoing burden taken by the Bureau is 53,216 hours or $3.058 million annually.[74]

The Bureau has determined that the final rule does not contain any new or substantively revised information collection requirements as defined by the PRA and that the burden estimate for the previously approved information collections should be revised as explained above. The Bureau requested comments on these determinations or any other aspect of the proposal for purposes of the PRA, but received none.

SUMMARY OF BURDEN CHANGES

Information collections	Previously approved total burden hours	Net change in burden hours	New total burden hours
Notices and disclosures	366,134	−53,216	312,917

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Bureau will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 12 CFR Part 1016

Banks, Banking, Consumer protection, Credit, Credit unions, Foreign banking, Holding companies, National banks, Privacy, Reporting and recordkeeping requirements, Savings associations, Trade practices.

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation P, 12 CFR part 1016, as set forth below:

PART 1016—PRIVACY OF CONSUMER FINANCIAL INFORMATION (REGULATION P)

■ 1. The authority citation for part 1016 continues to read as follows:

Authority: 12 U.S.C. 5512, 5581; 15 U.S.C. 6804.

■ 2. Section 1016.3 is amended by revising paragraph (s)(1) to read as follows:

§ 1016.3 Definitions.

* * * * *

(s)(1) *You* means a financial institution for which the Bureau has rulemaking authority under section 504(a)(1)(A) of the GLB Act (15 U.S.C. 6804(a)(1)(A)).

* * * * *

Subpart A—Privacy and Opt Out Notices

■ 3. Section 1016.5 is amended by revising the first sentence of paragraph (a)(1) and adding paragraph (e) to read as follows:

§ 1016.5 Annual privacy notice to customers required.

(a)(1) * * * Except as provided by paragraph (e) of this section, you must provide a clear and conspicuous notice to customers that accurately reflects your privacy policies and practices not less than annually during the continuation of the customer relationship. * * *

* * * * *

(e) *Exception to annual privacy notice requirement.* (1) *When exception available.* You are not required to deliver an annual privacy notice if you:

(i) Provide nonpublic personal information to nonaffiliated third parties only in accordance with the provisions of § 1016.13, § 1016.14, or § 1016.15; and

(ii) Have not changed your policies and practices with regard to disclosing nonpublic personal information from the policies and practices that were disclosed to the customer under § 1016.6(a)(2) through (5) and (9) in the most recent privacy notice provided pursuant to this part.

(2) *Delivery of annual privacy notice after financial institution no longer meets requirements for exception.* If you have been excepted from delivering an annual privacy notice pursuant to paragraph (e)(1) of this section and change your policies or practices in such a way that you no longer meet the requirements for that exception, you must comply with paragraph (e)(2)(i) or (e)(2)(ii) of this section, as applicable.

(i) *Changes preceded by a revised privacy notice.* If you no longer meet the requirements of paragraph (e)(1) of this section because you change your policies or practices in such a way that

[72] The total hours and costs consist of: (a) 51,230 hours at banks and credit unions evaluated at $61.65/hour; and (b) 10,967 hours at entities regulated by the FTC also subject to the rule, evaluated at $21.07/hour.

[73] *See* 79 FR 64057, 64080 (Oct. 28, 2014).

[74] The total hours and costs consist of: (a) 47,733 hours at banks and credit unions evaluated at $61.65/hour; and (b) 5,484 hours at entities regulated by the FTC also subject to the rule, evaluated at $21.07/hour.

§ 1016.8 requires you to provide a revised privacy notice, you must provide an annual privacy notice in accordance with the timing requirements in paragraph (a) of this section, treating the revised privacy notice as an initial privacy notice.

(ii) *Changes not preceded by a revised privacy notice.* If you no longer meet the requirements of paragraph (e)(1) of this section because you change your policies or practices in such a way that § 1016.8 does not require you to provide a revised privacy notice, you must provide an annual privacy notice within 100 days of the change in your policies or practices that causes you to no longer meet the requirements of paragraph (e)(1) of this section.

(iii) *Examples.* (A) You change your policies and practices in such a way that you no longer meet the requirements of paragraph (e)(1) of this section effective April 1 of year 1. Assuming you define the 12-consecutive-month period pursuant to paragraph (a) of this section as a calendar year, if you were required to provide a revised privacy notice under § 1016.8 and you provided that notice on March 1 of year 1, you must provide an annual privacy notice by December 31 of year 2. If you were not required to provide a revised privacy notice under § 1016.8, you must provide an annual privacy notice by July 9 of year 1.

(B) You change your policies and practices in such a way that you no longer meet the requirements of paragraph (e)(1) of this section, and so provide an annual notice to your customers. After providing the annual notice to your customers, you once again meet the requirements of paragraph (e)(1) of this section for an exception to the annual notice requirement. You do not need to provide additional annual notices to your customers until such time as you no longer meet the requirements of paragraph (e)(1) of this section.

■ 4. Section 1016.9 is amended by revising paragraph (c) to read as follows:

§ 1016.9 Delivering privacy and opt out notices.

* * * * *

(c) *Annual notices only.* You may reasonably expect that a customer will receive actual notice of your annual privacy notice if:

(1) The customer uses your website to access financial products and services electronically and agrees to receive notices at the website, and you post your current privacy notice continuously in a clear and conspicuous manner on the website; or

(2) The customer has requested that you refrain from sending any information regarding the customer relationship, and your current privacy notice remains available to the customer upon request.

* * * * *

Dated: August 9, 2018.

Mick Mulvaney,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018–17572 Filed 8–16–18; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0303; Product Identifier 2018–NM–006–AD; Amendment 39–19360; AD 2018–17–06]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. This AD was prompted by a report that the retraction actuator eye-end of a Goodrich main landing gear (MLG) failed. This AD requires a one-time general visual inspection of the left-hand (LH) and right-hand (RH) MLG retraction actuators and replacement if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 21, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 21, 2018.

ADDRESSES: For service information identified in this final rule, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* internet *http://www.myfokkerfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0303.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0303; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. The NPRM published in the **Federal Register** on April 27, 2018 (83 FR 18488). The NPRM was prompted by a report that the retraction actuator eye-end of a Goodrich MLG failed. The NPRM proposed to require a one-time general visual inspection of the LH and RH MLG retraction actuators and replacement if necessary.

We are issuing this AD to address failure of the retraction actuator eye-end of a Goodrich MLG, which could prevent retraction of the MLG and/or its complete extension, possibly resulting in damage to the airplane during landing, and consequent injury to occupants.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0001, dated January 4, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. The MCAI states:

> An occurrence was reported where, following take-off after gear up selection, the retraction actuator eye-end (P/N [part number] 41518–3) of a Goodrich MLG failed. After the LG UNSAFE indication, the flight crew successfully selected gear down and locked by applying the alternate extension

procedure, and an uneventful landing was made. Investigation results showed that the final overload fracture of the eye-end was preceded by fatigue cracks, believed to have been caused by interference between the MLG retraction actuator eye-end and the actuator bracket. It was also highlighted that the affected eye-end had been installed incorrectly, *i.e.* with the grease nipple located on the lower side, thus causing damage to the eye-end due to interference with the bracket. Further investigations revealed other occurrences of interference between retraction actuator eye-end and bracket with resulting damage.

This condition, if not detected and corrected, could prevent retraction of the MLG and/or its complete extension, possibly resulting in damage to the aeroplane during landing, and consequent injury to occupants.

To address this potential unsafe condition, Fokker Services published SBF100–32–168 to provide inspection and replacement instructions.

For the reasons described above, this AD requires a one-time [general visual] inspection [for deficiencies] (check the eye-end for presence of interference/damage and for orientation of the greasing nipple) of the MLG retraction actuators, left-hand (LH) and right-hand (RH) sides, and, depending on findings, replacement.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0303.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Fokker Services B.V. has issued Fokker Service Bulletin SBF100–32–168, dated May 22, 2017. This service information describes procedures for a one-time general visual inspection for deficiencies of the Goodrich MLG retraction actuators and replacement of the actuator if necessary (*e.g.,* if the retraction actuator greasing nipple is not located on the upper side MLG retraction actuator eye-end or if interference damage or evidence of removed damage is present on the eye-end of the MLG retraction actuator). This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 5 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	1 work-hour × $85 per hour = $85 per inspection cycle.	$0	$85 per inspection cycle	$425 per inspection cycle.

We estimate the following costs to do any necessary replacements that would be required based on the results of the inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	1 work-hour × $85 per hour = $85	$0	$85

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2018–17–06 Fokker Services B.V.: Amendment 39–19360; Docket No. FAA–2018–0303; Product Identifier 2018–NM–006–AD.

(a) Effective Date

This AD is effective September 21, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes, certificated in any category, all serial numbers, if equipped with Goodrich main landing gear (MLG), part number (P/N) 41050-x (all dashes) or P/N 41060-x (all dashes).

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by a report that the retraction actuator eye-end of a Goodrich MLG failed. We are issuing this AD to address failure of the retraction actuator eye-end of a Goodrich MLG, which could prevent retraction of the MLG and/or its complete extension, possibly resulting in damage to the airplane during landing, and consequent injury to occupants.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definition

For the purposes of this AD, a ''serviceable part'' is a serviceable retraction actuator with an eye-end that does not have any indication of interference or damage, as specified in the Accomplishment Instructions of Fokker Service Bulletin SBF100–32–168, dated May 22, 2017.

(h) Inspection and Corrective Action

Within 12 months after the effective date of this AD, perform a general visual inspection of the left-hand (LH) and right-hand (RH) MLG retraction actuators for deficiencies (*i.e.,* check for the presence of interference damage, including evidence of removed damage, and for the orientation of the greasing nipple), in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–32–168, dated May 22, 2017. If any deficiency is found, before further flight, replace the affected MLG retraction actuator with a serviceable part, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–32–168, dated May 22, 2017.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Fokker Services B.V.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0001, dated January 4, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0303.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Fokker Service Bulletin SBF100–32–168, dated May 22, 2017.

(ii) Reserved.

(3) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* internet *http://www.myfokkerfleet.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on August 7, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–17624 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0259; Product Identifier 2018–NE–09–AD; Amendment 39–19358; AD 2018–17–04]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Corporation Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Rolls-Royce Corporation (RRC) AE 2100D2A and AE 2100D3 model turboprop engines and AE 3007A2 model turbofan engines. This AD was prompted by the possibility of a low-cycle fatigue failure on certain turbine wheels. This AD requires removing the affected turbine wheels at the next engine shop visit or before reaching the new reduced life limit, whichever occurs first, and replacing them with parts eligible for installation. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 21, 2018.

The Director of the Federal Register approved the incorporation by reference

of certain publications listed in this AD as of September 21, 2018.

ADDRESSES: For service information identified in this final rule, contact Rolls-Royce Corporation, 450 South Meridian Street, Indianapolis, IN 46225; phone: 317–230–3774. You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0259.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0259; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Docket Operations, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kyri Zaroyiannis, Aerospace Engineer, Chicago ACO Branch, FAA, 2300 E. Devon Ave., Des Plaines, IL 60018; phone: 847–294–7836; fax: 847–294–7834; email: *kyri.zaroyiannis@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain RRC AE 2100D2A and AE 2100D3 model turboprop engines and AE 3007A2 model turbofan engines. The NPRM published in the **Federal Register** on April 30, 2018 (83 FR 18751). The NPRM was prompted by the possibility of a low-cycle fatigue failure on certain turbine wheels. The affected turbine wheels include 1st-stage gas generator turbine wheels, installed on AE 2100D2A and AE 2100D3 model turboprop engines, and 1st-stage high-pressure turbine (HPT) wheels, installed on AE 3007A2 turbofan engines. The NPRM proposed to require removing the affected turbine wheels at the next engine shop visit or before reaching the new reduced life limit, whichever occurs first, and replacing them with parts eligible for installation. We are issuing this AD to address the unsafe condition on these products.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comment received. RRC supported the NPRM.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed.

Related Service Information Under 1 CFR Part 51

We reviewed RRC Alert Service Bulletin (ASB) AE 2100D2–A–72–090, Revision 1, dated July 11, 2014, and RRC ASB AE 2100D3–A–72–286, Revision 1, dated July 11, 2014 (one document, referred to herein as ''RRC ASB AE 2100D2–A–72–090/AE 2100D3–A–72–286''), and RRC ASB AE 3007A–A–72–419, Revision 2, dated December 4, 2017. RRC ASB AE 2100D2–A–72–090/AE 2100D3–A–72–286 provides removal and replacement instructions and a new life limit for the affected 1st-stage gas generator turbine wheels installed on RRC AE 2100D2A and AE 2100D3 model turboprop engines. ASB AE 3007A–A–72–419 provides removal and replacement instructions and a new life limit for 1st-stage HPT wheels installed on RRC AE 3007A2 model turbofan engines. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects nine engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace turbine wheels	0 work-hours × $85 per hour = $0	$160,829	$160,829	$1,447,461

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2018–17–04 Roll-Royce Corporation (Type Certificate previously held by Allison Engine Company): Amendment 39–19358; Docket No. FAA–2018–0259; Product Identifier 2018–NE–09–AD.

(a) Effective Date

This AD is effective September 21, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to:

(1) Rolls-Royce Corporation (RRC) AE 2100D2A turboprop engines with 1st-stage gas generator turbine wheels, part number (P/N) 23089692, with serial numbers (S/Ns) MW65898 or MW68310, installed.

(2) RRC AE 2100D3 turboprop engines with 1st-stage gas generator turbine wheels, P/N 23088906, with S/Ns MW65895, MW65896, MW65900, MW65901, MW65903, MW68305, MW68306, MW68307, MW68312, MW68314, MW68316, MW68318, or MW68319, installed.

(3) RRC AE 3007A2 turbofan engines with 1st-stage high-pressure turbine (HPT) wheels, P/N 23088906, with S/Ns MW65894, MW68303, or MW68315, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine section.

(e) Unsafe Condition

This AD was prompted by the possibility of steel inclusions in the turbine wheel forging. We are proposing this AD to prevent a low-cycle fatigue failure of a 1st-stage gas generator turbine wheel or 1st-stage HPT wheel. The unsafe condition, if not addressed, could result in uncontained turbine wheel release, damage to the engine, and damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Remove the affected 1st-stage gas generator turbine wheel and replace with a part eligible for installation at the next engine shop visit or before exceeding the life limit of 4,800 engine cycles, whichever occurs first, in accordance with the Accomplishment Instructions, Paragraph 2, of RRC Alert Service Bulletin (ASB) AE 2100D2–A–72–090, Revision 1, dated July 11, 2014, and RRC ASB AE 2100D3–A–72–286, Revision 1, dated July 11, 2014 (co-published as one document).

(2) Remove the affected 1st-stage HPT wheel and replace with a part eligible for installation at the next engine shop visit or before exceeding the life limit of 5,600 engine cycles, whichever occurs first, in accordance with the Accomplishment Instructions, Paragraph 2, of RRC ASB AE 3007A–A–72–419, Revision 2, dated December 4, 2017.

(h) Definition

For the purpose of this AD, an ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges, except that the separation of engine flanges solely for the purposes of transportation without subsequent engine maintenance is not an engine shop visit.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

For more information about this AD, contact Kyri Zaroyiannis, Aerospace Engineer, Chicago ACO Branch, FAA, 2300 E. Devon Ave., Des Plaines, IL, 60018; phone: 847–294–7836; fax: 847–294–7834; email: *kyri.zaroyiannis@faa.gov*.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Rolls-Royce Corporation (RRC) Alert Service Bulletin (ASB) AE 2100D2–A–72–090, Revision 1, dated July 11, 2014, and RRC ASB AE 2100D3–A–72–286, Revision 1, dated July 11, 2014 (co-published as one document).

(ii) RRC ASB AE 3007A–A–72–419, Revision 2, dated December 4, 2017.

(3) For RRC service information identified in this AD, contact Rolls-Royce Corporation, 450 South Meridian Street, Indianapolis, IN, 46225; phone: 317–230–3774.

(4) You may view this service information at FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call 781–238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on August 13, 2018.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–17704 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0712; Product Identifier 2018–NM–089–AD; Amendment 39–19361; AD 2018–17–07]

RIN 2120–AA64

Airworthiness Directives; ATR—GIE Avions de Transport Régional Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: We are superseding Airworthiness Directive (AD) 2017–24–01, which applied to certain ATR—GIE Avions de Transport Régional Model ATR42–500 airplanes and Model ATR72–212A airplanes. AD 2017–24–01 required an inspection for routing attachments of electrical harness bundles and for wire damage, and corrective actions if necessary. This new AD adds additional airplanes to the applicability. This AD was prompted by a determination that additional airplanes are affected by the unsafe condition. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 4, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 4, 2018 .

We must receive comments on this AD by October 1, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact ATR—GIE Avions de Transport Régional, 1 Allée Pierre Nadot, 31712 Blagnac Cedex, France; telephone +33 (0) 5 62 21 62 21; fax +33 (0) 5 62 21 67 18; email *continued.airworthiness@atr-aircraft.com; http://www.atr-aircraft.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0712.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0712; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–321–3220.

SUPPLEMENTARY INFORMATION:

Discussion

We issued AD 2017–24–01, Amendment 39–19105 (82 FR 55755, November 24, 2017) (''AD 2017–24–01''), which applied to certain Model ATR42–500 airplanes and Model ATR72–212A airplanes. AD 2017–24–01 was prompted by reports of electrical harness bundle chafing with a window blinding panel in the fuselage due to missing routing attachments. AD 2017–24–01 required an inspection for routing attachments (*i.e.,* brackets) of electrical harness bundles and for wire damage, and corrective actions if necessary. We issued AD 2017–24–01 to detect and correct missing routing attachments of fuselage electrical harness bundles, which could result in wire failure (cut or shorted) and, in case of several failures in combination, the loss of systems, possibly resulting in reduced control of the airplane.

Since we issued AD 2017–24–01, we have determined that additional airplanes are affected by the unsafe condition.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2018–0105, dated May 08, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Model ATR42–500 airplanes and Model ATR72–212A airplanes. The MCAI states:

> An event was reported of several spurious alarms on a recently delivered ATR 72 aeroplane. During subsequent trouble-shooting, damage was found on the electrical harness wire bundle (Route 1M), due to chafing with a window blinding panel located on the left-hand (LH) side of the fuselage, zone 231. A bracket, necessary to maintain the harness wire bundle close to the structure of the fuselage and avoid chafing, was missing. The same bracket was also found missing on the right-hand (RH) side of the fuselage, zone 232, Route 2M, although without damage on the harness wire bundle. A quality investigation revealed another aeroplane on the production line where same brackets were not installed.
>
> This condition, if not detected and corrected, may lead to wire failure (cut or shorted) and, in case of several failures in combination, to loss of systems, possibly resulting in reduced control of the aeroplane.
>
> To address this potential unsafe condition, ATR published the applicable SB [service bulletin] to provide inspection instructions. Consequently, EASA issued AD 2017–0118 [which corresponds to FAA AD 2017–24–01] to require verification of the installation of the brackets, a one-time inspection of the wire bundles, and depending on findings, accomplishment of applicable corrective action(s).
>
> Since that [EASA] AD was issued, an occurrence was reported of engine intermittent auto-feather, caused by damage on the electrical harness bundle Route 1M. The affected aeroplane MSN [manufacturer serial number] was not identified in the Applicability of EASA AD 2017–0118.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2017–0118, which is superseded, and expands the Applicability to include additional aeroplanes, identified by MSN in Group 2 as specified in section 'Definitions' of this [EASA] AD.

The MCAI includes MSNs 1071, 1141, 1341, 1367, and 1377 in its applicability, but those MSNs are not identified in the definitions for the affected groups. Those MSNs are not affected by the identified unsafe condition. Therefore, we have not included those MSNs in our applicability. You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0712.

Related Service Information Under 1 CFR Part 51

ATR has issued Service Bulletin ATR42–92–0033, Revision 02, dated April 12, 2018; and Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018. This service information describes procedures for an inspection of routing attachments (*i.e.,* brackets) of electrical harness bundles and for wire damage, and corrective actions if necessary. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

FAA's Justification and Determination of the Effective Date

There are currently no domestic operators of this product. Therefore, we good cause find that notice and opportunity for prior public comment are unnecessary and that, for the same reason, good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0712; Product Identifier 2018–NM–089–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, we provide the following cost estimates to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product
Inspection	3 work-hours × $85 per hour = $255	$0	$255

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2017–24–01, Amendment 39–19105 (82 FR 55755, November 24, 2017), and adding the following new AD:

2018–17–07 ATR—GIE Avions de Transport Régional: Amendment 39–19361; Docket No. FAA–2018–0712; Product Identifier 2018–NM–089–AD.

(a) Effective Date

This AD is effective September 4, 2018.

(b) Affected ADs

This AD replaces AD 2017–24–01, Amendment 39–19105 (82 FR 55755, November 24, 2017) (''AD 2017–24–01'').

(c) Applicability

This AD applies to the ATR—GIE Avions de Transport Régional airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Model ATR42–500 airplanes, manufacturer serial numbers (MSNs) 1001 through 1014 inclusive, 1016 through 1019 inclusive, and 1201 through 1212 inclusive.

(2) Model ATR72–212A airplanes, MSNs 1048 through 1070 inclusive, 1072 through 1140 inclusive, 1142 through 1200 inclusive, 1220 through 1340 inclusive, 1342 through 1353 inclusive, 1355 through 1366 inclusive, 1368 through 1376 inclusive, 1378 through 1380 inclusive, 1382, 1385, and 1388.

(d) Subject

Air Transport Association (ATA) of America Code 92, Electric.

(e) Reason

This AD was prompted by reports of electrical harness bundle chafing with a window blinding panel in the fuselage due to missing routing attachments and by a determination that additional airplanes that were not identified in AD 2017–24–01 are affected by the unsafe condition. We are issuing this AD to detect and correct missing

routing attachments of fuselage electrical harness bundles, which could result in wire failure (cut or shorted), and, in case of several failures in combination, the loss of systems, possibly resulting in reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

(1) For the purposes of this AD, Group 1 airplanes are identified as the following: MSNs 1014, 1016 through 1019 inclusive, 1165 through 1212 inclusive, 1220 through 1340 inclusive, 1342 through 1353 inclusive, 1355 through 1366 inclusive, 1368 through 1376 inclusive, 1378 through 1380 inclusive, 1382, 1385 and 1388.

(2) For the purposes of this AD, Group 2 airplanes are identified as the following: MSNs 1001 through 1013 inclusive, 1048 through 1070 inclusive, 1072 to 1140 inclusive 1142 through 1164 inclusive.

(h) Retained Inspection With New Service Information and Revised Compliance Language

This paragraph restates the requirements of paragraph (g) of AD 2017–24–01, with new service information and revised compliance language. For Group 1 airplanes: Within 6 months or 500 flight hours after December 11, 2017 (the effective date of AD 2017–24–01), whichever occurs first, do a detailed inspection for missing brackets and damage (including but not limited to chafing and electrical shorting) to wire bundles of the Route 1M and Route 2M electrical harness, in accordance with the flowchart in paragraph 1.C., ''Description,'' and the Accomplishment Instructions of ATR Service Bulletin ATR42–92–0033, Revision 02, dated April 12, 2018 (for Model ATR42–500 airplanes); or ATR Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018 (for Model ATR72–212A airplanes); as applicable. Although ATR Service Bulletin ATR42–92–0033, Revision 02, dated April 12, 2018; and ATR Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018; specify reporting, this AD does not include that requirement.

(i) New Requirement of This AD: Inspection

For Group 2 airplanes: Within 6 months or 500 flight hours after the effective date of this AD, whichever occurs first, do a detailed inspection for missing brackets and damage (including but not limited to chafing and electrical shorting) to wire bundles of the Route 1M and Route 2M electrical harness, in accordance with the flowchart in paragraph 1.C., ''Description,'' and the Accomplishment Instructions of ATR Service Bulletin ATR42–92–0033, Revision 02, dated April 12, 2018 (for Model ATR42–500 airplanes); or ATR Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018 (for Model ATR72–212A airplanes); as applicable. Although ATR Service Bulletin ATR42–92–0033, Revision 02, dated April 12, 2018; and ATR Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018; specify reporting, this AD does not include that requirement.

(j) New Requirements of This AD: Corrective Action

If the inspection required by paragraph (h) or (i) of this AD reveals that any bracket is missing or any wire is damaged, before further flight, do applicable corrective actions, in accordance with the flowchart in paragraph 1.C., ''Description,'' and the Accomplishment Instructions of ATR Service Bulletin ATR42–92–0033, Revision 02, dated April 12, 2018 (for Model ATR42–500 airplanes); or ATR Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018 (for Model ATR72–212A airplanes); as applicable. Where ATR Service Bulletin ATR42–92–0033, Revision 02, dated April 12, 2018; and ATR Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018; specify to contact ATR–GIE Avions de Transport Régional for appropriate action, before further flight, accomplish corrective actions in accordance with the procedures specified in paragraph (l)(2) of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (h), (i), and (j) of this AD, if those actions were performed before the effective date of this AD using ATR Service Bulletin ATR42–92–0033, dated May 3, 2017, or Revision 01, dated July 20, 2017; or ATR Service Bulletin ATR72–92–1044, dated May 3, 2017, or Revision 01, dated July 20, 2017, as applicable. ATR Service Bulletin ATR42–92–0033, dated May 3, 2017; and ATR72–92–1044, dated May 3, 2017, were previously incorporated by reference in AD 2017–24–01. ATR Service Bulletin ATR42–92–0033 Revision 01, dated July 20, 2017; and ATR72–92–1044, Revision 01, dated July 20, 2017, were not previously incorporated by reference.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or, the European Aviation Safety Agency (EASA); or, ATR—GIE Avions de Transport Régional's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2018–0105, dated May 08, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0712.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–321–3220.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (n)(3) and (n)(4) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) ATR Service Bulletin ATR42– 92–0033, Revision 02, dated April 12, 2018.

(ii) ATR Service Bulletin ATR72–92–1044, Revision 02, dated April 12, 2018.

(3) For service information identified in this AD, contact ATR—GIE Avions de Transport Régional, 1 Allée Pierre Nadot, 31712 Blagnac Cedex, France; telephone +33 (0) 5 62 21 62 21; fax +33 (0) 5 62 21 67 18; email *continued.airworthiness@atr-aircraft.com;* internet *http://www.atr-aircraft.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on August 8, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–17661 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2018–0728; Airspace Docket No. 18–ASO–2]

RIN 2120–AA66

Amendment of Multiple Restricted Area Boundary Descriptions; Florida

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: This action makes minor adjustments to the boundary descriptions of restricted areas R–2905A and R–2905B, Tyndall AFB, FL; R–2914B, and R–2919B, Valparaiso, FL; R–2915A and R–2915C, Eglin AFB, FL. The changes are needed because the FAA has adopted updated digital data that more precisely define maritime limits and other geophysical features used in the boundary descriptions. This requires minor changes to certain latitude/longitude points in the boundary descriptions of the above restricted areas in order to match the updated data and ensure accurate boundary depiction on aeronautical charts.

DATES: *Effective date:* 0901 UTC, November 8, 2018.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, AJV–11, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it supports updating certain boundary coordinates for restricted areas Tyndall AFB, FL, Valparaiso, FL, and, Eglin AFB, FL.

Background

Some restricted area boundary descriptions use maritime limits, such as references to the shoreline of the U.S., to identify the shape of the area (*e.g.,* ''3 nautical miles from and parallel to the shoreline''). These boundary descriptions contain latitude/longitude coordinates that were intended to intersect a line running 3 NM from, and parallel to, the shoreline. In other cases, boundaries are defined with reference to geophysical features such as a railroad track or highway.

For a variety of reasons, maritime limits change over time. The FAA has received updated digital data for maritime limits from the National Oceanic and Atmospheric Administration (NOAA). Digital data are more precise than measurements used in the past. The FAA, through the implementation of its data-driven charting process, was able to utilize this new data to accurately update the U.S. maritime limit boundaries used for aeronautical charting. Prior to the update, the maritime limit boundary data used for charting were over 25 years old. In applying the updated data, FAA found that some restricted area boundary descriptions that were based on the maritime limits, did not correspond to the updated shoreline data. Consequently, there are minor mismatches between some restricted area latitude/longitude coordinates and the actual shoreline position. Similarly, more accurate digital data is available for railroads and highways and the FAA is applying that information as well.

This rulemaking action updates the affected boundary coordinates of restricted areas R–2905A, R–2905B, R–2914B, R–2915C, and R–2919B, in Florida to ensure that the published boundaries match the actual relation to the U.S. shoreline, and maintain aeronautical chart accuracy. R–2915A is amended to reflect digital positional data for the L and N Railroad and the Navarre-Milton Highway, which form part of that restricted area's boundary.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 73 by making minor updates to certain latitude/longitude coordinates in the descriptions of restricted areas R–2905A, R–2905B, R–2914B, R–2915A, R–2915C, and R–2919B, in Florida. The changes are needed because the FAA has adopted the use of digital data for aeronautical charting. This more precise digital plotting of points revealed minor mismatches between some current restricted area boundary coordinates and the updated digital data for those points. The specific restricted area boundary updates are shown below:

R–2905A: The point ''lat. 29°56′01″ N, long. 85°33′00″ W'' is amended to ''lat. 29°56′06″ N, long. 85°32′57″ W.'' The point ''lat. 29°59′01″ N, long. 85°36′30″ W'' is amended to ''lat. 29°59′05″ N, long. 85°36′24″ W.'' These changes reflect updated digital shoreline data.

R–2905B: The point ''lat. 29°54′01″ N, long. 85°27′00″ W'' is amended to ''lat. 29°54′09″ N, long. 85°27′00″ W.'' The point ''lat. 29°56′01″ N, long. 85°33′00″ W'' is amended to ''lat. 29°56′06″ N, long. 85°32′57″ W.'' These changes reflect updated digital shoreline data.

R–2914B: The point ''lat. 30°11′01″ N, long. 85°56′00″ W'' is amended to ''lat. 30°11′08″ N, long. 85°56′00″W.'' The point ''lat. 30°15′01″ N, long. 86°06′15″ W'' is amended to ''lat. 30°15′18″ N, long. 86°06′19″ W.'' These changes reflect updated digital shoreline data.

R–2915A: The point ''lat. 30°33′41″ N, long. 86°55′00″ W'' is amended to ''lat. 30°33′30″ N, long. 86°55′00″ W.'' The point ''lat. 30°38′46″ N, long. 86°55′00″ W'' is amended to ''lat. 30°38′52″ N, long. 86°55′00″ W.'' The point ''lat. 32°42′46″ N, long. 86°45′45″ W'' is amended to ''lat. 30°42′46″ N, long. 86°45′23″ W.'' The point ''lat. 30°26′31″ N, long. 86°52′20″ W'' is amended to ''lat. 30°26′31″ N, long. 86°52′00″ W.'' These amended points are based on digital data for the L and N Railroad and the Navarre-Milton Highway.

R–2915C: The point ''lat. 30°20′51″ N, long. 86°38′50″ W'' is amended to ''lat. 30°20′47″ N, long. 86°38′51″ W.'' The point ''lat. 30°19′31″ N, long. 86°51′30″ W'' is amended to ''lat. 30°19′45″ N, long. 86°51′30″ W.'' These changes reflect updated digital shoreline data.

R–2919B: The point ''lat. 30°15′01″ N, long. 86°06′15″ W'' is amended to ''lat. 30°15′18″ N, long. 86°06′19″ W.'' The point ''lat. 30°19′46″ N, long. 86°23′45″ W'' is amended to ''lat. 30°19′41″ N, long. 86°23′46″ W.'' These changes reflect updated digital shoreline data.

These minor editorial changes update existing restricted area boundaries with more precise digital information. It does not affect the location, designated altitudes, or activities conducted within the restricted areas; therefore, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Regulatory Notices and Analyses

The FAA has determined that this action only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under

Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of making minor adjustments to the boundary descriptions of restricted areas R–2905A and R–2905B, Tyndall AFB, FL; R–2914B, Valparaiso, FL; R–2915A and R–2915C, Eglin AFB, FL; and R–2919B, Valparaiso, FL qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5.d, Modification of the technical description of special use airspace (SUA) that does not alter the dimension, altitudes, or times of designation of the airspace. This airspace action makes minor updates to certain boundary coordinates of restricted areas R–2905A and R–2905B, Tyndall AFB, FL; R–2914B, Valparaiso, FL; R–2915C, Eglin AFB, FL; and R–2919B, Valparaiso, FL, to match the more precise digital shoreline data received from the National Oceanic and Atmospheric Administration (NOAA). This ensures that the affected boundaries continue to match the NOAA-defined position of the U.S. shoreline, and more accurate digital data for geophysical references. It does not alter the location, altitudes, or activities conducted within the airspace; therefore, it is not expected to cause any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73, as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.29 [Amended]

■ 2. Section 73.29 is amended as follows:

* * * * *

R–2905A Tyndall AFB, FL [Amended]

By removing the current boundaries and adding in its place the following:

Boundaries. Beginning at lat. 30°01′31″ N, long. 85°32′30″ W; to lat. 30°01′16″ N, long. 85°30′00″ W; to lat. 29°56′06″ N, long. 85°32′57″ W; thence 3 nautical miles from and parallel to the shoreline to lat. 29°59′05″ N, long. 85°36′24″ W; to the point of beginning.

R–2905B Tyndall AFB, FL [Amended]

By removing the current boundaries and adding in its place the following:

Boundaries. Beginning at lat. 30°01′16″ N, long. 85°30′00″ W; to lat. 30°01′01″ N, long. 85°27′00″ W; to lat. 29°54′09″ N, long. 85°27′00″ W; thence 3 nautical miles from and parallel to the shoreline to lat. 29°56′06″ N, long. 85°32′57″ W; to the point of beginning.

R–2914B Valparaiso, FL [Amended]

By removing the current boundaries and adding in its place the following:

Boundaries. Beginning at lat. 30°22′01″ N, long. 86°08′00″ W; to lat. 30°19′16″ N, long. 85°56′00″ W; to lat. 30°11′08″ N, long. 85°56′00″ W; thence 3 nautical miles from and parallel to the shoreline to lat. 30°15′18″ N, long. 86°06′19″ W; to the point of beginning.

R–2915A Eglin AFB, FL [Amended]

By removing the current boundaries and adding in its place the following:

Boundaries. Beginning at lat. 30°33′30″ N, long. 86°55′00″ W; to lat. 30°38′52″ N, long. 86°55′00″ W; thence along the L and N Railroad to lat. 30°42′46″ N, long. 86°45′23″ W; to lat. 30°42′51″ N, long. 86°38′02″ W; to lat. 30°29′02″ N, long. 86°38′02″ W; to lat. 30°26′31″ N, long. 86°51′30″ W; to lat. 30°26′31″ N, long. 86°52′00″ W; thence along the Navarre-Milton Highway to the point of beginning.

R–2915C Eglin AFB, FL [Amended]

By removing the current boundaries and adding in its place the following:

Boundaries. Beginning at lat. 30°22′47″ N, long. 86°51′30″ W; thence along the shoreline to lat. 30°23′46″ N, long. 86°38′15″ W; to lat. 30°20′47″ N, long. 86°38′51″ W; thence 3 nautical miles from and parallel to the shoreline to lat. 30°19′45″ N, long. 86°51′30″ W; to the point of beginning.

R–2919B Valparaiso, FL [Amended]

By removing the current boundaries and adding in its place the following:

Boundaries. Beginning at lat. 30°25′01″ N, long. 86°22′26″ W; to lat. 30°22′01″ N, long. 86°08′00″ W; to lat. 30°15′18″ N, long. 86°06′19″ W; thence 3 NM from and parallel to the shoreline to lat. 30°19′41″ N, long. 86°23′46″ W; to the point of beginning.

Issued in Washington, DC, on August 13, 2018.

Rodger A. Dean, Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018–17766 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31207; Amdt. No. 3812]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 17, 2018. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 17, 2018.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey

Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on July 27, 2018.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
13-Sep-18	ID	Coeur D'Alene	Coeur D'Alene—Pappy Boyington Field.	8/0531	7/23/18	ILS OR LOC/DME RWY 6, Amdt 5D.
13-Sep-18	AK	Homer	Homer	8/1026	7/23/18	LOC RWY 4, Amdt 11A.
13-Sep-18	CA	Palm Springs	Bermuda Dunes	8/1171	7/10/18	RNAV (GPS) RWY 28, Orig.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
13-Sep-18	CA	Palm Springs	Bermuda Dunes	8/1175	7/10/18	VOR–C, Orig-A.
13-Sep-18	MO	Salem	Salem Memorial	8/1892	7/25/18	RNAV (GPS) RWY 17, Orig.
13-Sep-18	MO	Salem	Salem Memorial	8/1893	7/25/18	RNAV (GPS) RWY 35, Orig.
13-Sep-18	TX	Graham	Graham Muni	8/1894	7/25/18	RNAV (GPS) RWY 3, Orig.
13-Sep-18	TX	Graham	Graham Muni	8/1899	7/25/18	RNAV (GPS) RWY 21, Orig.
13-Sep-18	NC	Elizabethtown	Curtis L Brown Jr Field	8/1954	7/10/18	RNAV (GPS) RWY 33, Orig.
13-Sep-18	MD	Churchville	Harford County	8/2250	7/23/18	RNAV (GPS)-B, Orig.
13-Sep-18	MO	St Louis	Creve Coeur	8/2299	7/23/18	RNAV (GPS) RWY 34, Amdt 1.
13-Sep-18	MO	St Louis	Creve Coeur	8/2302	7/23/18	VOR–A, Amdt 5.
13-Sep-18	MO	St Louis	Creve Coeur	8/2309	7/23/18	RNAV (GPS) RWY 16, Amdt 1A.
13-Sep-18	AL	Troy	Troy Muni At N Kenneth Campbell Field.	8/2470	7/23/18	RNAV (GPS) RWY 25, Amdt 3.
13-Sep-18	MD	Ocean City	Ocean City Muni	8/2476	7/25/18	VOR–A, Amdt 3A.
13-Sep-18	MD	Ocean City	Ocean City Muni	8/2477	7/25/18	RNAV (GPS) RWY 2, Orig-B.
13-Sep-18	MD	Ocean City	Ocean City Muni	8/2478	7/25/18	RNAV (GPS) RWY 32, Orig-B.
13-Sep-18	MD	Ocean City	Ocean City Muni	8/2479	7/25/18	RNAV (GPS) RWY 14, Orig-F.
13-Sep-18	MD	Ocean City	Ocean City Muni	8/2480	7/25/18	LOC RWY 14, Amdt 2A.
13-Sep-18	IN	Indianapolis	Indy South Greenwood	8/2629	7/25/18	RNAV (GPS) RWY 19, Amdt 1B.
13-Sep-18	WI	Neillsville	Neillsville Muni	8/2675	7/25/18	RNAV (GPS) RWY 28, Orig.
13-Sep-18	WI	Rhinelander	Rhinelander—Oneida County	8/3121	7/25/18	Takeoff Minimums and Obstacle DP, Amdt 4.
13-Sep-18	GA	Griffin	Griffin—Spalding County	8/3323	7/23/18	RNAV (GPS) RWY 14, Orig-D.
13-Sep-18	AL	Birmingham	Birmingham—Shuttlesworth Intl.	8/3333	7/23/18	RNAV (GPS) Y RWY 6, Amdt 1B.
13-Sep-18	TX	Austin	Austin—Bergstrom Intl	8/3410	7/25/18	ILS OR LOC RWY 35L, Amdt 6.
13-Sep-18	TX	Crosbyton	Crosbyton Muni	8/3666	7/23/18	RNAV (GPS) RWY 35, Orig-A.
13-Sep-18	CA	Napa	Napa County	8/3668	7/23/18	ILS OR LOC RWY 36L, Orig-B.
13-Sep-18	CA	Napa	Napa County	8/3669	7/23/18	RNAV (GPS) Y RWY 36L, Amdt 2B.
13-Sep-18	NE	Fairbury	Fairbury Muni	8/3783	7/23/18	NDB–A, Amdt 3B.
13-Sep-18	NE	Fairbury	Fairbury Muni	8/3785	7/23/18	RNAV (GPS) RWY 35, Orig-A.
13-Sep-18	MD	Annapolis	Lee	8/3830	7/23/18	RNAV (GPS)-A, Orig.
13-Sep-18	WI	Medford	Taylor County	8/4100	7/23/18	RNAV (GPS) RWY 9, Orig-A.
13-Sep-18	WI	Medford	Taylor County	8/4102	7/23/18	RNAV (GPS) RWY 16, Orig-A.
13-Sep-18	WI	Medford	Taylor County	8/4103	7/23/18	RNAV (GPS) RWY 34, Orig-A.
13-Sep-18	AK	Kenai	Kenai Muni	8/4752	7/10/18	RNAV (GPS) RWY 2L, Amdt 3.
13-Sep-18	AK	Kenai	Kenai Muni	8/4753	7/10/18	RNAV (GPS) RWY 20R, Amdt 4.
13-Sep-18	AK	Kenai	Kenai Muni	8/4754	7/10/18	VOR RWY 2L, Amdt 10.
13-Sep-18	AK	Kenai	Kenai Muni	8/4755	7/10/18	VOR RWY 20R, Amdt 21.
13-Sep-18	AK	Kenai	Kenai Muni	8/4756	7/10/18	Takeoff Minimums and Obstacle DP, Amdt 2.
13-Sep-18	ND	Harvey	Harvey Muni	8/4762	7/10/18	RNAV (GPS) RWY 11, Orig.
13-Sep-18	ND	Harvey	Harvey Muni	8/4763	7/10/18	RNAV (GPS) RWY 29, Orig-B.
13-Sep-18	TX	Angleton/Lake Jackson.	Texas Gulf Coast Rgnl	8/5556	7/23/18	RNAV (GPS) RWY 35, Amdt 2.
13-Sep-18	TX	Angleton/Lake Jackson.	Texas Gulf Coast Rgnl	8/5557	7/23/18	RNAV (GPS) RWY 17, Amdt 2.
13-Sep-18	NY	Le Roy	Le Roy	8/5610	7/25/18	VOR–A, Amdt 1B.
13-Sep-18	NY	Le Roy	Le Roy	8/5616	7/25/18	RNAV (GPS) RWY 28, Orig-C.
13-Sep-18	NY	Le Roy	Le Roy	8/5617	7/25/18	RNAV (GPS) RWY 10, Orig-B.
13-Sep-18	MA	Worcester	Worcester Rgnl	8/5622	7/25/18	RNAV (GPS) RWY 33, Orig-A.
13-Sep-18	IL	Mount Sterling	Mount Sterling Muni	8/5665	7/23/18	RNAV (GPS) RWY 36, Orig.
13-Sep-18	IL	Mount Sterling	Mount Sterling Muni	8/5667	7/23/18	RNAV (GPS) RWY 18, Orig.
13-Sep-18	IA	Mapleton	James G Whiting Memorial Field.	8/5671	7/23/18	RNAV (GPS) RWY 2, Orig.
13-Sep-18	IA	Mapleton	James G Whiting Memorial Field.	8/5673	7/23/18	RNAV (GPS) RWY 20, Orig.
13-Sep-18	WV	Summersville	Summersville	8/6177	7/25/18	Takeoff Minimums and Obstacle DP, Amdt 3A.
13-Sep-18	PA	Grove City	Grove City	8/6588	7/23/18	RNAV (GPS) RWY 28, Amdt 1A.
13-Sep-18	PA	Grove City	Grove City	8/6590	7/23/18	RNAV (GPS) RWY 10, Amdt 1A.
13-Sep-18	KS	Topeka	Topeka Rgnl	8/6797	7/23/18	RNAV (GPS) RWY 13, Orig-B.
13-Sep-18	IL	Litchfield	Litchfield Muni	8/6815	7/23/18	RNAV (GPS) RWY 9, Orig.
13-Sep-18	AR	Magnolia	Ralph C Weiser Field	8/6897	7/23/18	RNAV (GPS) RWY 36, Amdt 1A.
13-Sep-18	TX	Houston	George Bush Intercontinental/ Houston.	8/7516	7/23/18	RNAV (RNP) Y RWY 27, Amdt 2.
13-Sep-18	TX	Houston	George Bush Intercontinental/ Houston.	8/7530	7/23/18	RNAV (RNP) Y RWY 8L, Orig-A.
13-Sep-18	TX	Houston	George Bush Intercontinental/ Houston.	8/7531	7/23/18	RNAV (RNP) Y RWY 9, Orig-A.
13-Sep-18	OH	Shelby	Shelby Community	8/7532	7/23/18	VOR–A, Amdt 5.
13-Sep-18	TX	Houston	George Bush Intercontinental/ Houston.	8/7533	7/23/18	RNAV (RNP) Y RWY 26R, Orig-C.
13-Sep-18	CA	Van Nuys	Van Nuys	8/7957	7/10/18	LDA–C, Amdt 3.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8174	7/10/18	ILS OR LOC RWY 10L, Amdt 24.
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8183	7/10/18	ILS OR LOC RWY 10R, Amdt 1.
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8189	7/10/18	ILS OR LOC RWY 28R, Amdt 11.
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8201	7/10/18	RNAV (GPS) RWY 10R, Amdt 1.
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8211	7/10/18	RNAV (GPS) RWY 28L, Amdt 1.
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8232	7/10/18	RNAV (RNP) Y RWY 10L, Amdt 1A.
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8240	7/10/18	RNAV (GPS) Y RWY 28R, Amdt 4.
13-Sep-18	FL	Fort Lauderdale	Fort Lauderdale/Hollywood Intl.	8/8244	7/10/18	RNAV (GPS) Z RWY 10L, Amdt 4.
13-Sep-18	GA	Calhoun	Tom B David Fld	8/8262	7/23/18	RNAV (GPS) RWY 35, Amdt 1B.
13-Sep-18	GA	Calhoun	Tom B David Fld	8/8265	7/23/18	RNAV (GPS) RWY 17, Amdt 1A.
13-Sep-18	AL	Mobile	Mobile Downtown	8/8670	7/10/18	RNAV (GPS) RWY 14, Amdt 2.
13-Sep-18	NJ	Ocean City	Ocean City Muni	8/8675	7/10/18	GPS RWY 6, Orig-B.
13-Sep-18	NJ	Ocean City	Ocean City Muni	8/8676	7/10/18	VOR–A, Orig-B.
13-Sep-18	TX	Houston	David Wayne Hooks Memorial.	8/8861	7/25/18	RNAV (GPS) RWY 35L, Amdt 1C.
13-Sep-18	TX	Houston	David Wayne Hooks Memorial.	8/8862	7/25/18	RNAV (GPS) RWY 17R, Amdt 1D.
13-Sep-18	TX	Houston	David Wayne Hooks Memorial.	8/8863	7/25/18	LOC RWY 17R, Amdt 3D.
13-Sep-18	OK	Oklahoma City	Will Rogers World	8/9620	7/23/18	VOR RWY 17L, Amdt 2.
13-Sep-18	KS	Independence	Independence Muni	8/9691	7/23/18	RNAV (GPS) RWY 17, Amdt 2.
13-Sep-18	MN	Moose Lake	Moose Lake Carlton County	8/9703	7/25/18	NDB RWY 4, Amdt 1.

[FR Doc. 2018–17616 Filed 8–16–18; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31206; Amdt. No. 3811]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective August 17, 2018. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 17, 2018.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4,

8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on July 27, 2018.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 13 September 2018

Ketchikan, AK, Ketchikan Intl, RNAV (GPS) RWY 29, Orig
Ketchikan, AK, Ketchikan Intl, RNAV (GPS)-B, Amdt 1
Geneva, AL, Geneva Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Fayetteville, AR, Drake Field, LDA RWY 34, Amdt 5
Fayetteville, AR, Drake Field, VOR/DME–B, Orig-B, CANCELED
Oakland, CA, Metropolitan Oakland Intl, RNAV (RNP) Z RWY 12, Amdt 2
San Francisco, CA, San Francisco Intl, ILS OR LOC RWY 19L, Amdt 22
San Francisco, CA, San Francisco Intl, RNAV (GPS) RWY 19R, Amdt 3
Watsonville, CA, Watsonville Muni, Takeoff Minimums and Obstacle DP, Amdt 5A
Watsonville, CA, Watsonville Muni, WATSONVILLE FOUR, Graphic DP
Augusta, GA, Daniel Field, RNAV (GPS) RWY 5, Orig
Cedartown, GA, Polk County Airport—Cornelius Moore Field, RNAV (GPS) RWY 10, Orig-B
Cedartown, GA, Polk County Airport—Cornelius Moore Field, RNAV (GPS) RWY 28, Orig-B
Paris, ID, Bear Lake County, RNAV (GPS) RWY 10, Orig
Paris, ID, Bear Lake County, RNAV (GPS) RWY 28, Orig
Paris, ID, Bear Lake County, Takeoff Minimums and Obstacle DP, Orig
Bolingbrook, IL, Bolingbrook's Clow Intl, RNAV (GPS)-B, Amdt 1A
Bolingbrook, IL, Bolingbrook's Clow Intl, VOR–A, Amdt 1A
Springfield, IL, Abraham Lincoln Capital, ILS OR LOC RWY 22, Amdt 9C
French Lick, IN, French Lick Muni, RNAV (GPS) RWY 8, Amdt 1C
French Lick, IN, French Lick Muni, RNAV (GPS) RWY 26, Orig-C
Indianapolis, IN, Indianapolis Rgnl, RNAV (GPS) RWY 34, Amdt 1B
Topeka, KS, Topeka Rgnl, TACAN RWY 13, Amdt 4B
New Roads, LA, False River Rgnl, LOC RWY 36, Amdt 2
New Roads, LA, False River Rgnl, NDB RWY 36, Amdt 2A, CANCELED
New Roads, LA, False River Rgnl, RNAV (GPS) RWY 18, Amdt 1
New Roads, LA, False River Rgnl, RNAV (GPS) RWY 36, Amdt 1
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 4R, Amdt 2B
Detroit, MI, Detroit Metropolitan Wayne County, ILS OR LOC RWY 4R, ILS RWY 4R SA CAT I, ILS RWY 4R CAT II, ILS RWY 4R CAT III, Amdt 19A
Detroit, MI, Detroit Metropolitan Wayne County, ILS PRM RWY 4R (CLOSE PARALLEL), ILS PRM RWY 4R (CLOSE PARALLEL) SA CAT I, ILS PRM RWY 4R (CLOSE PARALLEL) CAT II, ILS PRM RWY 4R (CLOSE PARALLEL) CAT III, Amdt 3A
Greenville, MI, Greenville Muni, Takeoff Minimums and Obstacle DP, Amdt 2B
Marquette, MI, Sawyer Intl, ILS OR LOC RWY 1, Amdt 1
Marquette, MI, Sawyer Intl, RNAV (GPS) RWY 1, Amdt 1
Marquette, MI, Sawyer Intl, RNAV (GPS) RWY 19, Amdt 2
Marquette, MI, Sawyer Intl, VOR RWY 19, Amdt 1
Hinckley, MN, Field of Dreams, RNAV (GPS) RWY 24, Orig-A, CANCELED
Red Wing, MN, Red Wing Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2A
Bismarck, ND, Bismarck Muni, ILS OR LOC RWY 31, Amdt 34A

Garrison, ND, Garrison Muni, RNAV (GPS) RWY 13, Amdt 2
Garrison, ND, Garrison Muni, RNAV (GPS) RWY 31, Amdt 2
Manchester, NH, Manchester, Takeoff Minimums and Obstacle DP, Amdt 10B
Mesquite, NV, Mesquite, RNAV (GPS) Y RWY 2, Orig
Mesquite, NV, Mesquite, RNAV (GPS) Z RWY 2, Orig
Mesquite, NV, Mesquite, Takeoff Minimums and Obstacle DP, Orig
Minden, NV, Minden-Tahoe, RNAV (GPS)-A, Amdt 1
Minden, NV, Minden-Tahoe, RNAV (GPS)-B, Amdt 1
Columbus, OH, Bolton Field, ILS OR LOC RWY 4, Amdt 5A
Columbus, OH, Bolton Field, NDB RWY 4, Amdt 7A
Columbus, OH, Bolton Field, RNAV (GPS) RWY 4, Orig-B
Lebanon, OH, Warren County/John Lane Field, NDB–A, Amdt 6
Idabel, OK, Mc Curtain County Rgnl, RNAV (GPS) RWY 2, Amdt 1
Idabel, OK, Mc Curtain County Rgnl, RNAV (GPS) RWY 20, Amdt 1
Corvallis, OR, Corvallis Muni, ILS OR LOC RWY 17, Amdt 5
Corvallis, OR, Corvallis Muni, RNAV (GPS) RWY 35, Amdt 3
Corvallis, OR, Corvallis Muni, VOR RWY 17, Amdt 8
Corvallis, OR, Corvallis Muni, VOR RWY 35, Amdt 12
Corvallis, OR, Corvallis Muni, VOR–A, Amdt 11
Borger, TX, Hutchinson County, RNAV (GPS) RWY 17, Amdt 1
Borger, TX, Hutchinson County, RNAV (GPS) RWY 35, Amdt 1
Dallas, TX, Dallas Love Field, ILS OR LOC RWY 31L, Amdt 22A
Dallas, TX, Dallas Love Field, ILS OR LOC RWY 31R, ILS RWY 31R SA CAT I, ILS RWY 31R SA CAT II, Amdt 7
Dallas, TX, Dallas Love Field, ILS Y OR LOC Y RWY 13L, Amdt 33A
Dallas, TX, Dallas Love Field, ILS Y OR LOC Y RWY 13R, Amdt 6A
Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 13L, Amdt 1C
Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 13R, Orig-B
Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 31L, Amdt 1E
Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 31R, Amdt 3
Dallas, TX, Dallas Love Field, RNAV (GPS) Z RWY 13L, Amdt 3B
Dallas, TX, Dallas Love Field, RNAV (GPS) Z RWY 13R, Amdt 2A
Dallas, TX, Dallas Love Field, RNAV (RNP) W RWY 13L, Orig-C
Dallas, TX, Dallas Love Field, RNAV (RNP) X RWY 13L, Orig-C
Houston, TX, West Houston, RNAV (GPS) RWY 15, Amdt 1C
Houston, TX, West Houston, RNAV (GPS) RWY 33, Amdt 1B
Houston, TX, West Houston, VOR–D, Amdt 1, CANCELED
La Grange, TX, Fayette Rgnl Air Center, Takeoff Minimums and Obstacle DP, Amdt 1
Port Lavaca, TX, Calhoun County, Takeoff Minimums and Obstacle DP, Orig-A

RESCINDED: On July 16, 2018 (83 FR 32766), the FAA published an Amendment in Docket No. 31202, Amdt No. 3807, to Part 97 of the Federal Aviation Regulations under section 97.25, 97.29, 97.33, and 97.37. The following entries for Asheville, NC, and Cleveland, TN, effective September 13, 2018, are hereby rescinded in their entirety:

Asheville, NC, Asheville Rgnl, ILS OR LOC RWY 35, Orig
Asheville, NC, Asheville Rgnl, ILS OR LOC RWY 35, Orig, CANCELED
Asheville, NC, Asheville Rgnl, LOC RWY 17, Orig
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 17, Orig
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 17, Orig, CANCELED
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 35, Orig
Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 35, Orig, CANCELED
Asheville, NC, Asheville Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1
Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 3, Amdt 2
Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 21, Amdt 2
Cleveland, TN, Cleveland Rgnl Jetport, Takeoff Minimums and Obstacle DP, Amdt 2

[FR Doc. 2018–17619 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. FDA–2017–N–6730]

Medical Devices and Device-Led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; order granting alternative.

SUMMARY: The Food and Drug Administration's (FDA, Agency, or we) Center for Devices and Radiological Health and Center for Biologics Evaluation and Research are announcing that the Agency is granting an alternative that permits manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form on a quarterly basis. We refer to this alternative as the ''Voluntary Malfunction Summary Reporting Program.'' This voluntary program reflects goals for streamlining malfunction reporting outlined in the commitment letter agreed to by FDA and industry and submitted to Congress, as referenced in the Medical Device User Fee Amendments of 2017 (MDUFA IV Commitment Letter).

DATES: This voluntary program applies only to reportable malfunction events that manufacturers become aware of on or after August 17, 2018. See further discussion in section IV.F. ''Submission Schedule and Logistics.''

FOR FURTHER INFORMATION CONTACT: Michelle Rios, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3222, Silver Spring, MD 20993, 301–796–6107, *MDRPolicy@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; or CBER, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or by calling 1–800–835–4709 or 240–402–8010; or email: *ocod@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Every year, FDA receives hundreds of thousands of MDRs of suspected device-associated deaths, serious injuries, and malfunctions. The Agency's MDR program is one of the postmarket surveillance tools FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Malfunction reports represent a substantial fraction of the MDRs FDA receives on an annual basis.

Medical device reporting requirements for manufacturers are set forth in section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) and the regulations contained in part 803 (21 CFR part 803). Among other things, part 803 requires the submission of an individual MDR when a manufacturer becomes aware of information, from any source, which reasonably suggests that one of its marketed devices malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§§ 803.10(c)(1) and 803.50(a)(2). Throughout this document, we refer to such malfunctions as ''reportable malfunctions'' or ''reportable malfunction events.''

The Food and Drug Administration Amendments Act of 2007 (FDAAA)

(Pub. L. 110–85) amended section 519(a) of the FD&C Act related to the reporting of device malfunctions. FDAAA did not alter the malfunction reporting requirements for class III devices and those class II devices that are permanently implantable, life supporting, or life sustaining. Under section 519(a)(1)(B)(i) of the FD&C Act, as amended by FDAAA, manufacturers of those devices must continue to submit malfunction reports in accordance with part 803 (or successor regulations), unless FDA grants an exemption or variance from, or an alternative to, a requirement under such regulations under § 803.19. However, FDAAA amended the FD&C Act to require that malfunction MDRs for class I and those class II devices that are not permanently implantable, life supporting, or life sustaining—other than any type of class I or II device that FDA has, by notice, published in the **Federal Register** or by letter to the person who is the manufacturer or importer of the device, indicated should be subject to part 803 in order to protect the public health—be submitted in accordance with the criteria established by FDA. The criteria require the malfunction reports to be in summary form and made on a quarterly basis (section 519(a)(1)(B)(ii) of the FD&C Act). In the **Federal Register** of March 8, 2011 (76 FR 12743), FDA explained that, pending further notice from the Agency, all class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining would remain subject to individual reporting requirements under part 803 to protect the public health, pursuant to section 519(a)(1)(B)(i)(III) of the FD&C Act. Consequently, unless granted an exemption, variance, or alternative, manufacturers of those devices have continued to be required to submit individual malfunction reports under part 803. Under § 803.19, FDA may grant exemptions or variances from, or alternatives to, any or all of the reporting requirements in part 803, and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time period. FDA may grant such modifications upon request or at its discretion, and when granting such modifications, FDA may impose other reporting requirements to ensure the protection of the public health. (See § 803.19(c))

In the **Federal Register** of December 26, 2017 (82 FR 60922), FDA issued a notification outlining FDA's proposal to grant an alternative under § 803.19 to permit manufacturer reporting of certain device malfunctions in summary form on a quarterly basis, subject to certain conditions, and requested comments (2017 Proposal). As explained in the 2017 Proposal, the Voluntary Malfunction Summary Reporting Program is intended to reflect goals for streamlining malfunction reporting that FDA and industry agreed to in the MDUFA IV Commitment Letter (Ref. 1). The 2017 Proposal also summarized FDA's previous experience with summary reporting programs, key findings from an FDA pilot program for the submission of MDRs in summary format on a quarterly basis (see 80 FR 50010, August 18, 2015), additional background regarding the development of the proposal, and the anticipated benefits of summary reporting under the proposal. Interested persons were given the opportunity to submit comments by February 26, 2018.

II. Comments on the Proposed Alternative and FDA's Response

In response to the 2017 Proposal, FDA received 24 comments from industry, professional societies, trade organizations, and individual consumers by the close of the comment period, each containing one or more comments on one or more issues. A summary of the comments to the docket and our responses follow. To make it easier to identify comments and our responses, the word ''Comment'' appears in parentheses before the comment's description, and the word ''Response'' in parentheses precedes the response. The comments are grouped based on common themes and numbered sequentially.

A. General Comments

(Comment 1) Three comments suggested that the proposal was inconsistent with amendments made by section 227 of FDAAA to section 519(a) of the FD&C Act regarding malfunction reporting requirements. Two of these comments specifically recommended that FDA immediately implement summary, quarterly malfunction reporting under section 519(a)(1)(B)(ii) of the FD&C Act for all class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining.

(Response 1) FDA disagrees with these comments. As discussed in the 2017 Proposal, currently, there are still reportable malfunctions for which submission of individual malfunction reports on a prompter basis than quarterly is necessary to protect the public health—for example, when remedial action is needed to prevent an unreasonable risk of substantial harm to the public health. Those situations may involve class I devices and class II devices that are not permanently implantable, life supporting, or life sustaining, and it is not feasible for FDA to provide notice in the **Federal Register** or by letter to individual manufacturers, pursuant to section 519(a)(1)(B)(i)(III) of the FD&C Act, each time one of these situations arises. For example, FDA may not become aware of the situation until it receives an MDR from a manufacturer. Therefore, in accordance with section 519(a)(1)(B)(i)(III) of the FD&C Act, manufacturers of class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining remain subject to individual reporting requirements in part 803, unless granted an exemption, variance, or alternative, to protect the public health. However, FDA does believe that malfunction summary reporting on a quarterly basis, in accordance with the conditions described in section IV, will reduce burden on FDA and manufacturers and allow FDA to effectively monitor many devices. Accordingly, the Agency is granting an alternative under section 519(a)(1)(B)(i) of the FD&C Act and § 803.19 to permit manufacturers of those devices to submit summary, quarterly malfunction reports, with certain conditions.

(Comment 2) Several comments raised concerns that the proposed program would be unable to provide FDA with critical information on adverse event reporting. Many of the comments from individual consumers also raised concerns that the proposed program would limit transparency of malfunction event data that is publicly available to patients and physicians, including transparency regarding the number of reported malfunctions. However, another comment indicated that the proposed program would minimize burden while maintaining patient safety. That same comment further indicated that the proposed malfunction summary reporting format would enhance public visibility into the events and associated investigation compared to a format previously used for the Alternative Summary Reporting (ASR) program.

(Response 2) FDA disagrees with the comments suggesting that the Voluntary Malfunction Summary Reporting Program will negatively affect patient safety and the transparency of malfunction reports. Summary, quarterly reporting in accordance with this program will result in some malfunction reports being submitted to FDA and added to the publicly available Manufacturer and User Facility Device Experience (MAUDE) database later

than this occurs under FDA's current individual reporting requirements. However, as explained in our 2017 Proposal, we believe this reporting format and schedule will also yield benefits for FDA and the public, such as helping FDA process malfunction reports more efficiently and helping both FDA and the public more readily identify malfunction trends.

While summary malfunction reports submitted under this program will change the format in which information is presented to FDA, we do not believe there will be an adverse impact on the content of information provided to FDA. The format for summary reporting described in section IV.D includes a narrative section for describing malfunctions, similar to the narrative section required for individual reporting. In addition, each narrative section is required to include a sentence specifying the number of malfunction events summarized in the report, providing transparency for the public regarding the number of events that a summary report available in MAUDE represents. Therefore, we agree with the comment that the summary reporting format will improve transparency for the public when compared to some past summary reports submitted to FDA, such as reports submitted under the ASR program (Ref. 2).

(Comment 3) One comment requested clarification as to whether a manufacturer would need to apply or obtain permission to participate in the program and asked FDA to clarify how the proposed program would work with other alternative summary reporting situations. Another comment asked FDA to clarify whether manufacturers can still apply for an exemption or variance to be granted under § 803.19 for their devices that do not fall under an eligible product code.

(Response 3) FDA is clarifying in the description of the alternative that manufacturers do not need to submit a request or application to FDA before participating in the Voluntary Malfunction Summary Reporting Program. For devices that fall within eligible product codes, the alternative that FDA is granting under § 803.19 provides that manufacturers may choose or ''self-elect'' to participate, subject to the program conditions identified in section IV. If a manufacturer wishes to request a different exemption, variance, or alternative under § 803.19 (including for devices in product codes that are eligible for the Voluntary Malfunction Summary Reporting Program) the manufacturer may submit a request to FDA. For more information regarding the recommended content of such requests, see section 2.27 of the Agency's guidance entitled ''Medical Device Reporting for Manufacturers: Guidance for Industry and Food and Drug Administration Staff'' (MDR Guidance) (Ref. 3).

Whether participation in the Voluntary Malfunction Summary Reporting Program will have an impact on a manufacturer being granted a different exemption, variance, or alternative under § 803.19 will depend on the scope of the other exemption, variance, or alternative. FDA will make a case-by-case determination on requests for an exemption, variance, or alternative submitted under § 803.19(b).

B. Scope of Program

(Comment 4) Several comments also discussed the scope of product codes that should be eligible for the proposed program. One comment expressed concern about including class III devices and class II devices that are permanently implantable, life-supporting, or life-sustaining in the program and urged FDA to issue another **Federal Register** notice with the list of eligible product codes for these categories of devices for public comment before allowing summary, quarterly malfunction reporting for those devices. In contrast, another comment asserted that all devices should be eligible for malfunction summary reporting, unless there is an express determination, subject to public input, that permitting summary reporting for a device would present public health concerns. Other comments recommended that all device product codes should be eligible for summary, quarterly malfunction reporting, with the exception of product codes for class III devices and class II devices that are permanently implantable, life supporting, or life sustaining when those product codes have been in existence for less than 2 years.

(Response 4) FDA disagrees that it should publish another **Federal Register** notice for public comment listing product codes that would be eligible or ineligible for the program. Among other reasons, the Agency expressly requested comment on the product codes that should be eligible for the proposed program, and many commenters submitted proposed lists of eligible product codes or identified specific devices about which they had concerns. FDA has considered these comments and has also conducted an extensive review of all product codes, regardless of device class, to determine whether each product code would be eligible. In addition, consistent with its 2017 Proposal, product codes that have been in existence for less than 2 years are not included in the list of eligible product codes, unless the new product code was created solely for administrative reasons. In FDA's experience, this 2-year period is an important period for having more timely, detailed information to monitor malfunction events. That 2-year timeframe for new product codes is also consistent with the MDUFA IV Commitment Letter (Ref. 1).

(Comment 5) Three comments recommended that importers be included within the scope of the proposed program and indicated that FDA should provide a rationale for not including them. One of those comments suggested that without more information, it appeared arbitrary that FDA did not include importers and user facilities in the summary reporting program.

(Response 5) FDA disagrees with these comments. Unlike manufacturers, device user facilities are not required to submit malfunction reports under part 803. User facilities, such as hospitals or nursing homes, are required to submit MDRs to FDA and/or the manufacturer *only* for reportable death or serious injury events. (See section 519(b) of the FD&C Act; § 803.30(a)).

Importers are also subject to different requirements for reporting device malfunctions than those for manufacturers under part 803. Under § 803.40, importers are required to submit a report to the device manufacturer, not to FDA, within 30 days after becoming aware of a reportable malfunction event. Manufacturers then determine the reportability of the information received from the importer and accordingly submit those reports to FDA. This program specifically addresses malfunction summary reporting to FDA. In addition, we believe it is important for importers to continue to submit individual malfunction MDRs to device manufacturers in accordance with § 803.40 so that manufacturers receive detailed information necessary to conduct adequate investigations and follow up related to malfunction events.

C. Individual Reporting Conditions

(Comment 6) One comment suggested that when requesting that a manufacturer submit a 5-day report, FDA should have an objective and documented basis for making such a request, as well as an opportunity for manufacturers to appeal. Other comments asked FDA to define the term ''substantially similar'' as used in describing the program condition regarding 5-day reports and to clarify

what constitutes an ''imminent hazard'' and whether this is analogous to reportable malfunctions requiring a 5-day report.

(Response 6) The circumstances in which a 5-day report is required are defined under § 803.53, and those circumstances remain unchanged for manufacturers participating in the Voluntary Malfunction Summary Reporting Program. As stated in the 2017 Proposal, the reporting requirements at § 803.53 will continue to apply to manufacturers of devices in eligible product codes who participate in this program. We have added a separate heading to the description of the alternative to clarify this point further. For more information regarding the handling of a 5-day report, please see section 2.20 of the Agency's MDR Guidance (Ref. 3).

The first individual reporting condition requires that if a manufacturer submits a 5-day report for an event or events that require remedial action to prevent an unreasonable risk of substantial harm to public health, all subsequent reportable malfunctions of the same nature that involve substantially similar devices must be submitted as individual MDRs in accordance with §§ 803.50 and 803.52 until the date that the remedial action has been resolved to FDA's satisfaction. For purposes of this individual reporting condition, a ''substantially similar'' device could be, for example, a device that is the same except for certain performance characteristics or a device that is the same except for certain cosmetic differences in color or shape.

Regarding the term ''imminent hazard,'' FDA notes that the term is used to describe one of the general overarching principles for summary reporting, but is not included in the descriptions of any of the individual reporting conditions. For purposes of these overarching principles, we intend ''imminent hazard'' to capture situations in which a device poses a significant risk to health and creates a public health situation that should be addressed immediately to prevent injury. Use of that term in one of the overarching principles was not intended to indicate any change in the standard for a 5-day report under § 803.53.

(Comment 7) One comment indicated that there should be objective and documented criteria for when FDA would provide written notice that manufacturers must submit an individual, 30-day malfunction report in accordance with the proposed program conditions, along with an opportunity for appeal. The comment further asserted that due process considerations need to be made regarding these reporting requirements, including notice, a written justification for the request, and a process to appeal.

(Response 7) FDA disagrees that there should be fixed criteria for notifying a manufacturer that it must submit an individual, 30-day malfunction report in accordance with the program conditions. Manufacturers who are notified to submit individual reports in accordance with the individual reporting conditions will need to comply with MDR requirements to which they would otherwise be subject if not granted this alternative under § 803.19. FDA has provided examples of when it would make these notifications, but public health issues that require submission of individual MDRs to monitor device safety are not uniform and may arise in various ways.

FDA will provide written notice to manufacturers when they need to submit individual MDRs pursuant to individual reporting conditions 3 and 4, as described in section IV.B. In addition, the Agency already has a process in place for stakeholders to request review of decisions made by CDRH employees. For more information, refer to the FDA Guidance entitled ''Center for Devices and Radiological Health Appeals Processes'' (Ref. 4).

(Comment 8) Some comments disagreed with the proposed program condition that would have required manufacturers to submit individual, 30-day MDRs for reportable malfunction events that are the subject of any ongoing device recall and suggested that the condition be modified or removed. The comments cited several different reasons for objecting to this condition, including that the condition is not mentioned in the MDUFA IV Commitment Letter, that the condition may discourage manufacturers from conducting voluntary or class III recalls, that the condition is duplicative of information that FDA receives during a recall, and that it may be difficult for manufacturers to manage the requirements (*e.g.,* new events may be uncovered during a product investigation leading to confusion and multiple reports for the same incident). Suggestions from the commenters regarding this individual reporting condition included the following: (a) The condition should only apply to mandatory or FDA-initiated recalls, and summary reporting should be permitted for voluntary or low-risk class III recalls and for incidents related to remedial action after the first (parent) MDR is submitted, unless a death or serious injury is associated; (b) FDA should clarify how to handle malfunction events that were not submitted as individual MDRs, but subsequently, prior to the next summary reporting date, are identified to be the result of an issue addressed by a recall; (c) the timeframe for submitting individual MDRs should be changed from 90 days past the date of the termination of the recall to 90 days past the date of the recall; and (d) FDA should clarify what it means by ''malfunction events of the same nature.''

(Response 8) FDA disagrees with the comments recommending removal of this individual reporting condition. Recall classification takes into account both the severity of harm and the likelihood of occurrence, and it is important for FDA to have access to more timely information on malfunctions related to certain recalls to ensure that the recall has been appropriately classified and that the recall strategy is effective.

FDA also provides the following responses to the additional specific issues raised in the comments: (a) For the reasons discussed above, FDA continues to believe that it is important for malfunctions related to certain recalls to be reported as individual MDRs. However, after considering the comments, FDA has determined that this individual reporting condition should only apply to reportable malfunctions that are the subject of a recall involving a correction or removal that must be reported to FDA under part 806 (21 CFR part 806). Under part 806, manufacturers and importers are required to make a written report to FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, unless the information has already been submitted to FDA in accordance with other reporting requirements. (See § 806.10(a) and (f).) Because the definition of ''risk to health'' under part 806 tracks the definitions of class I and class II recalls in § 7.3(m) (21 CFR 7.3(m)), reports of corrections and removals are required for actions that meet the definition of class I and class II recalls. However, under part 806, manufacturers and importers need not report events that are categorized as class III recalls under § 7.3(m) (see 62 FR 27183, May 19, 1997). Therefore, an action that meets the definition of a class III recall would not, on its own, trigger the requirement to submit individual reports under the Voluntary Malfunction Summary Reporting Program.

(b) FDA agrees that it is important to provide clarity regarding when the requirement to submit individual MDRs is triggered under this individual reporting condition and the events to which that requirement applies. Therefore, FDA is revising the alternative to clarify that, as of the date a manufacturer submits a required report of a correction or removal under part 806 (or the date that the manufacturer submits a report of the correction or removal under 21 CFR part 803 or part 1004 instead, as permitted under § 806.10(f)), the manufacturer must submit reportable malfunction events related to that correction or removal as individual MDRs in accordance with §§ 803.50 and 803.52. We believe these revisions will help provide manufacturers with a clear date on which this individual reporting obligation is triggered.

With respect to malfunction events that were identified for inclusion in a summary report but are subsequently identified as the subject of a reportable correction or removal prior to the end of the relevant summary reporting period, FDA is revising the alternative to state that a summary MDR must be submitted for those reportable malfunctions within 30 calendar days of when the manufacturer submits the required report of correction or removal. In the summary report, the manufacturer must include a check on the box for ''Recall'' in SECTION H.7 of the electronic Form FDA 3500A. We have similarly revised the description of individual reporting conditions 3 and 4 to clarify the requirements for handling malfunction events identified for inclusion in a summary report (but not yet submitted) prior to the date that individual reporting is triggered.

(c) As part of its recall termination process, FDA considers MDR information, including reported malfunctions to help evaluate the effectiveness of the recall. Therefore, FDA disagrees with the suggestion to limit the duration of individual reporting under this condition to 90 days past the date of a recall. However, after considering the comments, we do not believe it is necessary to receive individual MDRs for reportable malfunction events that are the subject of a recall after FDA has terminated the recall. We have revised the alternative accordingly (see Section IV.B.2.). For similar reasons, we have revised the first individual reporting condition to state that individual MDRs associated with a 5-day report are only required until the remedial action at issue is resolved to FDA's satisfaction.

(d) By ''malfunction events of the same nature,'' FDA means additional reportable malfunction events involving the same malfunction that prompted the recall.

(Comment 9) One comment, regarding proposed individual reporting condition 3, suggested that FDA provide information on the timing for when the Agency will provide written notice to a manufacturer that the manufacturer can resume participation in the Voluntary Malfunction Summary Reporting Program.

(Response 9) FDA cannot provide a uniform timeframe for when the Agency would notify manufacturers submitting individual reports due to an identified public health issue that they can resume submission of summary, quarterly malfunction reports for those devices because the timing and resolution of public health issues is specific to each situation.

(Comment 10) Three comments recommended that FDA clarify what constitutes a ''new type of reportable malfunction'' that is exempt from summary reporting. One of these comments indicated that FDA should provide additional information regarding when a manufacturer can begin submitting summary reports for these new types of device malfunctions.

(Response 10) FDA disagrees that the meaning of the phrase ''new type of reportable malfunction'' was unclear in the proposal. Manufacturers are required under § 820.198 (21 CFR 820.198) to evaluate complaints to determine if they represent events that must be reported to FDA under part 803 or if an investigation is required. Through this process, if a manufacturer identifies a new type of reportable malfunction that has not previously been reported to FDA over the life of that device, this information must be submitted to FDA as an individual MDR in accordance with §§ 803.50 and 803.52 and may not be reported to FDA in a summary malfunction report. This will allow FDA and manufacturers to better understand and address emergent issues with medical devices. We have revised this individual reporting condition to clarify that after manufacturers submit an individual MDR for the initial occurrence of a previously unreported type of reportable malfunction for a device, subsequent reports for that same type of malfunction for that device may be in summary form, unless they are subject to individual reporting for another reason.

D. Reporting Format

(Comment 11) Some comments suggested that FDA allow manufacturers to ''bundle together'' reportable malfunction events in a summary report by product code or product family and allow the use of International Medical Device Regulators Forum's (IMDRF) Level 1,2 codes to bundle like events in a summary report.

(Response 11) FDA disagrees with the suggestion that manufacturers be permitted to bundle reportable malfunction events by product code or product family for purposes of submitting a summary report. Each unique combination of device brand name (corresponding to SECTION D1 of the Form FDA 3500A), device model, and device problem code(s) (corresponding to SECTION F10/H6 of the Form FDA 3500A) can be summarized together in reports submitted under this program. (Comments regarding the number of brand names that should be included in each summary report are further addressed in the response to Comment 16 below, and we have made corrections to the summary reporting instructions for SECTION D.4 to be clear that each summary malfunction report should summarize events for a single device model.) Bundling together malfunction reports by product codes or device families would make summarizing and interpreting the information in a summary report difficult for manufacturers, FDA, and the public because a product code or product family could contain several devices with different functions, components, and modes of operation that are important for purposes of understanding malfunction events and the causes of those events. The intent of the Voluntary Malfunction Summary Reporting Program is to streamline reporting of events that are the same or similar, yet not to over bundle reports such that important details regarding device performance are obscured.

The IMDRF (Ref. 5) is working towards harmonization of all medical device coding, including device problem codes. To harmonize medical device coding globally, device problem codes have been organized in a hierarchical arrangement, such that higher level codes (*e.g.,* electrical issue) describe more general device problems, while lower level codes (*e.g.,* insulation issue) provide more granularity into the type of device problem described. For purposes of grouping device issues for reports submitted under this Voluntary Malfunction Summary Reporting Program, we recommend that all coding

be grouped at the lowest level of coding available, when IMDRF codes are available. Based on our experience, FDA does not believe grouping by the lowest level of coding will eliminate the efficiency benefits of summary reporting. FDA does not specify a specific level of coding, but expects the most specific appropriate code to be used.

(Comment 12) One comment noted that it was unclear whether a summary malfunction report will be available in MAUDE or another database. Another comment recommended that FDA allow Excel spreadsheets with malfunction report data to be uploaded to MAUDE.

(Response 12) FDA plans to make summary reports submitted under the Voluntary Malfunction Summary Reporting Program publicly available in MAUDE. However, FDA will not upload Excel spreadsheets to MAUDE because they are incompatible with the MAUDE interface.

(Comment 13) One comment indicated that FDA should consider amending the requirement that an individual process the complaints twice—once for reporting assessment and then quarterly.

(Response 13) FDA disagrees with this comment. FDA is granting an alternative to the individual reporting requirements under part 803 for certain reportable malfunction events. The Quality System (QS) regulation requires manufacturers to evaluate all complaints to determine if they represent events that must be reported to FDA under part 803 (§ 820.198(a)). If a complaint represents an MDR reportable event, then the manufacturer must, among other things, investigate it and submit an MDR to FDA. (See §§ 803.10(c), 803.50, and 820.198(d)) The difference for manufacturers that have been granted the alternative described in this document is that they could choose to report certain malfunction events to FDA as a summary report instead of as an individual report.

(Comment 14) One comment requested that FDA provide more detail concerning the terms ''similar device'' and ''similar complaint,'' as used in the discussion of the rationale for the proposed summary reporting format.

(Response 14) The term ''similar device'' is used in FDA's MDR regulations to describe malfunction events for which manufacturers must submit a report to FDA. (see *e.g.,* § 803.50(a)(2)) As used in this alternative, the term ''similar device'' is intended to have the same meaning as it does for purposes of part 803. FDA's MDR Guidance (Ref. 3), provides more information regarding the factors that FDA and manufacturers may consider in determining if a device is ''similar'' to another device.

FDA does not believe it is necessary to provide a formal definition of the term ''similar complaint'' for purposes of this alternative because that term is not used in describing any of the conditions of the Voluntary Malfunction Summary Reporting Program, including the required reporting format. Whether a complaint constitutes a ''similar complaint'' for purposes of conducting an investigation under FDA's QS regulation is outside the scope of this alternative.

(Comment 15) One comment asked FDA to provide further information on how a manufacturer is to provide supplemental information, including whether FDA expects such information to be shared with the Agency. Some comments also noted that FDA should explain how a previously submitted summary malfunction report should be updated with new information, including how to handle new information regarding a previously reported event that would change the categorization of the event (*e.g.,* if the manufacturer subsequently became aware that a serious injury was associated with a previously reported malfunction event).

(Response 15) FDA understands the need for clarification of how to handle additional information and supplemental reporting under this program and has revised the alternative to address this issue. A manufacturer participating in the Voluntary Malfunction Summary Reporting Program must submit an initial summary report within the Summary Malfunction Reporting Schedule timeframe described in table 1. Supplemental reports to a summary malfunction report must also be submitted within that timeframe. For example, if a manufacturer submits a summary report for certain malfunction events of which it became aware in January to March and in May of that same year becomes aware of additional information that would have been required in the initial summary report if it had been known to the manufacturer, then the manufacturer must submit a supplemental report with that additional information by July 31. Manufacturers do not need to submit a supplemental report for new information if they would not have been required to report that information had it been known or available at the time of filing the initial summary malfunction report.

However, this timing for supplemental reports would not apply when additional information is learned about an event or events included in a previously submitted summary report that triggers individual reporting requirements. For example, if the manufacturer becomes aware of additional information reasonably suggesting that a previously reported malfunction meets the criteria for a reportable serious injury or death event, then the manufacturer must submit an initial, individual MDR for the identified serious injury or death within 30 calendar days of becoming aware of the additional information. The manufacturer must simultaneously submit a supplement to the initial MDR summary report reducing the number of events summarized by 1, so that the total number of events remains the same. The alternative has been revised to reflect that these are requirements for participating in the Voluntary Malfunction Summary Reporting Program.

(Comment 16) One comment stated that Form FDA 3500A is not an optimal format because it is only used for single event reporting. Other comments made specific recommendations and/or raised issues regarding the proposed summary reporting format using Form FDA 3500A, including the following: (a) In Form FDA 3500A, SECTIONS B.5 and H.10, FDA should request that information be entered in a summary, high-level form, rather than requiring detailed descriptions or itemized investigation findings; (b) clarify the most ''up to date'' information that is expected to be received in the report; (c) clarify that only one brand name per product code should be entered in the field with additional brand names being provided in a separate attachment (SECTION D.1); (d) inclusion of patient age, weight, and breakdown of gender and race is inappropriate for summary malfunction reporting, and it is not clear if such information is required in a summary malfunction report; (e) clarify that manufacturers can submit summary malfunction reports for devices manufactured at multiple manufacturing sites (SECTION D.3); (f) the summary format should permit a serial number to be used instead of a lot number to identify the devices that are the subject of a summary report (SECTION D.4); and (g) address how a manufacturer should link a device problem code with a method code, result code, and evaluation conclusion code (if different) for a single summary report that includes more than one device problem.

(Response 16) FDA does not believe the summary reporting format should be changed to use a new form. The

Voluntary Malfunction Summary Reporting Program aims to, among other things, consolidate reporting of same or similar events into a single summary report to reduce the overall volume of reports, while still providing critical content to FDA. While the Form FDA 3500A was developed for individual MDRs, manufacturers successfully used the Form FDA 3500A to submit summary malfunction reports in FDA's pilot program. In addition, as explained in our 2017 Proposal, for purposes of streamlining changes that FDA and manufacturers must make to process or submit summary reports under the Voluntary Malfunction Summary Reporting Program, we believe that using the Form FDA 3500A is the most efficient approach. We provide the following responses to the specific recommendations/issues raised regarding the summary reporting format: (a) FDA continues to believe that it is important for summary malfunction reports submitted under this program to provide a similar level of detail in text narratives as is available in an individual report to allow for sufficient understanding of the malfunction, any circumstances that led to the malfunction, and any follow-up steps the manufacturer has taken to investigate, correct, and prevent the malfunction from happening again. These narrative text fields are key to helping ensure that summary reporting under this program streamlines malfunction reporting without reducing the reporting of important details regarding device performance and transparency to the public. (b) Each summary report must be ''up to date,'' meaning that it must include all required information available, as of the close of the quarterly time period listed in the Summary Malfunction Reporting Schedule (see table 1). FDA has clarified this in section IV.F. (c) FDA disagrees that separate attachments with additional brand names should be permitted to accompany a summary malfunction report. Each summary malfunction report may only summarize malfunction events for a single brand name. We further clarified this in the instructions for the summary reporting format at section IV.D. Including multiple brand names in an attachment to a single summary report would, among other things, result in FDA having difficulty identifying the specific malfunction event to the exact device brand. (d) FDA agrees that information summarizing patient age, weight, gender, race, and ethnicity may not be relevant for many summary malfunction reports. FDA is revising the description of the summary reporting format to clarify that inclusion of this information in Section B.5 is not a required entry for the form. However, FDA recommends including descriptors such as patient weight or race in a text narrative for a malfunction summary report if the information is available and indicates that a malfunction is more likely to affect a specific group of patients. (e) FDA is revising the description of the summary reporting format to clarify that multiple manufacturing sites could be entered in SECTION G.1 if the device is manufactured at multiple sites. We note that depending on their roles, each manufacturing site may be responsible for submitting MDRs. (See *e.g.,* section 2.17 of FDA's MDR Guidance (Ref. 3), which provides additional information regarding reporting obligations for contract manufacturers.) (f) FDA agrees that a serial number may be included in SECTION D.4 and has added ''serial number'' to the reporting format instructions for that section. (g) The summary reporting format requires firms to identify the method, result, and conclusion codes in Block H6 of the Form FDA 3500A, including as many codes as are necessary to describe the event problem and evaluation for the reportable malfunction events that are being summarized. If the report summarizes reportable events that involved more than one type of device problem (see *e.g.,* Case Scenario #2, Report #3 in Appendix A (Ref. 6)), differences in the conclusion code according to the different device problems can be explained in SECTION H.10.

E. Consideration of Combination Products

(Comment 17) Some comments raised issues regarding the application of the malfunction summary reporting for combination products that contain a device constituent part but that are marketed under drug or biological product marketing authorization pathways (referred to in this document as drug and biologic-led combination products), as opposed to those under device marketing authorization pathways (device-led combination products). Issues raised in these comments include: Concerns about a device product code-based eligibility approach for drug and biologic-led combination products because such products may not have a device product code; the quarterly schedule proposed because it would create redundancies for drug and biologic-led combination products, which are subject to periodic reporting; the format proposed because it might not be compatible with the reporting systems for drugs or biological products that are utilized for drug and biologic-led combination products; and development of a single report that includes malfunction summary reporting and satisfies other combination product reporting requirements.

(Response 17) Among other things, the final rule on postmarketing safety reporting (PMSR) for combination products (81 FR 92603, December 20, 2016), codified in part 4, subpart B (21 CFR part 4, subpart B), clarified that all combination product applicants must comply with malfunction reporting requirements as described in part 803 if their combination product contains a device constituent part. Accordingly, in the 2017 Proposal, FDA requested comment on how the Voluntary Malfunction Summary Reporting Program might be implemented for combination products, including drug and biologic-led combination products. Shortly after the issuance of the proposal for this program, FDA also published a draft guidance entitled, ''Postmarketing Safety Reporting for Combination Products; Guidance for Industry and FDA Staff'' (PMSR draft guidance) (Ref. 7) regarding compliance with the final rule on PMSR for combination products, and an Immediately in Effect guidance announcing FDA's compliance policy for that rule (Ref. 8). The PMSR draft guidance noted that the Agency was proposing the Voluntary Malfunction Summary Reporting Program and stated that the Agency intends to update the PMSR draft guidance if combination products are included in the program. The compliance policy guidance announced the Agency's intent to delay enforcement of certain provisions of the rule, including malfunction reporting requirements for drug and biologic-led combination products, to provide applicants with additional time to consider Agency recommendations and technical specifications as they update their systems and procedures to comply with those provisions.

Applicants of device-led combination products must submit MDRs in accordance with part 803 (see § 4.104 (21 CFR 4.104)), and therefore, they report malfunctions using the same system as device manufacturers. Thus, FDA believes the eMDR data system and instructions support use of the Voluntary Malfunction Summary Reporting Program for such products. Accordingly, we are including device-led combination products in the Voluntary Malfunction Summary Reporting Program. However, combination product applicants for drug

and biologic-led combination products with a device constituent part must submit malfunction reports under a different system. Under § 4.104(b), malfunction reports must be submitted in accordance with 21 CFR 314.80(g) or 600.80(h)) for these combination products. Additional considerations, including the issues raised in comments as discussed above, need to be addressed before drug and biologic-led combination products could be included in the Voluntary Malfunction Summary Reporting Program. As noted above, the Agency intends to delay enforcement of the malfunction reporting requirements for drug and biologic-led combination products under the PMSR final rule. FDA will consider all relevant comments submitted on the 2017 Proposal as well as those submitted on the PMSR draft guidance in developing an approach for voluntary malfunction summary reporting for such combination products.

F. Submission Schedule and Logistics

(Comment 18) One comment recommended that FDA permit manufacturers to submit individual reports for each adverse event within 90 calendar days from the date they become aware of the reportable event, while using the summary format. The comment also suggested that FDA provide an additional 30 days for the submission of summary reports because the manufacturer may need more than a month between the end of the reporting period and the due date to aggregate reports.

(Response 18) FDA disagrees with this comment. Permitting manufacturers to submit individual reports using the summary format within 90 calendar days would delay the submission of malfunction information to FDA without providing the anticipated benefits of summary reporting that FDA identified in the 2017 Proposal, such as increased efficiency in processing malfunction reports and more readily apparent malfunction trends. While we recognize that a manufacturer may become aware of some reportable malfunction events toward the end of a quarter, manufacturers will have at least 30 days from that time to prepare and submit summary malfunction reports. FDA does not believe that manufacturers will need an additional 30 days beyond the reporting schedule outlined in the 2017 Proposal to aggregate malfunction reports into a summary report. Therefore, we have retained the Summary Malfunction Reporting Schedule that was included in the 2017 Proposal (see table 1).

(Comment 19) One comment suggested that FDA use a more generic reporting number format or a completely different reporting number format.

(Response 19) FDA disagrees with this comment. The required reporting number format for this program uses the existing common format that manufacturers must use to submit individual reports through their electronic reporting systems under part 803. Therefore, we believe there is no need for a separate MDR reporting number format to identify summary reports.

(Comment 20) One comment suggested that FDA clarify what the manufacturer should do if an investigation is not completed within the reported timeframe.

(Response 20) As discussed in response to Comment 15, FDA has revised the alternative to include instructions regarding supplemental reporting for summary reports submitted under this voluntary program. In situations where a manufacturer is not able to complete its investigation regarding a reportable malfunction by the deadline for submitting a summary report, the manufacturer is still required to report the event within the timeframes specified in the Summary Malfunction Reporting Schedule (see table 1). If additional information becomes known or available to the manufacturer after submission of a summary report, including additional information that becomes known through an investigation, the manufacturer is required to submit supplemental reports amending its initial submission as needed.

G. Addition of Product Codes to the Program

(Comment 21) Some comments suggested that FDA should explain more clearly how industry would make a request under § 803.19(b) and provide a mechanism for industry to request an exemption, when appropriate, for product codes that may be newly assigned within the first 2 years.

(Response 21) FDA is not making any changes to the alternative in response to this comment. As discussed in section VI, FDA intends to periodically assess the eligibility of product codes after they have been in existence for 2 years and will update the FDA's Product Classification database accordingly. Manufacturers can also send a request for a product code to be added to the list of eligible product codes and for manufacturers of devices within that product code to be granted the same alternative for malfunction events associated with those devices. Information about where to send such requests is provided in section VI.

H. Other Comments

(Comment 22) One comment stated that the average Paperwork Reduction Act (PRA) burden on manufacturers of 6 minutes per response appears to be a very low estimate.

(Response 22) FDA disagrees with this comment. The estimation of time is the amount of time needed to submit a summary malfunction report. It is essentially the same amount of time needed to submit an individual report because the event narrative should be similar, with the exception of one additional line that is entered that indicates the number of adverse events represented by the report. It does not include the time needed to evaluate and investigate complaints that may represent reportable malfunction events.

(Comment 23) Two comments suggested that FDA should provide clarity on how the program will apply with national competent authorities via the National Competent Authority Report (NCAR) exchange program.

(Response 23) FDA disagrees with this comment. The NCAR exchange program is separate from FDA's MDR reporting requirements. Malfunction summary reporting under this program does not change the information shared through the NCAR exchange program, and the NCAR program is currently outside the scope of the Voluntary Malfunction Summary Reporting Program.

(Comment 24) One comment suggests that FDA should use IBM's Watson Platform for Health GxP (Watson) to conduct an analysis to identify the product codes that represent the largest opportunity described in the business case for patients, industry, and FDA instead of other database systems.

(Response 24) FDA disagrees with this comment. Among other reasons, the IBM Watson Platform is not an FDA-owned resource; therefore, it is not logistically feasible for FDA to use this platform to identify product codes eligible for the Voluntary Malfunction Summary Reporting Program at this time.

III. Principles for Malfunction Summary Reporting

Informed by the findings from the Pilot Program for Medical Device Reporting on Malfunctions, FDA identified the following overarching principles for summary reporting of malfunctions:

- The collection of information in summary format should allow FDA to

collect sufficient detail to understand reportable malfunction events.

- To increase efficiency, summary malfunction reporting should occur in a common format for the electronic reporting system used.
- Information about reportable malfunctions should be transparent to FDA and to the public, regardless of whether the information is reported as an individual MDR or a summary report. Information contained in a summary malfunction report that is protected from public disclosure under applicable disclosure laws would be redacted prior to release of the report.
- Manufacturers should communicate information regarding an imminent hazard at the earliest time possible.
- Summary reporting is meant to streamline the process of reporting malfunctions. It does not change regulatory requirements for MDR-related investigations or recordkeeping by manufacturers. (For example, manufacturers participating in the Voluntary Malfunction Summary Reporting Program remain subject to requirements for establishing and maintaining MDR event files under § 803.18. In addition, under the QS regulation, manufacturers must evaluate, review, and investigate any complaint that represents an MDR reportable event (see § 820.198).
- Summary reporting information should not be duplicative of information received through other MDR reporting processes.

IV. Voluntary Malfunction Summary Reporting Program

For the reasons discussed in the 2017 Proposal and in section II, the Agency has determined that, at this time, pursuant to section 519(a)(1)(B)(i)(III) of the FD&C Act, all devices should remain subject to the reporting requirements of part 803, to protect the public health. However, based on the findings from the 2015 Pilot Program, the Agency's experience with summary reporting programs, its experience with MDR reporting generally, and the comments received on 2017 Proposal, FDA has determined that for many devices, it is appropriate to permit manufacturers to submit malfunction summary reports on a quarterly basis, for certain malfunctions, instead of individual, 30-day malfunction reports.

Therefore, under § 803.19, FDA is granting the manufacturers of devices within eligible product codes, as identified in FDA's Product Classification Database (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*) on August 17, 2018, an alternative to the reporting requirements at §§ 803.10(c)(1), 803.20(b)(3)(ii), 803.50(a)(2), 803.52, and 803.56 with respect to reportable malfunction events associated with those devices. The list reflects FDA's consideration of a list proposed by industry representatives, consistent with the MDUFA IV Commitment Letter, as well as the comments received on the 2017 Proposal regarding eligible product codes. To assist manufacturers and the public in identifying which product codes are eligible for participation in this voluntary program, FDA's searchable Product Classification Database (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*) has been updated to reflect such eligibility. As discussed in section II, FDA is also making some changes to the conditions of the alternative after considering the comments received on the 2017 Proposal.

The alternative permits manufacturers of devices within eligible product codes to submit malfunction reports in summary format on a quarterly basis for those devices, subject to the conditions of the alternative described in the remainder of this section. Such manufacturers ''self-elect'' to participate by submitting summary malfunction reports in accordance with the conditions of the alternative. They do not need to submit a separate application to FDA to participate.[1]

The remainder of this section describes the following conditions that manufacturers must follow if they choose to submit summary malfunction reports for devices within eligible product codes under the alternative: (1) The conditions under which individual malfunction reports are required; (2) submission of supplemental reports; (3) the format for summary malfunction reports; (4) considerations for combination products; and (5) the schedule and other logistics for submission of summary reports. Because this is an alternative, if a manufacturer does not submit summary reports for reportable malfunction events in accordance with the conditions described in this section, including the reporting schedule and format, then the manufacturer must submit individual malfunction reports in compliance with all requirements under part 803 (unless the manufacturer has been granted a different exemption, variance, or alternative that applies).

A. Events Outside the Scope of This Alternative

The Voluntary Malfunction Summary Reporting Program does not apply to reportable death or serious injury events, which are still required to be reported to FDA within the mandatory 30-calendar-day timeframe, under §§ 803.50 and 803.52, or within the 5-work day timeframe under § 803.53. Thus, if a manufacturer participating in the program becomes aware of information reasonably suggesting that a device that it markets may have caused or contributed to a death or serious injury, then the manufacturer must submit an individual MDR for that event because it involves a reportable death or serious injury.

The reporting requirements at § 803.53 also continue to apply to manufacturers participating in the program. Under § 803.53(a), a 5-day report must be filed if a manufacturer becomes aware of an MDR reportable event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Further, under § 803.53(b), if FDA has made a written request for the submission of a 5-day report, the manufacturer must submit, without further requests, a 5-day report for all subsequent reportable malfunctions of the same nature that involve substantially similar devices for the time period specified in the written request. FDA may extend the time period stated in the original written request if the Agency determines it is in the interest of the public health (see § 803.53(b)).

B. Individual Reporting Conditions

Manufacturers of devices in eligible product codes may continue submitting individual, 30-day malfunction reports in compliance with §§ 803.50 and 803.52 if they choose to do so. However, those manufacturers may submit all reportable malfunction events for devices in eligible product codes in the summary format and according to the schedule described below in section IV.D and F, unless one of the following individual reporting conditions applies:

1. A Reportable Malfunction Is Associated With a 5-Day Report

After submitting a 5-day report required under § 803.53(a), all subsequent reportable malfunctions of the same nature that involve substantially similar devices must be submitted as individual MDRs in

[1] We note that the Voluntary Malfunction Summary Reporting Program does not apply to importers or device user facilities. Therefore, requirements under part 803 for importers and device user facilities are unaffected by this alternative. For example, importers will continue to submit individual MDRs to the manufacturer under § 803.40.

compliance with §§ 803.50 and 803.52 until the date that the remedial action has been terminated to FDA's satisfaction. Summary reporting of malfunctions may then resume on the regularly scheduled summary reporting cycle. Submission of reportable malfunctions associated with 5-day reports in this manner will assist FDA in monitoring the time course and resolution of the issue presenting an unreasonable risk of substantial harm to the public health.

2. A Reportable Malfunction Is the Subject of Certain Device Recalls

When a device is the subject of a recall involving the correction or removal of the device to address a malfunction and that correction or removal is required to be reported to FDA under part 806,[2] all reportable malfunction events of the same nature that involve the same device or a similar device marketed by the manufacturer must be submitted as individual MDRs in accordance with §§ 803.50 and 803.52 until the date that the recall is terminated. After the recall is terminated, summary reporting may resume on the regularly scheduled summary reporting cycle. The requirement to submit individual reports under this condition is triggered on the date that the manufacturer submits a report of a correction or removal required under part 806 (or the date that the manufacturer submits a report of the correction or removal under part 803 or part 1004 instead, as permitted under § 806.10(f)). This will allow FDA to monitor the frequency of reportable malfunctions associated with the recall and effectiveness of the recall strategy.

If a manufacturer becomes aware of reportable malfunction events before the date that the requirement to submit individual reports is triggered and a summary report for those events has not yet been submitted to FDA, then the manufacturer must submit any of those malfunction events related to the recall in a summary MDR format within 30 calendar days of submitting the required report of correction or removal. In the summary MDR, the manufacturer must include a check box of recall in section H.7 of the electronic Form FDA 3500A.

3. FDA Has Determined That Individual MDR Reporting Is Necessary To Address a Public Health Issue

If FDA has determined that individual malfunction reports are necessary to provide additional information and more rapid reporting for an identified public health issue involving certain devices, manufacturers must submit reportable malfunction events for those devices as individual MDRs in compliance with §§ 803.50 and 803.52. Under these circumstances, FDA will provide written notification to manufacturers of relevant devices that individual MDR submissions are necessary. FDA will provide further written notice when manufacturers of those devices may resume participation in summary malfunction reporting.

The requirement to submit individual reports under this condition is triggered on the date the manufacturer receives the written notification from FDA. If a manufacturer became aware of reportable malfunction events before the date that the requirement to submit individual reports is triggered and a summary report for those events has not yet been submitted to FDA, then the manufacturer must submit any of those malfunction events for the identified devices to FDA within 30 calendar days of receiving notification from FDA.

4. FDA Has Determined That a Device Manufacturer May Not Report in Summary Reporting Format

FDA may determine that a specific manufacturer is no longer allowed to participate in the Voluntary Malfunction Summary Reporting Program for reasons including, but not limited to, failure to comply with applicable MDR requirements under part 803, failure to follow the conditions of the program, or the need to monitor a public health issue. In that case, FDA will provide written notification to the device manufacturer to submit individual malfunction reports in compliance with §§ 803.50 and 803.52. The requirement to submit individual reports under this condition is triggered on the date the manufacturer receives the written notification from FDA. If a manufacturer became aware of reportable malfunction events before the date that the requirement to submit individual reports is triggered under this condition and a summary report for those events has not yet been submitted to FDA, then the manufacturer must submit those malfunction events within 30 calendar days of receiving notification from FDA.

5. A New Type of Reportable Malfunction Occurs for a Device

If a manufacturer becomes aware of information reasonably suggesting a reportable malfunction event has occurred for a device that the manufacturer markets and the reportable malfunction is a new type of malfunction that the manufacturer has not previously reported to FDA for that device, then the manufacturer must submit an individual report for that reportable malfunction in compliance with §§ 803.50 and 803.52. After the manufacturer submits this initial individual report, subsequent malfunctions of this type may be submitted in summary form according to the reporting schedule in table 1, unless another individual reporting condition applies.

C. Supplemental Reports

In general, if a manufacturer obtains information required in a malfunction summary report (see section IV.D. describing the required content of a summary report), that the manufacturer did not provide because it was not known or was not available when the manufacturer submitted the initial summary malfunction report, the manufacturer must submit the supplemental information to FDA in an electronic format in accordance with § 803.12(a). The supplemental information must be submitted to FDA by the submission deadline described in the Summary Malfunction Reporting Schedule (table 1), according to the date on which the manufacturer becomes aware of the supplemental information. Manufacturers must continue to follow the requirements for the content of supplemental reports set forth at § 803.56(a) thorough (c), meaning that on a supplemental or follow up report, the manufacturer must: (a) Indicate that the report being submitted is a supplemental or follow up report; (b) submit the appropriate identification numbers of the report that you are updating with the supplemental information (*e.g.,* your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and (c) include only the new, changed, or corrected information.

However, if a manufacturer submits a summary malfunction report and subsequently becomes aware of information reasonably suggesting that

[2] FDA regulations provide that ''[e]ach device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device or (2) to remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).'' We note that under part 806, manufacturers and importers are not required to report a correction or removal that meets the definition of a class III recall under 21 CFR part 7. (See 21 CFR 7.3(g) and (m), 806.2(d) and (j) through (k), and 806.10; see also 62 FR 27183 at 27184.)

an event (or events) summarized therein represents a reportable serious injury or death event, or a new type of reportable malfunction, then the manufacturer must submit reports as follows: The manufacturer must submit an initial, individual MDR for the identified serious injury, death, or new type of reportable malfunction event within 30 calendar days of becoming aware of the additional information. The manufacturer must simultaneously submit a supplement to the initial malfunction summary report reducing the number of events summarized accordingly, so that the total number of events remains the same.

D. Malfunction Reporting Summary Format

Manufacturers of devices in eligible product codes who elect to participate in the Voluntary Malfunction Summary Reporting Program must submit summary malfunction reports in the format described below. As detailed in the 2017 Proposal and Appendix, the format largely adopts the format that was tested in FDA's Pilot Program for Medical Device Reporting on Malfunctions and is compatible with the Form FDA 3500A (Ref. 9), which allows manufacturers to submit MDRs using the same electronic submission form that they use to submit individual MDRs, in accordance with the eMDR Final Rule (79 FR 8832, February 14, 2014). Because summary malfunction reports represent a grouping of malfunction events for a specific model of a device, the summary reporting format would require an additional element in the summary text narrative to identify the number of reportable malfunctions that each report represents. As described below, the XML tags ''<NOE>'' and ''<NOE/>'' are placed on both sides of the number of events (NOE) to make the number extractable from the report. FDA believes that submission of summary reports in the format described below will provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively.

Format Instructions: Separate summary malfunction reports must be submitted for each unique combination of brand name, device model, and problem code(s). (See Appendix A for case examples of how to report (Ref. 6).) Each summary malfunction report must include at least the following information collected on Form FDA 3500A and must be submitted in an electronic format:

- SECTION B.5: Describe Event or Problem—To distinguish this report as a summary malfunction report, the first sentence of the device event narrative must read: ''This report summarizes <NOE> XXX </NOE> malfunction events,'' where XXX is replaced by the number of malfunction events being summarized.

The device event narrative must then include a detailed description of the nature of the events and, if relevant and available, we recommend including a range of patient age and weight and a breakdown of patient gender, race, and ethnicity.

- SECTION D.1: Brand Name.
- SECTION D.2 and D.2.b: Common Device Name and Product Code. Include the common name of the device and Product Classification Code (Procode).
- SECTION D.3: Manufacturer Name, City, and State.
- SECTION D.4: Device Identification—Enter the model and/or catalog number and lot number(s) and/or serial number(s) for the devices that are the subject of the MDR. Include any device identifier (DI) portion of the unique device identifier (UDI) for the device version or model that is the subject of the MDR.
- SECTION G.1: Contact Office (and Manufacturing Site(s) for Devices)—Enter the name, address, and email of the manufacturer reporting site (contact office), including the contact name for the summary report being submitted. Enter the name and address of the manufacturing site(s) for the device, if different from the contact office.
- SECTION G.2: Phone Number of Contact Office.
- SECTION G.5: Combination Products—If applicable, indicate that the report involves a combination product (see section IV.E.).
- SECTION H.1: Type of Reportable Event—Check ''Malfunction'' in this box.
- SECTION H.6: Event Problem and Evaluation Codes—
  - Enter the device problem code(s). (See Appendix A for case examples of how to report (Ref. 6).)
  - Enter the evaluation code(s) for the following categories: Method, Results, Conclusion.
  - Enter a Conclusion Code, even if the device was not evaluated.
- SECTION H.10: Additional Manufacturer Narrative—Provide a summary of the results of the investigation for the reported malfunctions, including any follow up actions taken, and any additional information that would be helpful in understanding how the manufacturer addressed the malfunction events summarized in the report. Enter a breakdown of the malfunction events summarized in the report, including the number of devices that were returned, the number of devices that were labeled ''for single use'' (if any), and the number of devices that were reprocessed and reused (if any).

E. Combination Product Considerations

As noted in the response to comment 17 above, device-led combination products are included in this alternative that we are granting under § 803.19 to permit voluntary malfunction summary reporting. The eMDR data system and instructions support use of the Voluntary Malfunction Summary Reporting Program for device-led combination products. However, as discussed in response to comment 17 above, additional considerations need to be addressed before drug and biologic-led combination products could be included in the Voluntary Malfunction Summary Reporting Program. As noted in Response 17, the Agency intends to delay enforcement of the malfunction reporting requirements for drug and biologic-led combination products under the PMSR final rule. FDA will consider the relevant comments received on the 2017 Proposal, as well as any additional, relevant comments relating to malfunction reporting for drug and biologic-led combination products submitted in relation to the PMSR draft guidance in developing an approach for voluntary malfunction summary reporting for such combination products.

F. Submission Schedule and Logistics

Manufacturers submitting malfunction summary reports or supplemental reports to a malfunction summary report must use electronic reporting (Ref. 10) to submit those reports on a quarterly basis according to the schedule in table 1. The summary malfunction report must include the MDR Number, which consists of the registration number of the manufacturer, the year in which the event is being reported, and a 5-digit sequence number. Information included in a malfunction summary report must be current as of the last date of the quarterly timeframe identified in the first column of table 1.

TABLE 1—SUMMARY MALFUNCTION REPORTING SCHEDULE

Reportable malfunctions or supplemental information that you become aware of during these timeframes:	Must be submitted to FDA by:
January 1–March 31	April 30.
April 1–June 30	July 31.
July 1–September 30	October 31.
October 1–December 31	January 31.

The Voluntary Malfunction Summary Reporting Program applies only to reportable malfunction events that manufacturers become aware of on or after August 17, 2018. The deadline for FDA accepting the first round of quarterly reports for this program is October 31, 2018.

Under §§ 803.17 and 803.18, manufacturers are required to develop, maintain, and implement written MDR procedures and establish and maintain MDR event files, and those requirements remain applicable for manufacturers that elect to participate in this program. Among other things, a manufacturer must develop, maintain, and implement MDR procedures that provide for timely transmission of complete MDRs to FDA. (See § 803.17(a)(3)). Manufacturers participating in the Voluntary Malfunction Summary Reporting Program will need to update their internal MDR processes and procedures to provide for submitting summary malfunction reports within the Summary Malfunction Reporting Schedule.

V. Implementation Strategy

The goal of the Voluntary Malfunction Summary Reporting Program is to permit manufacturers of devices under certain product codes to report malfunctions on a quarterly basis and in a summary format, as outlined in the MDUFA IV Commitment Letter (Ref. 1), in a manner that provides for effective monitoring of devices and is beneficial for FDA, industry, and the public. An important part of this voluntary program is providing clarification to manufacturers regarding the product codes eligible for the program.

Consistent with the MDUFA IV Commitment Letter (Ref. 1), FDA has identified eligible product codes for the Voluntary Malfunction Summary Reporting Program in FDA's Product Classification Database, available on FDA's website, as part of granting the alternative (see *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*). Manufacturers that choose to participate in quarterly, summary reporting through this program will remain responsible for complying with applicable MDR requirements under part 803 (*e.g.,* requirements to establish and maintain MDR event files under § 803.18) and QS requirements under part 820 (21 CFR part 820) (*e.g.,* the requirement to evaluate, review, and investigate any complaint that represents an MDR reportable event under § 820.198).

If FDA determines that individual malfunction reports are necessary from a specific manufacturer or for specific devices, FDA will notify relevant manufacturers that they must submit individual reports and provide an explanation for that decision and, as appropriate, the steps necessary to return to summary, quarterly reporting. The Agency also notes that, under § 803.19(d), it may revoke or modify in writing an exemption, variance, or alternative reporting requirement if it determines that revocation or modification is necessary to protect the public health.

VI. Updating Product Codes for Inclusion Into the Program

FDA recognizes that new product codes will be created after the date of granting the Voluntary Malfunction Summary Reporting Program alternative under § 803.19. In general, FDA does not intend to consider devices under product codes in existence for less than 2 years to be eligible for the program, unless the new product code was issued solely for administrative reasons. Any product code in existence after the publication date will be initially ineligible to participate in the program. However, FDA will periodically evaluate new product codes after they have been in existence for 2 years to determine whether they should be added to the list of product codes eligible for the Voluntary Malfunction Summary Reporting Program. If FDA determines that a new product code should be added, then it will grant manufacturers of devices within that product code the same alternative under § 803.19 for malfunction events associated with those devices and update FDA's Product Classification database accordingly to reflect the changes.

Manufacturers can send a request for a product code to be added to the list of eligible product codes and for manufacturers of devices within that product code to be granted the same alternative for malfunction events associated with those devices to the *MDRPolicy@fda.hhs.gov* mailbox. You may also mail your written request to MDR Policy Branch, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3217, Silver Spring, MD 20993–0002.

VII. Conclusion

In accordance with section 519(a)(1)(B)(i) of the FD&C Act and § 803.19, FDA is granting the alternative described in section IV to manufacturers of devices in eligible product codes, as identified in the FDA Product Classification Database (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm*) on August 17, 2018. FDA believes that for the devices in eligible product codes, quarterly, summary reporting in accordance with the conditions of the alternative will be as effective as the current MDR regulatory requirements for purposes of identifying and monitoring potential device safety concerns and device malfunctions. The Voluntary Malfunction Summary Reporting Program will allow manufacturers to submit summary reports with event narratives that will help FDA more efficiently process malfunction reports and identify malfunction trends. In addition, FDA's determination of product code eligibility and the conditions of participation in the program will require submission of individual 30-day or 5-day malfunction reports in circumstances where such reports are necessary to protect public health.

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

The Voluntary Malfunction Summary Reporting Program described in this Notice contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). These provisions have been approved under OMB control number 0910–0437.

This document also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA (44 U.S.C. 3501–3520). The collections of information in part 4, subpart B, regarding postmarketing safety reporting for combination products have been approved under OMB control number 0910–0834; the collections of information in part 803, regarding medical device reporting, have been approved under OMB control number 0910–0437; the collections of information in 806, regarding corrections and removals, have been approved under OMB control number 0910–0359; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 810, regarding medical device recall authority, have been approved under OMB control number 0910–0432; the collections of information in part 820, regarding quality system regulations, have been approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 1002 through 1050, regarding radiological health, have been approved under OMB control number 0910–0025; the collections of information regarding the MedWatch: The Food and Drug Administration Medical Products Reporting Program have been approved under OMB control number 0910–0291; and the collections of information regarding the Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun)) have been approved under OMB control number 0910–0471.

X. References

The following references are on display in the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Medical Device User Fee Agreement IV Commitment Letter, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.*
2. Food and Drug Administration, ''Medical Device Reporting—Alternative Summary Reporting (ASR) Program; Guidance for Industry,'' (October 19, 2000); available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072102.pdf.*
3. Food and Drug Administration, ''Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff,'' (November 8, 2016); available at *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm359566.pdf.*
4. Food and Drug Administration, ''Center for Devices and Radiological Health Appeals Processes; Guidance for Industry and Food and Drug Administration Staff,'' (May 17, 2013); available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf.*
5. Food and Drug Administration, ''International Medical Device Regulators Forum,'' available at *https://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/default.htm.*
6. Appendix A, ''Case Examples of Summary Malfunction Reporting,'' available in Docket No. FDA–2017–N–6730.
7. Food and Drug Administration, ''Postmarketing Safety Reporting for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff,'' (March 2018); available at *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM601454.pdf.*
8. Food and Drug Administration, ''Compliance Policy for Combination Product Postmarketing Safety Reporting, Immediately in Effect Guidance for Industry and Food and Drug Administration Staff,'' available at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm601456.htm.*
9. Food and Drug Administration, Form FDA 3500A, available at *https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm048334.pdf.* 5.
10. Electronic Medical Device Reporting (eMDR) (manufacturers may obtain information on how to prepare and submit reports in an electronic format that FDA can process, review, and archive), available at: *https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm.*

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17770 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0775]

Drawbridge Operation Regulation; Columbia River, Portland, OR and Vancouver, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Interstate 5 (I–5) Bridges across the Columbia River, mile 106.5, between Portland, Oregon, and Vancouver, Washington. The deviation is necessary to facilitate the presence of participants in the Hands Across the Bridge Project. This deviation allows the bridges to remain in the closed-to-navigation position during the event.

DATES: This deviation is effective from 11 a.m. to 2 p.m. on September 3, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0775 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: Oregon Department of Transportation (bridge owner) requested a temporary deviation from the operating schedule for the I–5 Bridges, mile 106.5, across the Columbia River between Vancouver, WA, and Portland, OR, to facilitate safe passage of participants in the Hands Across the Bridge Project. The I–5 Bridges provides three designated navigation channels with vertical clearances ranging from 39 to 72 feet above Columbia River Datum 0.0 while the lift spans are in the closed-to-navigation position. The normal operating schedule for the I–5 Bridges is 33 CFR 117.869. The subject bridges need not open to marine vessels during

the deviation period from 11 a.m. to 2 p.m. on September 3, 2018. The bridge shall operate in accordance with 33 CFR 117.869 at all other times. Waterway usage on this part of the Columbia River includes vessels ranging from large commercial ships, tug and tow vessels to recreational pleasure craft.

Vessels able to pass under the bridges in the closed-to-navigation positions may do so at any time. Both bridges will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 9, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–17801 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0676]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation; modification.

SUMMARY: The Coast Guard has modified a temporary deviation from the operating schedule that governs the Hawthorne Bridge crosses the Willamette River, mile 13.1, at Portland, OR. The deviation is necessary to accommodate a filming event for a movie. This modified deviation changes the period the bridge is authorized to remain in the closed-to-navigation position.

DATES: This modified deviation is effective from 6 p.m. on September 8, 2018, to 12:01 a.m. on September 9, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0676 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this modification, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: On July 19, 2018, we published a temporary deviation entitled ''Drawbridge Operation Regulation; Willamette River at Portland, OR'' in the **Federal Register** (83 FR 34041). That temporary deviation allowed the subject bridge to not open to marine vessels from 6 p.m. on September 1, 2018 to 12:01 a.m. on September 2, 2018. Multnomah County, the bridge owner, requested a modification of the current published deviation to the following times: 6 p.m. on September 8, 2018, to 12:01 a.m. on September 9, 2018. This change is due to scheduling issues with the filming crew for a movie.

The Hawthorne Bridge provides a vertical clearance of 49 feet in the closed-to-navigation position referenced to the vertical clearance above Columbia River Datum 0.0. The subject bridge operates per 33 CFR 117.897(c)(3)(v). Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. The Coast Guard requested objections to this modification from local mariners via email. No objections were submitted to us. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 9, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–17800 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2017–0414; FRL–9971–37]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 27 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action requires persons who intend to manufacture (defined by statute to include import) or process any of these 27 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

DATES: This rule is effective on October 16, 2018. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on August 31, 2018.

Written adverse comments on one or more of these SNURs must be received on or before September 17, 2018 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**). If EPA receives written adverse comments on one or more of these SNURs before September 17, 2018, EPA will withdraw the relevant sections of this direct final rule before its effective date.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID)

number EPA–HQ–OPPT–2017–0414, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule on or after September 17, 2018 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What action is the Agency taking?

1. *Direct Final Rule.* EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices obligates EPA to assess risks that may be associated with the significant new uses under the conditions of use and, if appropriate, to regulate the proposed uses before they occur.

2. *Proposed Rule.* In addition to this Direct Final Rule, elsewhere in this issue of the **Federal Register**, EPA is issuing a Notice of Proposed Rulemaking for this rule. If EPA receives no adverse comment, the Agency will not take further action on the proposed rule and the direct final rule will become effective as provided in this action. If EPA receives adverse comment on one or more of SNURs in this action by September 17, 2018 (see Unit VI. of the **SUPPLEMENTARY INFORMATION**), the Agency will publish in the **Federal Register** a timely withdrawal of the specific SNURs that the adverse comments pertain to, informing the public that the actions will not take effect. EPA would then address all adverse public comments in a response to comments document in a subsequent final rule, based on the proposed rule.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once

EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to This Rule

EPA is establishing significant new use and recordkeeping requirements for 27 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) Order.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.

This information may include testing required in a TSCA section 5(e) Order to be conducted by the PMN submitter, as well as testing not required to be conducted but which would also help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VIII. for more information.

- CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of each rule specifies the activities designated as significant new uses. Certain new uses, including exceedance of production volume limits (*i.e.,* limits on manufacture volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

These rules include 27 PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that it has insufficient information to conduct a reasoned evaluation and the activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) Order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) Orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELs approach for SNURs that are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA section 5(e) Order for the same chemical substance.

PMN Numbers: P–12–277, P–12–278, P–12–280, P–12–281, P–12–282, P–12–283, and P–12–284

Chemical names: Alkanes, $C_{20–28}$, chloro (P–12–277), Slack waxes (petroleum), chloro (P–12–278), Hexacosane, chloro derivs. and octacosane, chloro derivs. (P–12–280), Alkanes, $C_{20–24}$, chloro (P–12–281), Alkanes, $C_{14–16}$, chloro (P–12–282), Tetradecane, chloro derivs. (P–12–283), and Octadecane, chloro derivs. (P–12–284).

CAS numbers: 2097144–43–7 (P–12–277), 2097144–44–8 (P–12–278), 2097144–46–0 and 2097144–47–1 (P–12–280), 2097144–45–9 (P–12–281), 1372804–76–6 (P–12–282), 198840–65–2 (P–12–283), 2097144–48–2 (P–12–284).

Effective date of TSCA section 5(e) Order: June 5, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the PMN substances will be used as flame retardants and plasticizers in polyvinyl chloride (PVC), polymers, and rubber; flame retardants, plasticizers, and

lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL–6097–7) and test data on structurally similar medium-chain chlorinated paraffins (MCCP), the PMN substances are a potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on data on MCCP, EPA has identified concerns for systemic toxicity as well as aquatic and terrestrial toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health or the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the representative congener groups prior to exceeding a certain time period specified in the Order.

2. Use of the PMN substances only for the uses specified in the Order: Flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the fate, and terrestrial and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed a certain time limit without performing chronic aquatic and terrestrial toxicity and biodegradation testing.

CFR citations: 40 CFR 721.11068 (P–12–277), 40 CFR 721.11069 (P–12–278), 40 CFR 721.11070 (P–12–280), 40 CFR 721.11071 (P–12–281), 40 CFR 721.11072 (P–12–282 and P–14–684), 40 CFR 721.11073 (P–12–283 and P–14–683), and 40 CFR 721.11074 (P–12–284).

PMN Numbers: P–12–433, P–12–453, and P–12–505

Chemical names: Alkanes, $C_{18–20}$, chloro (P–12–433), Alkanes, $C_{14–17}$, chloro (P–12–453) and Alkanes, $C_{22–30}$, chloro (P–12–505).

CAS numbers: 106262–85–3 (P–12–433), 85535–85–9 (P–12–453) and 288260–42–4 (P–12–505).

Effective date of TSCA section 5(e) Order: June 5, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the PMN substances will be used as flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL–6097–7) and test data on structurally similar medium-chain chlorinated paraffins (MCCP), the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Based on test data on MCCP EPA has identified concerns for systemic toxicity as well as aquatic and terrestrial toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health or the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the representative congener groups prior to exceeding a certain time period specified in the Order.

2. Use of the PMN substances only for the uses specified in the Order: Flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the fate, and terrestrial and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed a certain time limit without performing chronic aquatic and terrestrial toxicity and biodegradation testing.

CFR citations: 40 CFR 721.11075 (P–12–433), 40 CFR 721.11076 (P–12–453), 40 CFR 721.11077 (P–12–505).

PMN Numbers: P–14–683 and P–14–684

Chemical names: Tetradecane, chloro derivs. (P–14–683) and Alkanes, $C_{14–16}$, chloro (P–14–684).

CAS numbers: 198840–65–2 (P–14–683) and 1372804–76–6 (P–14–684).

Effective date of TSCA section 5(e) Order: May 17, 2017.

Basis for TSCA section 5(e) Order: The PMNs state that the substances will be used as flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles. Based on the physical/chemical properties of the PMN substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL–6097–7) and test data on structurally similar medium-chain chlorinated paraffins (MCCP), the PMN substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the PMN substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Further, EPA has identified concerns for systemic toxicity, as well as aquatic and terrestrial toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health or the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the representative congener groups prior to exceeding a certain time period specified in the Order.

2. Use of the PMN substances only for the uses specified in the Order: Flame retardants and plasticizers in PVC, polymers, and rubber; flame retardants, plasticizers, and lubricants in adhesives, caulk, sealants, and coatings; additives in lubricants including metalworking fluids; and flame retardants and waterproofers in textiles.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the fate, and terrestrial and aquatic toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed a certain time limit without performing chronic aquatic and terrestrial toxicity and biodegradation testing.

CFR citations: 40 CFR 721.11072 (P–12–282 and P–14–684), 40 CFR 721.11073 (P–12–283 and P–14–683).

PMN Number: P–16–150

Chemical name: Chloroflurocarbon (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 31, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an intermediate. Based on test data on the PMN substance, EPA identified concerns for acute human toxicity. Based on analogue data EPA identified concerns for toxicity to aquatic and terrestrial organisms. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I), 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment and that the substance will be produced in substantial quantities and may be reasonably anticipated to enter the environment in substantial quantities. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the substance prior to exceeding the production limits specified in the Order.

2. Use of personal protective equipment to prevent dermal exposure (where there is a potential for dermal exposure).

3. Use of a National Institute of Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 1000 (where there is a potential for inhalation exposure) in conjunction with a minimum set of engineering controls described in the PMN, or compliance with a new chemical exposure limit (NCEL) of 170 parts per billion (ppb) as an 8-hour time-weighted average to prevent inhalation exposure.

4. Use of engineering controls to limit worker exposure and air release of the PMN substance to the environment.

5. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the Safety Data Sheet (SDS).

6. Manufacture, processing, and use in an enclosed process.

7. Use only as a chemical intermediate.

8. No release of the substance resulting in surface water concentrations that exceed 240 ppb.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity testing, reproductive and developmental toxicity testing, and acute and chronic aquatic toxicity testing.

CFR citation: 40 CFR 721.11078.

PMN Number: P–16–379

Chemical name: Silane, 1,1′-(1,2-ethanediyl)bis[1,1-dichloro-1-methyl]-, hydrolysis products with chloroethenyldimethylsilane.

CAS number: 1485477–78–8.

Effective date of TSCA section 5(e) Order: June 8, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance is as a chemical intermediate for polymer synthesis. Based on SAR analysis of test data on analogous substances, EPA has identified concerns for liver toxicity and mutagenicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.

2. Use of personal protective equipment including impervious gloves and clothing which covers any other exposed areas of the arms, legs and torso (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No domestic manufacture of the substance.

5. Use of the substance only for the confidential uses specified in the Order.

6. No use involving application methods that generate a dust, mist, vapor, or aerosol.

7. Disposal of the substance only by water or landfill.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing specific target organ toxicity and mutagenicity testing. In addition, EPA has determined that the results of other specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11079.

PMN Number: P–16–410

Chemical name: Silicophosphonate—sodium silicate (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 4, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance will be as an automotive engine fluid additive. Based on test data on the PMN substance, EPA has identified concerns for skin and eye irritation, corrosion, and systemic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to human health. To protect against these risks, the Order requires:

1. No domestic manufacture of the substance.

2. Use of the substance in formulations containing no greater than 0.2% of the chemical substance and for the confidential uses specified in the Order.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of irritation testing may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11080.

PMN Number: P–16–438

Chemical name: 3-Butenenitrile, 2-(acetyloxy)-.

CAS number: 15667–63–7.

Effective date of TSCA section 5(e) Order: June 23, 2017.

Basis for TSCA section 5(e) Order: The PMN states the substance will be used as a chemical intermediate for a pesticide inert. Based on test data on the PMN substance, EPA identified concerns for acute toxicity, irritation to all tissues, developmental toxicity, and neurotoxicity. EPA identified concerns for aquatic organism toxicity based on submitted data. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment. Further, based on SAR analysis of test data on analogous vinyl/allyl esters vinyl/allyl esters nitriles and test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 8 ppb in surface waters. To protect against these risks, the Order requires:

1. Submission of monitoring data on the substance.

2. Use of personal protective equipment including impervious gloves and protective clothing (where there is a potential for dermal exposures) and a NIOSH-certified powered air purifying particulate respirator with an Assigned Protection Factor (APF) of at least 1000 (where there is a potential for inhalation exposures).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. Manufacture, process, and use of the substance in a closed system as specified in the PMN.

5. Use of the substance only as a chemical intermediate.

6. No release of the substance into the surface waters of the United States.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic aquatic toxicity testing of the PMN substance may be potentially useful in characterizing the environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and use will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11081.

PMN Number: P–16–543

Chemical name: Halogenophosphoric acid metal salt (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 24, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use will be as a battery ingredient. Based on test data on the PMN substance and an analogue, EPA has identified concerns for irritation, corrosion, acute toxicity, immunotoxicity, developmental toxicity, neurotoxicity, and cancer. Further, based on test data on the PMN substance, EPA identified concerns for aquatic organism toxicity at surface water concentrations that exceed 3 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Submission of monitoring data as specified in the Order.

2. Use of personal protective equipment as specified in the Order (where there is a potential for dermal exposure).

3. Use of a NIOSH-certified respirator with an APF of at least 1000 (where there is a potential for inhalation exposure).

4. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

5. No domestic manufacture of the substance.

6. Use of the substance only in an enclosed process.

7. Use of the substance only for the confidential uses specified in the Order.

8. Manufacture, process, or use of the substance without the engineering controls required by the Order to control dermal and inhalation exposure.

9. Disposal of the substance by hazardous waste incineration except when in wastewater.

10. No release of the substance resulting in surface water concentrations that exceed 3 ppb.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity, human exposure, aquatic toxicity, and fate of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed to conduct an exposure monitoring program for employees who are reasonably likely to be exposed to the PMN substance and a hydrolysis product of the PMN substance. In addition, EPA has determined that the results of specific target organ toxicity, acute aquatic toxicity, and biodegradation testing of the PMN substance may be potentially useful in characterizing the health and environmental effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines

is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11082.

PMN Number: P–16–596

Chemical names: Alkenoic acid, reaction products with polyethylene glycol ether with hydroxyalkyl substituted alkane (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: June 5, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a site-limited intermediate used for production of ultraviolet (UV) curable coating resin. Based on SAR analysis on structurally similar substances, EPA has identified concerns for irritation, sensitization, developmental toxicity, liver and kidney effects, and oncogenicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health and the environment. EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified below would not result in inhalation exposure. To protect against these risks, the Order requires:

1. Submission of test data on the substance prior to exceeding the confidential production volume limit specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No domestic manufacture of the substance.

5. Use of the substance only as a site-limited intermediate for the production of UV curable coating resin.

6. No release of the substance to surface waters of the United States.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of a reproductive/developmental toxicity testing may be potentially useful in characterizing the health effects of the PMN substance. The submitter has agreed not to manufacture beyond a certain production volume limit without performing reproductive/developmental toxicity testing.

CFR citation: 40 CFR 721.11083.

PMN Number: P–17–10

Chemical name: Alkyl substituted alkenoic acid, alkyl ester, polymer with alkyl substituted alkenoate and alkenoic acid, hydroxy substituted[(oxoalkyl)oxy]alkyl ester, reaction products with alkanoic acid, dipentaerythritil and isocyanate substituted carbomonocycle, compds. with alkylamine (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: June 31, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a UV curable coating resin. Based on test data on structurally similar substances, EPA has identified concerns for irritation, sensitization, developmental effects, internal organ effects (liver and kidney), and cancer. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves to prevent dermal exposure (where there is a potential for dermal exposure).

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

3. No domestic manufacture of the substance.

4. No manufacture, process, or use of the substance that results in generation of a vapor, mist, or aerosol.

5. No manufacture of the substance where there is more than 0.1% residual isocyanate by weight.

6. Use of the substance only as a UV curable coating resin.

7. Only import the substance in totes.

8. Manufacture of the substance to have an average molecular weight of greater than 2,000 daltons.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of reproductive/developmental toxicity testing may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions on manufacture, processing, distribution in commerce, and use will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11084.

PMN Number: P–17–15

Chemical name: Heteromonocycle ester with alkanediol (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: June 13, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the PMN substance is a precursor for a photochromatic substance. Based on SAR analysis of test data on analogous esters, EPA has identified concerns for irritation to skin, eye, and mucous membrane, and systemic toxicity. Further, based on SAR analysis of test data on analogous nonionic esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb of the PMN substance in surface waters. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health and the environment. EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation of the uses identified below) would not result in inhalation exposure. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.

2. Use of personal protective equipment including impervious gloves to prevent dermal exposure (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No domestic manufacture of the substance.

5. No use of the substance other than other than for the confidential uses identified in the Order.

6. No release of the substance resulting in surface water concentrations that exceed 3 ppb.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing reproductive/developmental toxicity and acute aquatic toxicity testing.

CFR citation: 40 CFR 721.11085.

PMN Number: P–17–29

Chemical name: Substituted carbomonocycle, polymer with (aminoalkyl)-alkanediamine, (haloalkyl)oxirane, dialkyl-alkanediamine and alkyl-alkanamine, reaction products with dialkanolamine and [[(alkyl)oxy]alkyl]oxirane (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: May 10, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance is an intermediate prepolymer. Based on the physical/chemical properties of the substance and SAR analysis of test data on analogous aliphatic amines, EPA has identified concerns for irritation, lung effects, and aquatic toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.

2. Use of personal protective equipment including impervious gloves to prevent dermal exposure (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No use other than for the confidential uses identified in the Order.

5. No use involving an application method that generates a vapor, mist, or aerosol.

6. No domestic manufacture of the substance.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health and aquatic toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing irritation and acute aquatic toxicity testing. In addition, EPA has determined that the results of a pulmonary effects testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11086.

PMN Numbers: P–17–154, P–17–155, and P–17–156

Chemical names: Carboxylic acid amine (1:1) (generic) (P–17–154), Mix fatty acids compd. with amine (1:1) (generic) (P–17–155), and Mix fatty acids compd. with amine (1:1) (generic) (P–17–156).

CAS number: Not available.

Effective date of TSCA section 5(e) Order: June 15, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substances is as a coating. Based on physical/chemical properties of the substances and SAR analysis of test data on amines, EPA identified concerns for irritation, corrosion, developmental toxicity, reproductive toxicity, neurotoxicity, and thyroid toxicity. Further, based on test data on analogous anionic surfactants and aliphatic amines, EPA identified concern for toxicity to aquatic organisms at surface water concentrations that exceed 240 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health and the environment. EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses for the chemical substance would not result in increased inhalation exposure. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the substances prior to exceeding the confidential production volume limit specified in the Order.

2. Use of personal protective equipment to prevent dermal exposure (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health and environmental precautionary statements on each label and in the SDS.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed to not exceed a confidential production volume without performing reproductive/developmental toxicity testing.

CFR citation: 40 CFR 721.11087 (P–17–154), 40 CFR 721.11088 (P–17–155), 40 CFR 721.11089 (P–17–156).

PMN Number: P–17–218

Chemical name: Bicyclo[2.2.1]heptane-1-methanesulfonic acid, 7,7-dimethyl-2-oxo-, compd. with N,N-diethylethanamine (1:1).

CAS number: 67019–84–5.

Effective date of TSCA section 5(e) Order: May 19, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substance is a processing aid for membrane production. Based on SAR analysis of test data on structurally similar respirable particles, EPA identified concerns for corrosivity, irritation, sensitization, developmental toxicity, specific target organ toxicity, and neurotoxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the substance prior to

exceeding the confidential production volume limit specified in the Order.

2. Use of personal protective equipment including impervious gloves to prevent dermal exposure (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No manufacture, processing, or use involving an application method that generates a vapor, mist, aerosol, or dust.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing a skin sensitization study. In addition, EPA has determined that the results of reproductive/developmental toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, and use will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11090.

PMN Number: P–17–226

Chemical name: Manganese(2+), bisoctahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7)tri-.mu.-oxidi-, hexafluorophosphate(1-) (1:2).

CAS number: 116633–52–4.

Effective date of TSCA section 5(e) Order: June 15, 2017.

Basis for TSCA section 5(e) Order: The PMN states the generic (non-confidential) use of the substance will be as a detergent additive. Based on test data on the substance and analogue test data, EPA has identified concerns for eye irritation, thyroid, blood, and liver toxicity, male reproductive toxicity, neurotoxicity, immunosuppression, respiratory sensitization, and mutagenicity. Based on test data on the substance and test data on analogous neutral organics, EPA identified concern for toxicity to aquatic organisms at surface water concentrations that exceed 240 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment to prevent dermal exposure (where there is a potential for dermal exposure).

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

3. No use other than the confidential use allowed in the Order.

4. No domestic manufacture of the substance.

5. No processing without appropriate engineering controls to prevent inhalation exposure, including dust removal with 99.9% efficiency when loading or unloading the substance in powder form.

6. No release of the substance resulting in surface water concentrations that exceed 240 ppb.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substance. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, and use will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

CFR citation: 40 CFR 721.11091.

PMN Numbers: P–17–228 and P–17–229

Chemical names: 2′-Fluoro-4″-alkyl-4-propyl-1,1′:4′1″-terphenyl (generic) (P–17–228) and 4-ethyl-2′-fluoro-4″-alkyl-1,1′:4′1″-terphenyl (generic) (P–17–229).

CAS numbers: Not available.

Effective date of TSCA section 5(e) Order: May 18, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the generic (non-confidential) use of the substances is a coating for displays. Based on the physical/chemical properties of the substances (as described in the New Chemical Program's PBT category at 64 FR 60194; November 4, 1999; FRL–6097–7) and test data on structurally similar substances, the substances are potentially persistent, bioaccumulative, and toxic (PBT) chemicals. EPA estimates that the substances will persist in the environment more than 2 months and estimates a bioaccumulation factor of greater than or equal to 1,000. Further, based on test data on structurally similar chemicals, EPA has identified concerns for reproductive effects, adrenal and liver toxicity. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substances may present an unreasonable risk of injury to health and the environment. To protect against these risks, the Order requires:

1. Use of personal protective equipment including impervious gloves to prevent dermal exposure (where there is a potential for dermal exposure).

2. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

3. No manufacture beyond the confidential annual production volume limit specified in the Order.

4. No processing or use of the substances in an application method that generates a dust, mist, or aerosol.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the fate and human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of biodegradation and reproductive/developmental toxicity testing of the PMN substances may be potentially useful in characterizing the health effects of the PMN substances. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other

information that EPA determines is relevant and needed to evaluate a modification request.

CFR citations: 40 CFR 721.11092 (P–17–228) and 40 CFR 721.11093 (P–17–229).

PMN Number: P–17–261

Chemical name: Poly(oxy-1,2-ethanediyl),-.alpha.-(2-benzoylbenzoyl)-.omega.-[(2-benzoylbenzoyl)oxy]-.

CAS number: Not available.

Effective date of TSCA section 5(e) Order: June 19, 2017.

Basis for TSCA section 5(e) Order: The PMN states that the substance will be used as a difunctional type II photoinitiator for use in inks and coatings. Based on physical/chemical properties, SAR analysis and test data on analogous esters with branched polyols, EPA has identified concerns for corrosion of the skin, eyes, and mucous membranes, developmental toxicity, systemic toxicity, and blood effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that the substance may present an unreasonable risk of injury to health and the environment. EPA's estimates indicate that variations of the parameters (including batch size, number of processing sites, days per year of operation) of the uses identified for the chemical substance would not result in increased inhalation exposure. To protect against these risks, the Order requires:

1. Submission of certain toxicity testing on the substance prior to exceeding the confidential production volume limit specified in the Order.

2. Use of personal protective equipment including impervious gloves (where there is a potential for dermal exposure).

3. Establishment and use of a hazard communication program, including human health precautionary statements on each label and in the SDS.

4. No domestic manufacture of the substance.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the effects of the PMN substance in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit in the Order without performing irritation testing.

CFR citation: 40 CFR 721.11094.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for all 27 chemical substances regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters.

The SNURs identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- EPA will be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.
- EPA will identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying Orders, consistent with TSCA section 5(f)(4).

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at *http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.*

VI. Direct Final Procedures

EPA is issuing these SNURs as direct final rules. The effective date of these rules is September 17, 2018 without further notice, unless EPA receives written adverse comments before September 17, 2018.

If EPA receives written adverse comments on one or more of these SNURs before September 17, 2018, EPA will withdraw the relevant sections of this direct final rule before its effective date.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse comments must identify the chemical substance and the new use to which it applies. EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) Orders have been issued for all of the chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) Orders from undertaking activities which will be designated as significant new uses. The identities of 13 of the 27 chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11) for a chemical substance covered by this action. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Therefore, EPA designates *August 17, 2018* as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach has been to ensure that a person could not defeat a SNUR by initiating a significant new use before the effective date of the direct final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date will have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons will have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

VIII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require developing any particular new information (*e.g.,* generating test data) before submission of a SNUN. There is an exception: Development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).

In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for all of the listed SNURs. Descriptions of this information are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.'' The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or SourceOECD at *http://www.sourceoecd.org.*

In certain of the TSCA section 5(e) Orders for the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) Orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) Orders required submissions at least 12 weeks) before reaching the specified production limit. The SNURs contain the same production volume limits as the TSCA section 5(e) Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

Any request by EPA for the triggered and pended testing described in the Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

Potentially useful information identified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to generate useful information.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at § 721.1725(b)(1).

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, *i.e.,* the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at *http://www.epa.gov/opptintr/newchems.*

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2017–0414.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This action establishes SNURs for several new chemical substances that were the subject of PMNs and TSCA section 5(e) Orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this action. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUR submitted by any small entity would not cost significantly more than $8,300.

A copy of that certification is available in the docket for this action.

This action is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than $8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This action does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this

action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

XIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: August 3, 2018.

Mark A. Hartman,

Acting Director, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.,* 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.,* 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.,* 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, add the following sections in numerical order under the undesignated center heading ''Significant New Uses of Chemical Substances'' to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Significant New Uses of Chemical Substances	
* * * * *	
721.11068	2070–0012
721.11069	2070–0012
721.11070	2070–0012
721.11071	2070–0012
721.11072	2070–0012
721.11073	2070–0012
721.11074	2070–0012
721.11075	2070–0012
721.11076	2070–0012
721.11077	2070–0012
721.11078	2070–0012
721.11079	2070–0012
721.11080	2070–0012
721.11081	2070–0012
721.11082	2070–0012
721.11083	2070–0012
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721.11085	2070–0012
721.11086	2070–0012
721.11087	2070–0012
721.11088	2070–0012
721.11089	2070–0012
721.11090	2070–0012
721.11091	2070–0012
721.11092	2070–0012
721.11093	2070–0012
721.11094	2070–0012
* * * * *	

* * * * *

PART 721—[AMENDED]

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 4. Add § 721.11068 to subpart E to read as follows:

§ 721.11068 Alkanes, $C_{20–28}$, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, $C_{20–28}$, chloro (PMN P–12–277, CAS No. 2097144–43–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 5. Add § 721.11069 to subpart E to read as follows:

§ 721.11069 Slack waxes (petroleum), chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as slack waxes (petroleum), chloro (PMN P–12–278, CAS No. 2097144–44–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 6. Add § 721.11070 to subpart E to read as follows:

§ 721.11070 Hexacosane, chloro derivs. and octacosane, chloro derivs.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as hexacosane, chloro derivs. and octacosane, chloro derivs. (PMN P–12–280, CAS Nos. 2097144–46–0 and 2097144–47–1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 7. Add § 721.11071 to subpart E to read as follows:

§ 721.11071 Alkanes, $C_{20–24}$, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, $C_{20–24}$, chloro (PMN P–12–281, CAS No. 2097144–45–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 8. Add § 721.11072 to subpart E to read as follows:

§ 721.11072 Alkanes, $C_{14–16}$, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, $C_{14–16}$, chloro (PMNs P–12–282 and P–14–684, CAS No. 1372804–76–6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 9. Add § 721.11073 to subpart E to read as follows:

§ 721.11073 Tetradecane, chloro derivs.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as tetradecane, chloro derivs. (PMNs P–12–283 and P–14–683, CAS No. 198840–65–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 10. Add § 721.11074 to subpart E to read as follows:

§ 721.11074 Octadecane, chloro derivs.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as octadecane, chloro derivs. (PMN P–12–284, CAS No. 2097144–48–2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 11. Add § 721.11075 to subpart E to read as follows:

§ 721.11075 Alkanes, $C_{18–20}$, chloro.

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as alkanes, $C_{18–20}$, chloro (PMN P–12–433, CAS No. 106262–85–3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 12. Add § 721.11076 to subpart E to read as follows:

§ 721.11076 Alkanes, $C_{14–17}$, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, $C_{14–17}$, chloro (PMN P–12–453, CAS No. 85535–85–9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 13. Add § 721.11077 to subpart E to read as follows:

§ 721.11077 Alkanes, $C_{22–30}$, chloro.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, $C_{22–30}$, chloro (PMN P–12–505, CAS No. 288260–42–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (flame retardants and plasticizers in polyvinyl chloride, polymers, and rubber; flame retardant, plasticizer, and lubricant in adhesives, caulk, sealants, and coatings; additive in lubricants including metalworking fluids; and flame retardant and waterproofer in textiles). It is a significant new use to manufacture the chemical substance more than 5 years.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 14. Add § 721.11078 to subpart E to read as follows:

§ 721.11078 Chloroflurocarbon (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as chloroflurocarbon (PMN P–16–150) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (3), and (4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000), (a)(6) (liquid), and (c).

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacturer or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA section 5(e) Order for this substance. The NCEL is 170 ppb as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA section 5(e) Order.

(B) [Reserved]

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1) (fatal if inhaled), (g)(2)(ii), (iv), (use respiratory protection or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 170 ppb), (g)(2)(v), (g)(3)(i), (ii), (g)(4) (release to water restrictions apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(a) through (c), (g), and (q). It is a significant new use to manufacture, process, or use the PMN substance without the engineering controls described in the corresponding TSCA section 5(e) Order to prevent worker and environmental exposures. It is a significant new use to manufacture the chemical substance more than one year.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N = 240.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 15. Add § 721.11079 to subpart E to read as follows:

§ 721.11079 Silane, 1,1′-(1,2-ethanediyl)bis[1,1-dichloro-1-methyl]-, hydrolysis products with chloroethenyldimethylsilane.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as Silane, 1,1′-(1,2-ethanediyl)bis[1,1-dichloro-1-methyl]-, hydrolysis products with chloroethenyldimethylsilane (PMN P–16–379, CAS No. 1485477–78–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (a)(6)(v), (vi), (b)(concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1) (liver toxicity), (mutagenicity), (g)(2)(i), (ii), (iii), (v), (g)(4)(i), (do not incinerate), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), (q), (y)(1) and (2).

(iv) *Disposal.* Requirements as specified in § 721.85(a) (water), (a)(2), (b) (water), (b)(2), (c) (water), and (c)(2).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (j) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 16. Add § 721.11080 to subpart E to read as follows:

§ 721.11080 Silicophosphonate—sodium silicate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as silicophosphonate—sodium silicate (PMN P–16–410) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (k). A significant new use is any use in formulations containing greater than 0.2% of the chemical substance.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

■ 17. Add § 721.11081 to subpart E to read as follows:

§ 721.11081 3-Butenenitrile, 2-(acetyloxy).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 3-butenenitrile, 2-(acetyloxy) (PMN P–16–438, CAS No. 15667–63–7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (a)(3), (a)(4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5)(respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1000), (a)(6)(particulate), (a)(6)(v), (vi), (b)(concentration set at 1.0%), and (c). It is a significant new use to manufacture, process or use the substance without following the monitoring procedure as specified in the worker protection section of the corresponding TSCA section 5(e) Order.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1) (fatal if swallowed), (fatal if in contact with skin), (toxic if inhaled), (g)(2)(i), (ii), (iii), (iv), (v), (g)(3)(i), (ii), (g)(4)(i), (ii), (iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g). It is a significant new use to manufacture or use the substance other than in an enclosed system as described in the PMN.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 18. Add § 721.11082 to subpart E to read as follows:

§ 721.11082 Halogenophosphoric acid metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as halogenophosphoric acid metal salt (PMN P–16–543) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(the confidential dermal protection described in the corresponding TSCA section 5(e) Order ''the Order''), (a)(2)(ii), (iii), (iv), (a)(3), (a)(4), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) and (4), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(5) (respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor of at least 1,000), (a)(6) (particulate), (a)(6)(v), (vi), (b)(concentration set at 0.1%), and (c). It is a significant new use to manufacture, process or use the substance without following the monitoring procedure as specified in the worker protection section of the Order.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1)(i), (ii), (iii), (iv), (v), (vii), (viii), (ix), (g)(2)(i), (ii), (iii), (use protective engineering controls or equipment for dermal and inhalation protection, (g)(3)(i), (ii), (g)(4)(i), (ii), (water release restrictions apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(c), (f), and (k). It is a significant new use to vary or alter, the manufacturing, processing, and use, distribution/transportation, treatment and disposal processes, process equipment, engineering controls, and handling practices (including worker activities and cleaning procedures) described in the PMN in such a way as to increase the magnitude of inhalation exposure.

(iv) *Disposal.* Requirements as specified in § 721.85. It is a significant new use to dispose of the substance other than by hazardous waste incineration according to 40 CFR parts 260 through 299 unless the substance is in waste water. When the substance is in wastewater it may be disposed of as required in paragraph (a)(2)(v) of this section.

(v) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=3.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraphs (a)(2)(i) and (iii) of this section.

■ 19. Add § 721.11083 to subpart E to read as follows:

§ 721.11083 Alkenoic acid, reaction products with polyethylene glycol ether with hydroxyalkyl substituted alkane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, reaction products with polyethylene glycol ether with hydroxyalkyl substituted alkane (PMN P–16–596) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b) (concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72 (a) through (e)(concentration set at 0.1%), (f), (g)(1)(i), (dermal sensitization), (g)(1)(iv), (cancer, if inhaled), (g)(1)(ix), (g)(2)(i), (ii), (iii), (v), (g)(4)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (q).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 20. Add § 721.11084 to subpart E to read as follows:

§ 721.11084 Alkyl substituted alkenoic acid, alkyl ester, polymer with alkyl substituted alkenoate and alkenoic acid, hydroxy substituted[(oxoalkyl)oxy]alkyl ester, reaction products with alkanoic acid, dipentaerythritil and isocyanate substituted carbomonocycle, compds. with alkylamine (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl substituted alkenoic acid, alkyl ester, polymer with alkyl substituted alkenoate and alkenoic acid, hydroxy substituted[(oxoalkyl)oxy]alkyl ester, reaction products with alkanoic acid, dipentaerythritil and isocyanate substituted carbomonocycle, compds. with alkylamine (PMN P–17–10) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6)(particulate), (a)(6)(v), (vi), (b) (concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1)(i), (sensitization), (g)(1)(vii), (systemic effects), (g)(1)(ix), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k) (ultraviolet curable coating resin), and (y)(1). It is a significant new use to manufacture the chemical substance with an average molecular weight below 2,000 daltons or containing greater than 0.1% residual isocyanate. It is a significant new use to import the substance other than in totes.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 21. Add § 721.11085 to subpart E to read as follows:

§ 721.11085 Heteromonocycle ester with alkanediol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteromonocycle ester with alkanediol (PMN P–17–15) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4) (release to water restrictions apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), and (q).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=3.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 22. Add § 721.11086 to subpart E to read as follows:

§ 721.11086 Substituted carbomonocycle, polymer with (aminoalkyl)-alkanediamine, (haloalkyl)oxirane, dialkyl-alkanediamine and alkyl-alkanamine, reaction products with dialkanolamine and [[(alkyl)oxy]alkyl]oxirane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted carbomonocycle, polymer with (aminoalkyl)-alkanediamine, (haloalkyl)oxirane, dialkyl-alkanediamine and alkyl-alkanamine, reaction products with dialkanolamine and [[(alkyl)oxy]alkyl]oxirane (PMN P–17–29) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (eye irritation), (g)(1)(ii), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4)(iii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (k), (q), and (y)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 23. Add § 721.11087 to subpart E to read as follows:

§ 721.11087 Carboxylic acid amine (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carboxylic acid amine (1:1) (PMN P–17–154) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6) (particulate), (a)(6)(v), (vi), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), (thyroid effects), (g)(1)(vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 24. Add § 721.11088 to subpart E to read as follows:

§ 721.11088 Mix fatty acids compd with amine (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as mix fatty acids compd with amine (1:1) (PMN P–17–155) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the PMN substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6) (particulate), (a)(6)(v), (vi), (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), (thyroid effects), (g)(1)(vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 25. Add § 721.11089 to subpart E to read as follows:

§ 721.11089 Mix fatty acids compd with amine (1:1) (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as mix fatty acids compd with amine (1:1) (PMN P–17–156) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6) (particulate), (a)(6)(v), (vi), (b) (concentration set a 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(i), (ii), (iii), (thyroid effects), (g)(1)(vi), (ix), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 26. Add § 721.11090 to subpart E to read as follows:

§ 721.11090 Bicyclo[2.2.1]heptane-1-methanesulfonic acid, 7,7-dimethyl-2-oxo-, compd. with N,N-diethylethanamine (1:1).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as bicyclo[2.2.1]heptane-1-methanesulfonic acid, 7,7-dimethyl-2-oxo-, compd. with N,N-diethylethanamine (1:1) (PMN P–17–218. CAS No. 67019–84–5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6) (particulate), (a)(6)(v), (vi), (b) (concentration set 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1)(i), (corrosivity), (sensitization), (g)(1)(iii), (iv), (ix), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q), (y)(1) and (2).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions

of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 27. Add § 721.11091 to subpart E to read as follows:

§ 721.11091 Manganese (2+), bisoctahydro-1,4,7-trimethyl-1H–1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7) tri-.mu.-oxidi-, hexafluorophosphate(1-) (1:2).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as manganese (2+), bisoctahydro-1,4,7-trimethyl-1H–1,4,7-triazonine-.kappa.N1,.kappa.N4,.kappa.N7) tri-.mu.-oxidi-, hexafluorophosphate(1-) (1:2) (1:1) (PMN P–17–226, CAS No. 116633–52–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (ii), (iii), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (a)(6) (particulate), (b) (concentration set at 0.1%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 0.1%), (f), (g)(1) (eye irritation), (respiratory sensitization), (g)(1)(iii), (iv), (vi), (vii), (viii), (g)(2)(i), (ii), (iii), (v), (g)(3)(i), (ii), (g)(4) (release to water provisions apply), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (k). It is a significant new use to process or use the substance without engineering controls to prevent exposure, including dust removal with 99.9% efficiency when loading or unloading the substance in powder form.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4) where N=240.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 28. Add § 721.11092 subpart E to read as follows:

§ 721.11092 2′-Fluoro-4″-alkyl-4-propyl-1,1′:4′1″-terphenyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 2′-fluoro-4″-alkyl-4-propyl-1,1′:4′1″-terphenyl (PMN P–17–228) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e)(concentration set at 1.0%), (f), (g)(1)(vi), (adrenal effects), (liver effects), (g)(2)(i), (ii), (iii), (v), and (g)(5). Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(t) and (y)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 29. Add § 721.11093 to subpart E to read as follows:

§ 721.11093 4-ethyl-2′-fluoro-4″-alkyl-1,1′:4′,1″-terphenyl (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 4-ethyl-2′-fluoro-4″-alkyl-1,1′:4′,1″-terphenyl (PMN P–17–229) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b) (concentration set 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set 1.0%), (f), (g)(1)(vi), (adrenal effects), (liver effects), (g)(2)(i), (ii), (iii), (v), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(t) and (y)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

■ 30. Add § 721.11094 to subpart E to read as follows:

§ 721.11094 Poly(oxy-1,2-ethanediyl),alpha-(2-benzoyl)-omega-[(2-benzoylbenzoyl)oxy]-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,2-ethanediyl),alpha-(2-benzoyl)-omega-[(2-benzoylbenzoyl)oxy]- (PMN P–17–261) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not

apply to quantities of the substance after they have been reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures (*e.g.,* enclosure or confinement of the operation, general and local ventilation) or administrative control measures (*e.g.,* workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible, (b) (concentration set at 1.0%), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (e) (concentration set at 1.0%), (f), (g)(1) (irritation), (photosensitization), (g)(2)(i), (ii), (iii), (v), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (q).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(iii) of this section.

[FR Doc. 2018–17348 Filed 8–16–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2018–0272; FRL–9981–09–Region 9]

Air Plan Approval; California; San Joaquin Valley Unified Air Pollution Control District; Reasonably Available Control Technology Demonstration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD or ''District'') portion of the California State Implementation Plan (SIP). These revisions concern the District's 2014 demonstration regarding Reasonably Available Control Technology (RACT) requirements for the 2008 8-hour ozone National Ambient Air Quality Standard (NAAQS). We are also taking final action to approve into the California SIP the following documents that help support the District's RACT demonstration: SJVUAPCD's supplement to its 2014 RACT SIP demonstration, which contains SJVUAPCD's negative declarations where the District concludes it has no sources subject to certain Control Techniques Guidelines (CTG) documents and relevant permit conditions to implement RACT level requirements for J.R. Simplot's Nitric Acid plant in Helm, California (CA); and SJVUAPCD's 2016 Ozone Plan for the 2008 8-Hour Ozone Standard—Chapter 3.4 and Appendix C only. We are approving local SIP revisions to demonstrate that RACT is implemented as required under the Clean Air Act (CAA or the ''the Act'').

DATES: This rule will be effective on September 17, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2018–0272. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, EPA Region IX, (415) 947–4122, *tong.stanley@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

On May 17, 2018 (83 FR 22908), the EPA proposed to approve SJVUACPD's ''2014 Reasonably Available Control Technology (RACT) Demonstration for the 8-Hour Ozone State Implementation Plan (SIP)'' (*2014 RACT SIP*), submitted to the EPA by the California Air Resources Board (CARB) on July 18, 2014,[1] for approval as a revision to the California SIP.

In addition to the *2014 RACT SIP,* our May 17, 2018 proposed rule was also based on our evaluation of the public draft version of SJVUAPCD's ''Supplement to the 2014 Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) for the 2008 8-hour Ozone Standard'' (*Supplement to the 2014 RACT SIP*) that was transmitted by CARB on May 4, 2018, along with a request for parallel processing.[2] The District's *Supplement to the 2014 RACT SIP* contained relevant RACT permit conditions in a permit to operate for J.R. Simplot's Nitric Acid plant in Helm, CA, and negative declarations where the District concluded it had no sources subject to the following CTG source categories: Surface coating of insulation of magnetic wire; manufacture of synthesized pharmaceutical products; manufacture of pneumatic rubber tires; leaks from synthetic organic chemical polymer and resin manufacturing equipment; volatile organic compound (VOC) emissions from manufacture of high-density polyethylene, polypropylene and polyester resins; VOC emissions from air oxidation processes in synthetic organic chemical manufacturing industry (SOCMI); VOC emissions from reactor processes and distillation operations in SOCMI; and surface coating operations at shipbuilding and ship repair facilities.[3] We indicated that we would not take final action on the *Supplement to the 2014 RACT SIP* until CARB submitted the final adopted version to the EPA as a SIP revision. On June 21, 2018, the SJVUAPCD held a public hearing and adopted the *Supplement to the 2014 RACT SIP.*[4] On June 29, 2018, CARB

[1] The SJVUAPCD adopted its *2014 RACT SIP* on June 19, 2014.

[2] CARB's May 4, 2018 transmittal letter contained a public draft version of the *Supplement to the 2014 RACT SIP* along with a request that the EPA provide parallel processing of the documents concurrently with the state's public process. See footnote 1 in our May 17, 2018 proposed rule.

[3] *See Supplement to the 2014 RACT SIP,* Appendix B.

[4] On June 21, 2018, the SJVUAPCD Governing Board adopted ''Revision to the State Implementation Plan (SIP) to Address Federal Clean Air Act Requirements for Reasonably Available Control Technology (RACT)''. Appendix A: ''J.R. Simplot Permit Conditions'' and Appendix B: ''Negative Declarations'', as contained in the adopted document, are substantially similar to the versions contained in the District's parallel processing request which the EPA proposed to

submitted the *Supplement to the 2014 RACT SIP* to the EPA for approval as a revision to the California SIP.[5] The final adopted version of the *Supplement to the 2014 RACT SIP* includes non-substantive changes from the public draft version that was the basis for our May 17, 2018 proposed rule. These changes include streamlining J.R. Simplot's introductory section listing the plant's major equipment to just state ''Nitric Acid Plant''; restoring a permit condition that EPA Reference Method 7 will be used to determine compliance with oxides of nitrogen (NO_X) limits; and removing reference citations to a local rule and federal regulations that were inadvertently left in the permit. The NO_X emission limits remain unchanged from the version of the permit included in our May 17, 2018 proposed rule. In addition, when comparing the public draft version included in our May 17, 2018 proposed rule and the final version adopted by the District on June 21, 2018, we noted minor editorial changes in the text preceding the list of negative declarations. The primary substance of the District's negative declarations, that is, recertification of three prior negative declarations, and the adoption of five new negative declarations, remain unchanged. We therefore consider these editorial changes to also be non-substantive. On July 11, 2018, we found the *Supplement to the 2014 RACT SIP,* including the relevant operating permit conditions to implement NO_X RACT for J.R. Simplot's Nitric Acid Plant in Helm, CA, and several negative declarations, met the completeness criteria in 40 CFR part 51, appendix V.

We are also approving portions of SJVUAPCD's ''2016 Ozone Plan for the 2008 8-Hour Ozone Standard'' (*2016 Ozone Plan*), which help to supplement the District's *2014 RACT SIP.* The plan was adopted by the District on June 16, 2016, and submitted by CARB to the EPA on August 24, 2016, as a revision to the California SIP. Specifically, as discussed in our May 17, 2018 proposed rule, Chapter 3.4 of the *2016 Ozone Plan* states that ''the District updated the RACT evaluation and included VOC sources in the evaluation in Appendix C.'' Appendix C of the *2016 Ozone Plan,* which is titled, ''Stationary and Area Source Control Strategy Evaluations,'' includes evaluations of individual rules for RACT. We are only approving Chapter 3.4 and Appendix C of the *2016 Ozone Plan* in order to demonstrate VOC RACT for all applicable sources for the 2008 NAAQS.

As discussed in our proposed rule, the District's *2014 RACT SIP* contains its analysis of NO_X RACT for the 2008 NAAQS. For more background information and a more extensive discussion of the *2014 RACT SIP,* the *Supplement to the 2014 RACT SIP,* Chapter 3.4 and Appendix C of the *2016 Ozone Plan,* and our evaluation of them for compliance with CAA RACT requirements, please see our proposed rule and related technical support document.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received one anonymous comment that was outside the scope of this rulemaking. The comment was not germane to our evaluation of the submitted SJVUAPCD documents to demonstrate that the District's stationary sources are subject to RACT requirements.

III. EPA Action

No comments were submitted that change our assessment of the submitted documents as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving the following documents into the California SIP: SJVUAPCD's *2014 RACT SIP*; the *Supplement to the 2014 RACT SIP* including relevant permit conditions for J.R. Simplot's Nitric Acid Plant in Helm, CA and negative declarations for the CTG source categories: Surface coating of insulation of magnetic wire; manufacture of synthesized pharmaceutical products; manufacture of pneumatic rubber tires; leaks from synthetic organic chemical polymer and resin manufacturing equipment; VOC emissions from manufacture of high-density polyethylene, polypropylene and polyester resins; VOC emissions from air oxidation processes in SOCMI; VOC emissions from reactor processes and distillation operations in SOCMI; and surface coating operations at shipbuilding and ship repair facilities; and the *2016 Ozone Plan*—only Chapter 3.4 and Appendix C.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of certain permit conditions for the J.R. Simplot Nitric Acid Plan in Helm, CA and described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

approve on May 17, 2018. We will reference the District's June 21, 2018 adopted document as ''*Supplement to the 2014 RACT SIP*'' to maintain consistency with how this action was referenced in our May 17, 2018 proposed rulemaking.

[5] As explained in our May 17, 2018 proposed rulemaking, the EPA is following its regulatory procedures for parallel processing. See 40 CFR part 51, appendix V. These procedures allow the EPA to approve a state's submittal, following parallel state and federal comment periods, provided the final provision adopted at the state level has no significant changes from the proposal.

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 16, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 12, 2018.

Michael Stoker,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(449)(ii)(D), (c)(496)(ii)(B), and (c)(507) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(449) * * *

(ii) * * *

(D) San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD).

(*1*) SJVUAPCD ''2014 Reasonably Available Control Technology (RACT) Demonstration for the 8-Hour Ozone State Implementation Plan (SIP),'' dated June 19, 2014, as adopted by the SJVUAPCD on June 19, 2014.

* * * * *

(496) * * *

(ii) * * *

(B) San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD).

(*1*) SJVUAPCD ''2016 Ozone Plan for 2008 8-Hour Ozone Standard,'' dated June 16, 2016, Chapter 3.4 and Appendix C only, as adopted by the SJVUAPCD on June 16, 2016.

* * * * *

(507) New regulations for the following APCD were submitted on June 29, 2018 by the Governor's designee.

(i) *Incorporation by reference.* (A) San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD).

(*1*) Permit #C–705–3–19, J.R. Simplot Company, Nitric Acid Plant, Helm, CA, adopted by the SJVUAPCD, Resolution No.18–06–14, June 21, 2018.

(ii) *Additional materials.* (A) San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD).

(*1*) SJVUAPCD ''Appendix B Negative Declarations For Proposed Revision to the State Implementation Plan (SIP) to Address Federal Clean Air Act Requirements for Reasonably Available Control Technology (RACT) June 21, 2018,'' containing negative declarations, as adopted by the SJVUAPCD on June 21, 2018.

■ 3. Section 52.222 is amended by adding paragraph (a)(8)(iii) to read as follows:

§ 52.222 Negative declarations.

(a) * * *

(8) * * *

(iii) The following negative declarations for the 2008 NAAQS were adopted by the San Joaquin Valley Unified Air Pollution Control District on June 21, 2018, and submitted to the EPA on June 29, 2018.

NEGATIVE DECLARATIONS FOR THE 2008 OZONE NAAQS

CTG document No.	Title
EPA–450/2–77–033	Control of Volatile Organic Emissions from Existing Stationary Sources—Volume IV: Surface Coating of Insulation of Magnet Wire.
EPA–450/2–78–029	Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products.
EPA–450/2–78–030	Control of Volatile Organic Emissions from Manufacture of Pneumatic Rubber Tires.
EPA–450/3–83–006	Control of Volatile Organic Compound Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.
EPA–450/3–83–008	Control of Volatile Organic Compound Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.
EPA–450/3–84–015	Control of Volatile Organic Compound Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.
EPA–450/4–91–031	Control of Volatile Organic Compound Emissions from Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.

NEGATIVE DECLARATIONS FOR THE 2008 OZONE NAAQS—Continued

CTG document No.	Title
EPA–453/R–94–032	Alternative Control Technology Document—Surface Coating Operations at Shipbuilding and Ship Repair Facilities
61 FR 44050 8/27/96	Control Techniques Guidelines for Shipbuilding and Ship Repair Operations (Surface Coating).

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[FR Doc. 2018–17714 Filed 8–16–18; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 6101 and 6102

[CBCA Case 2018–61–1; Docket No. 2018–0006; Sequence No. 1]

RIN 3090–AK02

Civilian Board of Contract Appeals; Rules of Procedure for Contract Disputes Act Cases

AGENCY: Civilian Board of Contract Appeals; General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The Civilian Board of Contract Appeals (Board) amends its rules of procedure for cases arising under the Contract Disputes Act, and for disputes between insurance companies and the Department of Agriculture's Risk Management Agency in which decisions of the Federal Crop Insurance Corporation are brought before the Board under the Federal Crop Insurance Act. The Board's current rules were issued in 2008 and were last amended in 2011. After considering the one responsive comment received, the Board now promulgates its final rules of procedure.

DATES: September 17, 2018.

FOR FURTHER INFORMATION CONTACT: Mr. J. Gregory Parks, Chief Counsel, Civilian Board of Contract Appeals, 1800 M Street NW, Suite 600, Washington, DC 20036; at 202–606–8787; or email at *greg.parks@cbca.gov,* for clarification of content. For information pertaining to the status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite BCA Case 2018–61–1.

SUPPLEMENTARY INFORMATION:

A. Background

The Board was established within GSA by section 847 of the National Defense Authorization Act for Fiscal Year 2006, Public Law 109–163. Board members are administrative judges appointed by the Administrator of General Services under 41 U.S.C. 7105(b)(2). Among its other functions, the Board hears and decides contract disputes between Government contractors and most civilian Executive agencies under the Contract Disputes Act, 41 U.S.C. 7101–7109, and its implementing regulations, and disputes pursuant to the Federal Crop Insurance Act, 7 U.S.C. 1501 *et seq.,* between insurance companies and the Department of Agriculture's Risk Management Agency (RMA) involving actions of the Federal Crop Insurance Corporation (FCIC).

The Board's rules of procedure for Contract Disputes Act cases and Federal Crop Insurance Act cases were adopted in May 2008 (73 FR 26947) and were last amended in August 2011 (76 FR 50926). The Board published in the **Federal Register** at 83 FR 13211, March 28, 2018, proposed, amended rules of procedure along with a notice inviting comments on those rules. This notice announced the intention to promulgate final rules, following the Board's review and consideration of all comments.

The period for comments closed on May 29, 2018. The Board has considered all comments received, revising the proposed rules, in part, as explained in part B below, and now promulgates its final rules of procedure. These rules simplify and modernize access to the Board by establishing a preference for electronic filing, increase conformity between the Board's rules and the Federal Rules of Civil Procedure, streamline the wording of the Board's rules, and clarify current rules and practices. In addition, the time for filing is amended from 4:30 p.m. to midnight Eastern Time, and the stated monetary limitations for electing the accelerated and small claims procedures are deleted and replaced with references to the requirements stated in the Contract Disputes Act.

B. Comments and Changes

The Board received comments from two commenters. Commenters included one attorney from a Federal agency and one anonymous source. Comments from the anonymous source concerned matters wholly unrelated to the proposed rule, and the concerns noted by the attorney were already addressed in the proposed rule. The Board carefully considered the comments but has not revised its proposed rule based on issues the commenters raised. The final rule incorporates minor, non-substantive corrections to the proposed rule. The corrections are addressed below.

Part 6101

Sections 6101.1, 6101.3, 6101.4, 6101.12, and 6101.23 are amended to correct spelling, grammatical, or spacing errors; include a cross-reference; and clarify a phrase.

C. Regulatory Flexibility Act

GSA certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 602 *et seq.,* and the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, because the final rule does not impose any additional costs on small or large businesses.

D. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* does not apply because this final rule does not impose any information collection requirements that require the approval of the Office of Management and Budget.

E. Congressional Review Act

The final rule is exempt from Congressional review under Public Law 104–121 because it relates solely to agency organization, procedure, and practice and does not substantially affect the rights or obligations of non-agency parties.

F. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of

harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993, or E.O. 13563, Improving Regulation and Regulatory Review, dated January 18, 2011. This final rule is not a major rule under 5 U.S.C. 804.

G. Executive Order 13771

This final rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

List of Subjects in 48 CFR Parts 6101 and 6102

Administrative practice and procedure; Government procurement; Agriculture.

Dated: August 6, 2018.

Jeri Kaylene Somers,

Chair, Civilian Board of Contract Appeals, General Services Administration.

Therefore, GSA revises 48 CFR parts 6101 and 6102 to read as follows:

PART 6101—RULES OF PROCEDURE OF THE CIVILIAN BOARD OF CONTRACT APPEALS

Sec.

Authority: 41 U.S.C. 7101–7109.

6101.1 General information; definitions [Rule 1].

(a) *Scope.* The rules of this chapter govern cases filed with the Board on or after September 17, 2018, and all further proceedings in cases then pending, unless the Board decides that using the rules in this part in a case pending on their effective date would be inequitable or infeasible. The Board may alter these procedures on its own initiative or on request of a party to promote the just, informal, expeditious, and inexpensive resolution of a case.

(b) *Definitions.*

Appeal; appellant. ''Appeal'' means a contract dispute filed with the Board under the Contract Disputes Act (CDA), 41 U.S.C. 7101–7109, or under a disputes clause in a non-CDA contract that allows for Board review. An ''appellant'' is the contractor filing an appeal.

Appeal file. ''Appeal file'' means the submissions to the Board under Rule 4 (48 CFR 6101.4).

Application; applicant. ''Application'' means a submission to the Board under Rule 30 (48 CFR 6101.30) of a request for an award of fees and other expenses under the Equal Access to Justice Act (EAJA), 5 U.S.C. 504, or another provision authorizing such an award. An ''applicant'' is a party filing an application.

Attorney. ''Attorney'' means a person licensed to practice law in a State, commonwealth, or territory of the United States or in the District of Columbia.

Board judge; judge. ''Board judge'' or ''judge'' means a member of the Board.

Business days and hours. The Board's business days are days other than Saturdays, Sundays, Federal holidays, days on which the Board is required to close before 4:30 p.m., or days on which the Board does not open for any reason, such as inclement weather. The Board's business hours are 8 a.m. to 4:30 p.m. Eastern Time.

Case. ''Case'' means an appeal, petition, or application.

Clerk of the Board. The ''Clerk'' of the Board receives filings, dockets cases, and prepares official correspondence for the Board.

Efile; efiling. The Clerk accepts electronic filings (''efilings''), meaning documents submitted through the Board's email system (''efiled''). Parties may efile documents by sending an email (usually with attachments) to *cbca.efile@cbca.gov,* except for documents that are classified or submitted *in camera* or under protective order (Rule 9). Efiling occurs upon receipt by the Board's email server, except that attachments must be in .pdf format and 18 megabytes (MB) or smaller or they will be rejected.

Electronically stored information. ''Electronically stored information'' means information created, manipulated, communicated, stored, and best used in digital form with computer hardware and software.

Equal Access to Justice Act (EAJA), 5 U.S.C. 504. This statute governs applications for awards of fees and other expenses in certain cases.

Facsimile (fax) transmissions. The Board sends and accepts facsimile transmissions. A document is filed by fax at the time the Board receives all of it. The Board does not automatically extend filing deadlines if its fax machine is busy or otherwise unavailable.

Filing. A notice of appeal or application is filed upon the earlier of its receipt by the Clerk or, if mailed through the United States Postal Service (USPS), the date it is mailed to the Board. A USPS postmark is prima facie evidence of a mailing date. Any other document is filed upon receipt by the Clerk.

Party. ''Party'' means an appellant, applicant, petitioner, or respondent.

Petition; petitioner. ''Petition'' means a request that the Board direct a contracting officer to issue a written decision on a claim. A ''petitioner'' is a party submitting a petition.

Receipt. The Board deems a party's ''receipt'' of a document to occur upon the earlier of the emailing of the document to the party's email address of record (without notice of delivery failure) or the party's possession of a document sent by other means.

Respondent. A ''respondent'' is the government agency whose decision,

action, or inaction is the subject of an appeal, petition, or application.

(c) *Construction.* The Board construes this part to promote the just, informal, expeditious, and inexpensive resolution of every case. The Board may apply principles of the Federal Rules of Civil Procedure (28 U.S.C. App.) to resolve issues not covered by this part.

(d) *Panels.* The Board assigns each case to a panel of three judges, one of whom presides. The presiding judge sets the case schedule, oversees discovery, and conducts conferences, hearings, and other proceedings. The presiding judge may without participation by other panel members decide any appeal under the small claims procedure of Rule 52, any nondispositive motion, or any petition, and may dismiss a case as permitted by Rule 12(c) (48 CFR 6101.12(c)). The Board decides all other matters by majority vote of a panel unless the full Board decides a matter under Rule 28 (48 CFR 6101.28). Only panel and full Board decisions are precedential.

(e) *Location and addresses.* The Board is physically located at 1800 M Street NW, 6th Floor, Washington, DC 20036. The mailing address is 1800 F Street NW, Washington, DC 20405. The Clerk's telephone number is (202) 606–8800. The Clerk's fax number is (202) 606–0019. The Clerk's email address for efiling is *cbca.efile@cbca.gov.* The Board's website is *http://www.cbca.gov.*

(f) *Clerk's office hours.* The Clerk's office is open to the public and for physical deliveries during business hours (Rule 1(b) (48 CFR 6101.1(b)). Efilings received after midnight are considered filed the next business day. The Clerk's office is closed when the Board's physical address is closed for any reason, including any closure of the Federal Government in the Washington, DC, metropolitan area.

6101.2 Filing appeals, petitions, and applications; consolidation [Rule 2].

(a) *Filing an appeal.* A notice of appeal shall be in writing; signed by the appellant, the appellant's attorney, or an authorized representative (see Rule 5 (48 CFR 6101.5)); and filed with the Board, with a copy to the contracting officer who received or issued the claim, or the successor contracting officer. A notice of appeal should include:

(1) The name, telephone number, and mailing and email addresses of the appellant and/or its attorney or authorized representative;

(2) The contract number;

(3) The name of the contracting officer who received or issued the claim, with that person's telephone number, mailing address, and email address;

(4) A copy of the claim with any certification; and

(5) A copy of the contracting officer's decision on the claim or a statement that the appeal is from a failure to issue a decision (''a deemed denial'').

(b) *Filing a petition.* A petition shall be in writing; signed by the petitioner, the petitioner's attorney, or an authorized representative (see Rule 5 (48 CFR 6101.5)); and filed with the Board, with a copy to the contracting officer who received the claim, or the successor contracting officer. A petition shall ask the Board to order the contracting officer to issue a decision and should include:

(1) The name, telephone number, and mailing and email addresses of the petitioner and/or its attorney or authorized representative;

(2) The contract number;

(3) The name of the contracting officer who received the claim, with that person's telephone number, mailing address, and email address; and

(4) A copy of the claim with any certification.

(c) *Filing an EAJA application.* See Rule 30 (48 CFR 6101.30).

(d) *Time limits.* (1) Under the CDA, a notice of appeal must be filed within 90 calendar days after the date of receipt of a contracting officer's decision on a claim.

(2) Alternatively, under the CDA, a contractor may appeal when a contracting officer has not issued a decision on a claim within the time allowed by the CDA or the time set by a tribunal acting on a petition.

(3) Under the CDA, a petition may be filed in the period between—

(i) Receipt of notice from a contracting officer, within 60 days after the submission of a claim, that the contracting officer intends to issue a decision on the claim more than 60 days after its submission, and

(ii) The due date stated by the contracting officer.

(4) Under EAJA, an application must be filed within 30 days after the date that the decision in the underlying appeal becomes no longer subject to appeal.

(e) *Notice of docketing.* Upon receipt of a notice of appeal, a petition, or an application, the Clerk issues a written notice of docketing to all parties.

(f) *Consolidation.* The Board may consolidate cases wholly or in part if they involve common questions of law or fact.

6101.3 Computing and extending time [Rule 3].

(a) *Computing time.* Consistent with Rule 6 of the Federal Rules of Civil Procedure: In computing any time period, omit the day of the event from which the period begins to run. Omit nonbusiness days only if the period is less than 11 days; otherwise include them. A period ends on a business day. If a computed period would otherwise end on a nonbusiness day, it ends on the next business day.

(b) *Extensions.* Parties should act sooner than required whenever practicable. However, the Board extends time when appropriate. A motion for an extension shall be in writing and shall state the other party's position on the motion or describe the movant's effort to learn the other party's position. The Board cannot extend statutory deadlines.

6101.4 Appeal file [Rule 4].

(a) *Filing.* Within 30 days after receiving the Board's docketing notice, the respondent shall file and serve all documents relevant to the appeal, including:

(1) The contracting officer's decision on the claim;

(2) The contract, including all pertinent specifications, amendments, plans, drawings, and incorporated proposals or parts thereof;

(3) All correspondence between the parties relevant to the appeal;

(4) The claim with any certification;

(5) Relevant affidavits, witness statements, or transcripts of testimony taken before the appeal;

(6) All documents relied on by the contracting officer to decide the claim; and

(7) Relevant internal memoranda, reports, and notes.

(b) *Organization of electronic appeal file.* (1) Unless otherwise ordered, parties shall file the appeal file and supplements thereto in an electronic storage medium (*e.g.,* hard disk or solid state drive, compact disc (CD), or digital versatile disc (DVD)), labeled with the docket number, case name, and range of exhibit numbers.

(2) A party may efile an appeal file or a supplement thereto by permission of the Board.

(3) Appeal file exhibits shall be in .pdf format or will be rejected. The appeal file index and each exhibit shall be separate documents, without embedded documents.

(4) Appeal file exhibits shall be complete, legible, arranged in chronological order, numbered, and indexed. Parties shall avoid filing duplicative exhibits and shall number exhibits continuously and consecutively from one filing to the next, so that a complete appeal file consists of one set of consecutively numbered exhibits.

(5) Parties shall number the pages of each exhibit consecutively, unless an exhibit is already paginated in another logical manner.

(6) The appeal file index shall describe each exhibit by date and content.

(7) Parties may file documents *in camera* only by permission of the Board.

(c) *Organization of paper appeal file.* (1) Appeal files and supplements thereto may be filed on paper only by permission of the Board.

(2) Appeal file exhibits shall be complete, legible, arranged in chronological order, tabbed, and indexed. Parties shall avoid filing duplicative exhibits and shall number exhibits continuously and consecutively from one filing to the next, so a complete appeal file consists of one set of consecutively tabbed exhibits.

(3) Parties shall number the pages of each paper exhibit consecutively, unless an exhibit is already paginated in another logical manner.

(4) Parties shall file exhibits in 3-ring binders with spines no wider than 3 inches, labeled on the cover and spine with the name of the appeal, CBCA number, and tab numbers in each binder. Include in each binder the index of the entire filing.

(5) The appeal file index shall describe each exhibit by date and content.

(6) Parties shall separately file and index documents submitted *in camera* or under a protective order. However, documents may be submitted *in camera* only by permission of the Board.

(d) *Supplements.* Within 30 days after the respondent files the appeal file, the appellant may file non-duplicative documents relevant to the claim, organized as instructed in Rule 4(b) or (c) (paragraph (b) or (c) of this section), starting with the next available exhibit number.

(e) *Classified or protected material.* Neither classified nor protected material may be efiled.

(f) *Submission by order.* The Board may order a party to supplement the appeal file, including by filing an exhibit in another format.

(g) *Status of exhibits.* The Board considers appeal file exhibits part of the record for decision under Rule 9(a) unless a party objects to an exhibit within the time set by the Board and the Board sustains the objection.

(h) *Other procedures.* The Board may postpone or waive the filing of an appeal file.

6101.5 Appearing; notice of appearance [Rule 5].

(a) *Appearing before the Board*—(1) *Appellant; petitioner; applicant.* An appellant, petitioner, or applicant may appear before the Board through an attorney. An individual appellant, petitioner, or applicant may appear for himself or herself. A corporation, trust, or association may appear by one of its officers. A limited liability corporation, partnership, or joint venture may appear by one of its members. Each individual appearing on behalf of an appellant, petitioner, or applicant must have legal authority to appear.

(2) *Respondent.* A respondent may appear before the Board through an attorney or, if allowed by the agency, by the contracting officer or the contracting officer's authorized representative.

(3) *Others.* The Board may permit a special or limited appearance of or for a nonparty, such as an *amicus curiae.*

(b) *Notice of appearance.* The Board deems the person who signed a notice of appeal, petition, or application to have appeared for the appellant, petitioner, or applicant. The Board deems the head of the respondent's litigation office to have appeared for the respondent unless otherwise notified. Other participating attorneys shall file notices of appearance including all of the information required by the sample notice of appearance posted on the Board's website. Attorneys representing parties before the Board shall list their bar numbers or other identifying data for each State bar to which they are admitted.

(c) *Withdrawal of appearance.* Anyone who has filed a notice of appearance and wishes to withdraw from a case must file a motion identifying by name, telephone number, mailing address, and email address the person who will assume responsibility for representing the party in question. The motion must state grounds for withdrawal, unless the motion represents that the party in question will meet the existing case schedule.

6101.6 Pleadings; amending pleadings [Rule 6].

(a) *Complaint.* Within 30 days after receiving the notice of docketing, the appellant shall file a complaint stating in simple, concise, and direct terms the factual basis for each claim and the amount in controversy. Alternatively, the appellant or the Board may designate as a complaint the notice of appeal, a claim submission, or any other document containing the information required in a complaint. The Board may in its discretion order a respondent asserting a claim to file a complaint.

(b) *Answer.* Within 30 days after receiving the complaint or a designation of a complaint, the respondent (or the appellant, if so ordered) shall file an answer stating in simple, concise, and direct terms its responses to the allegations of the complaint and any affirmative defenses it chooses to assert.

(c) *Amendments.* A party may amend a pleading once, before a responsive pleading is filed, with permission of the other party. Amending a pleading restarts the time to respond, if any. The Board may allow a party to amend a pleading in other circumstances.

(d) *Motion in lieu of answer.* The Board may allow a party to file a dispositive motion or to move for a more definite statement in lieu of filing an answer.

6101.7 Service of documents [Rule 7].

A party filing any document not submitted *in camera* (see Rule 9(c)(2) (48 CFR 6101.9(c)(2)) shall send a copy to the other party by a method at least as fast as the filing method. The filing party shall indicate the method and address of service, otherwise the Board may consider a document not served and not properly filed.

6101.8 Motions [Rule 8].

(a) *Generally.* A party may make a motion for a Board action orally on the record in the presence of the other party or in a written filing. A written motion shall be a document titled as a motion and shall state the relief sought and the legal basis (see Rule 23(b) (48 CFR 6101.23(b)). Except for joint or dispositive motions, all motions shall represent that the movant tried to resolve the motion with the other party before filing. The Board may hold oral argument on a motion.

(b) *Jurisdictional motions.* A party challenging the Board's jurisdiction should file such a motion promptly.

(c) *Procedural motions.* A party may move for an extension of time (Rule 3(b) (48 CFR 6101.3(b)). The Board may in its discretion consider motions on other procedural matters. A procedural motion shall state the other party's position on the motion or describe the movant's effort to learn the other party's position.

(d) *Discovery motions.* See Rule 13(e) (48 CFR 6101.13(e)).

(e) *Motions to dismiss for failure to state a claim.* A party may move to dismiss all or part of a claim for failure to state grounds on which the Board could grant relief. In deciding such motions, the Board looks to Rule 12(b)(6) of the Federal Rules of Civil Procedure for guidance.

(f) *Summary judgment motions.* A party may move for summary judgment on all or part of a claim or defense if the party believes in good faith it is entitled to judgment as a matter of law based on

undisputed material facts. In deciding motions for summary judgment, the Board looks to Rule 56 of the Federal Rules of Civil Procedure for guidance.

(1) *Statement of undisputed material facts.* The movant shall file with its summary judgment motion a separate document titled, ''Statement of Undisputed Material Facts.'' This document shall set forth facts supporting the motion in separate, numbered paragraphs, citing appeal file exhibits, admissions in pleadings, and/or evidence filed with the motion.

(2) *Statement of genuine issues.* The opposing party shall file with its opposition a separate document titled, ''Statement of Genuine Issues.'' This document shall respond to specific paragraphs of the movant's Statement of Undisputed Material Facts by identifying material facts in genuine dispute, citing appeal file exhibits, admissions in pleadings, and/or evidence filed with the opposition.

(g) *Briefing.* A party may file a brief in opposition to a motion under Rule 26, Rule 27, Rule 28, or Rule 29 (48 CFR 6101.26, 6101.27, 6101.28, or 6101.29) only by permission of the Board. Unless otherwise ordered, a brief in opposition to any other nonprocedural motion is due 30 days after receipt of the motion, and a movant's reply brief is due 15 days after receipt of an opposition brief. A nonmovant may file a surreply only by permission of the Board. Unless otherwise ordered, a brief in opposition to a procedural motion is due 5 days after receipt of the motion, and there shall be no reply.

(h) *Effect of pending motion.* Unless otherwise stated in this part, the filing of a motion does not affect a party's obligations under the Board's rules or orders.

6101.9 Record; content and access [Rule 9].

(a) *Record for decision.* The record on which the Board will decide a case includes the following:

(1) *Evidence.* Evidence in a case includes:

(i) Rule 4 (48 CFR 6101.4) appeal file exhibits other than those to which an objection is sustained;

(ii) Other documents or parts thereof admitted as evidence;

(iii) Tangible things admitted as evidence;

(iv) Transcripts or recordings of testimony before the Board; and

(v) Factual stipulations and factual admissions.

(2) *Other material.* The Board may also rely on to decide a case:

(i) The notice of appeal, petition, or application;

(ii) The complaint, answer, and amendments thereto;

(iii) Motions and briefs on motions;

(iv) Other briefs;

(v) Demonstrative hearing exhibits; and

(vi) Anything else the Board may expressly admit or take notice of.

(b) *Other contents of case file.* The Board's administrative record may be broader than the record for decision. Material in the Board's case file that is not listed in Rule 9(a) (48 CFR 6101.9(a)) is part of the administrative record but is not part of the record for decision.

(c) *Enlarging or reopening the record.* The Board may enlarge or reopen the record for decision on terms fair to the parties.

(d) *Protected and in camera submissions.* The Board may limit access to specified material in a record for decision.

(1) *Protective orders.* The Board may limit access to specified material in a record for decision if the Board finds good cause to treat the material as privileged, confidential, or otherwise sensitive.

(2) *In camera submissions.* The Board may allow a party to submit a document solely for the Board's review *in camera* if:

(i) The party submits the document to explain a discovery dispute;

(ii) The Board denies a motion for protective order, and the movant asks that the record include a document that the party would have used in the case with a protective order, for possible later review of the Board's denial; or

(iii) Good cause exists to find that *in camera* review may limit or prevent needless harm to a party, witness, or other person.

(3) *Status in record.* A document submitted and accepted under a protective order or *in camera* is part of the record for decision. If the Board's decision is judicially reviewed, the Board will endeavor to preserve the protected or *in camera* nature of the document to the extent consistent with judicial review.

(e) *Review and copying.* The Clerk makes records for decision, except evidence submitted under a protective order or *in camera,* available for review on reasonable notice during business hours, and provides copies of such available documents for a reasonable fee. The Clerk will not relinquish possession of material in the Board's files.

6101.10 Admissibility of evidence [Rule 10].

The Board may in its discretion receive any evidence to which no party objects. In ruling on evidentiary objections, the Board is guided but not bound by the Federal Rules of Evidence, except that the Board generally admits hearsay unless the Board finds it unreliable.

6101.11 Conferences [Rule 11].

The Board may order a conference of the parties for any purpose. Conferences are usually telephonic and are rarely recorded or transcribed. No one may record a conference by any means without Board approval. If the Board issues a memorandum or order memorializing a conference, a party has 5 days from receipt of the memorandum or order to object in writing to the memorialization.

6101.12 Stays and dismissals [Rule 12].

(a) *Stays.* The Board may stay a case for a specific duration, or until a specific event, for good cause.

(b) *Dismissals*—(1) *Generally.* The Board may dismiss a case or part of a case either on motion of a party or after permitting a response to an order to show cause. Dismissal is with prejudice unless a Board order or other applicable law provides otherwise.

(2) *Voluntary dismissal.* Subject to Rule 12(b)(3) (paragraph (b)(3) of this section), the Board will dismiss all or part of a case on the terms requested if the appellant, petitioner, or applicant moves for dismissal with prejudice or moves jointly with the respondent for dismissal with or without prejudice.

(3) *For lack of jurisdiction.* If the Board finds that it lacks jurisdiction to decide all or part of a case, the Board will dismiss the case or the part of the case, regardless of the parties' positions on jurisdiction or dismissal.

(4) *For failure to prosecute.* The Board may dismiss all or part of a case for failure to prosecute.

(c) *Dismissal orders and decisions.* The presiding judge acting alone may stay a case or grant voluntary dismissal with or without prejudice. A panel or the full Board may dismiss a case on other grounds.

(d) *Admonition.* Dismissal of a party's case without prejudice does not necessarily mean that the party may later refile the case at the Board or in another forum under the jurisdictional and procedural laws applicable to the case.

6101.13 Discovery generally [Rule 13].

(a) *Methods.* Parties may obtain discovery by depositions, interrogatories, requests for production, and requests for admission.

(b) *Scope.* Unless otherwise ordered, the scope of discovery is the same as

under Rule 26(b)(1) of the Federal Rules of Civil Procedure.

(c) *Limits.* The Board may limit the frequency or extent of discovery for a reason stated in Rule 26(b)(2) of the Federal Rules of Civil Procedure.

(d) *Timing.* The Board encourages parties to agree on a discovery plan that the Board may adopt in a scheduling order. The Board may modify an agreed discovery plan.

(e) *Disputes*—(1) *Objections.* A party objecting to a written discovery request must make the objection in writing no later than the date that its response to the discovery request is due.

(2) *Duty to cooperate.* Parties shall try in good faith to resolve objections to discovery requests without involving the Board. The Board may impose an appropriate sanction under Rule 35 (48 CFR 6101.35) on a party that does not meet its discovery obligations.

(3) *Motions to compel.* A party may move to compel a response or a supplemental response to a discovery request. The movant shall attach to its motion a copy of each discovery request and response at issue, and shall represent in the motion that the movant complied with Rule 13(e)(2) (paragraph (e)(2) of this section).

(f) *Subpoenas.* A party may request a subpoena under Rule 16 (48 CFR 6101.16).

6101.14 Interrogatories; requests for production; requests for admission [Rule 14].

(a) *Generally.* Interrogatories, requests for production, requests for admission, and responses thereto shall be in writing and served on the other party.

(b) *Interrogatories.* Interrogatories shall be answered or objected to separately in writing, under signed oath, within 30 days of service. A party may answer an interrogatory by specifying records from which the answer may be derived or ascertained when that response would be allowed under Rule 33(d) of the Federal Rules of Civil Procedure.

(c) *Requests for production.* Responses and objections to requests for production, inspection, and/or copying of documents, electronically stored information, or tangible things are due within 30 days of service of the requests and shall state when and how the responding party will make responsive material available.

(d) *Requests for admission*—(1) *Content.* A party may serve requests for admission that would be proper under Rule 36(a)(1) of the Federal Rules of Civil Procedure.

(2) *Responses and failure to respond.* Responses and objections shall comply with Rule 36(a)(4) and (5) of the Federal Rules of Civil Procedure. If the served party does not respond within 30 days of service of a request, the Board may on motion deem a matter admitted and conclusively established solely for the pending case.

(3) *Relief from admission.* The Board may allow a party to withdraw or amend an admission for good cause.

(e) *Altering time to respond.* The parties may agree to alter deadlines to respond to discovery requests. The Board may alter the deadlines to meet the needs of a case.

(f) *Supplementing and correcting responses.* A party must supplement or correct a response to a discovery request if and when this action would be required by Rule 26(e)(1) of the Federal Rules of Civil Procedure.

6101.15 Depositions [Rule 15].

(a) *Generally.* Unless otherwise ordered, parties may take depositions after service of the answer. If the parties agree in writing on the deponent, time, place, recording method, and maximum duration of a deposition, no formal deposition notice is needed. The Board may order a deposition on motion under Rule 8 (48 CFR 6101.8) or by subpoena under Rule 16 (48 CFR 6101.16).

(b) *Use.* Parties may use deposition testimony in a case to the extent that would be permitted by Rule 32(a) of the Federal Rules of Civil Procedure.

(c) *To perpetuate testimony.* If the Board has decided a case, and either the time to appeal has not expired or an appeal has been taken, the Board may for good cause grant leave to take a deposition as if the case were still before the Board in order to preserve testimony for possible further proceedings before the Board.

6101.16 Subpoenas [Rule 16].

(a) *Expectation of cooperation in lieu of subpoena.* Subpoenas should rarely be necessary, as the Board expects parties to respond cooperatively to discovery requests and to try in good faith to secure the cooperation of third parties who have or may have evidence responsive to discovery requests.

(b) *Generally.* The Board may issue a subpoena for a purpose for which a United States district court may issue a subpoena under Rule 45(a)(1) of the Federal Rules of Civil Procedure. Parties and the Board shall take all reasonable steps to avoid imposing undue burden on a person subject to a subpoena.

(c) *How requested; form.* A party may ask the Board to issue a subpoena by motion under Rule 8 (48 CFR 6101.8), substantially before the proposed compliance date. The movant shall attach to its motion a completed subpoena form for signing by a Board judge, and shall explain in the motion why the proposed subpoena scope is reasonable and how the evidence sought is relevant to the case.

(d) *Production cost.* The Board's policy is to require a requesting party to advance a subpoenaed person the reasonable cost of producing subpoenaed material.

(e) *Service.* The requesting party shall serve a subpoena and provide proof of service as would be required by Rule 45(b) of the Federal Rules of Civil Procedure.

(f) *Motion to quash or modify.* On or before the date specified for compliance, a subpoenaed person may file a motion to quash or modify the subpoena for a reason stated in Rule 45(d)(3) of the Federal Rules of Civil Procedure. The Board may rule on the motion any time after the party that served the subpoena receives the motion.

(g) *Enforcement.* As necessary, the Board may ask the Attorney General of the United States to petition a United States district court to enforce a Board subpoena.

(h) *Letter rogatory in lieu of subpoena.* If a person to be subpoenaed resides in a foreign country, the Board may facilitate the issuance of a letter rogatory to the person by the United States Department of State under 28 U.S.C. 1781–1784.

6101.17 Exhibits [Rule 17].

(a) *Marking exhibits.* Unless otherwise ordered, parties shall, to the fullest extent practicable, submit exhibits for inclusion in the appeal file before a hearing starts under Rule 20 (48 CFR 6101.20) or before the first brief is filed when a case is submitted on the written record under Rule 19 (48 CFR 6101.19). Parties shall mark any exhibits offered in evidence thereafter as sequential additions to the appeal file. Such exhibits shall become part of the appeal file if admitted as evidence.

(b) *Copies.* The Board expects all document exhibits to be true, complete, and legible copies rather than originals. The Board may order a party to substitute a better copy or to make an original document available for inspection.

(c) *Withdrawal.* The Board may allow a party to withdraw an exhibit from the appeal file and the record for decision on terms fair to the other party.

(d) *Disposition.* Unless the Board advises the parties of another deadline, the Board may discard physical (non-electronic) exhibits in its possession 90 days after the time to appeal the Board's decision in the case expires.

6101.18 Election of hearing or record submission [Rule 18].

(a) *Generally.* The Board will hold a hearing in a case if the Board must find facts and either party elects a hearing. A party may elect to submit its case for decision on the written record under Rule 19 (48 CFR 6101.19). The presiding judge will set the deadline for an election under this rule.

(b) *Hybrid election.* A party may elect to submit its case on the written record under Rule 19 (48 CFR 6101.19) and also elect to appear at a hearing, solely to cross-examine the other party's witnesses and to object to evidence offered at the hearing.

6101.19 Record submission without a hearing [Rule 19].

(a) *Generally.* If a party elects to submit its case on the record without a hearing, the Board will set a schedule for the parties to complete the evidentiary record and file briefs.

(b) *Evidence and objections.* When a party elects submission on the record without a hearing, that party may submit material for inclusion in the record no later than the date the party files its initial brief. Unless otherwise ordered, the other party may object to the admission of such material as evidence within 5 days after receiving the submission. If one party elects a hearing and the other party elects record submission (or makes a hybrid election under Rule 18(b) (48 CFR 6101.18(b)), the evidentiary record shall close at the end of the hearing. The Board may rule on objections either before or in its decision.

(c) *Briefs and argument.* The Board may receive briefs and/or oral argument on a record submission. If one party elects a hearing and the other party elects record submission, the first brief of the party submitting its case on the record shall be due no later than the start of the hearing.

6101.20 Scheduling hearings [Rule 20].

(a) *Generally.* The Board will set the time, place, duration, and subject matter of a hearing in a written order after consulting with the parties.

(b) *Subject matter.* The Board may schedule for hearing all or some of the claims or issues in a case, or all or some of the claims, issues, or questions of fact or law common to more than one case.

(c) *Unexcused absence.* If a party fails without good excuse to appear at a hearing of which it received notice under this rule, the Board will deem that party to have elected to submit its case on the record under Rule 19.

6101.21 Hearing procedures [Rule 21].

(a) *Generally.* The Board generally holds hearings in public hearing rooms. Except as necessary under a protective order or *in camera* procedures, hearings are open to the public. The Board entrusts the conduct of hearings to the discretion of the presiding judge.

(b) *Witnesses, evidence, other exhibits.* A party that intends to offer testimony, other evidence, or other material for the record at a hearing shall arrange for the witness, evidence, or other material to be present in the hearing room. The Board may in its discretion allow testimony by telephone or video.

(c) *Exclusion of witnesses.* The Board may exclude witnesses from a hearing, other than one designated representative for each party or a person authorized by statute to be present, so that witnesses are not influenced by the testimony of other witnesses.

(d) *Sworn testimony.* Hearing witnesses shall testify under oath or affirmation. If a person called as a witness refuses to so swear or affirm, the Board may receive the person's testimony under penalty of making a materially false statement in a Federal proceeding under 18 U.S.C. 1001. Alternatively, the Board may disallow the testimony and may draw inferences from the person's refusal to swear or affirm.

6101.22 Transcripts [Rule 22].

The Board arranges transcription of hearings, other than hearings under the small claims procedure of Rule 52 (48 CFR 6101.52). The Board may, but generally does not, arrange transcription of conferences or other proceedings. No one may record or transcribe a Board proceeding without the Board's permission. The Board may order or acknowledge corrections to an official transcript. Each party is responsible for obtaining its own copy of a transcript.

6101.23 Briefs [Rule 23].

(a) *Generally.* The Board may order or invite briefs on any issue in a case at any time. Briefs shall be formatted for 8.5 by 11-inch paper, double spaced, with body and footnote text no smaller than 13 point.

(b) *Prehearing, post-hearing, and other briefs.* Prehearing and post-hearing briefs, briefs filed under Rule 19, and briefs on non-procedural motions shall cite record evidence for factual statements and legal authority for legal arguments.

6101.24 Closing the record [Rule 24].

(a) *Closing the evidentiary record.* Unless otherwise ordered, the evidence as defined in Rule 9(a)(1) (48 CFR 6101.9(a)(1)) is closed at the end of a hearing under Rule 20 or at the start of merits briefing when a case is submitted on the record under Rule 19 (48 CFR 6101.19).

(b) *Closing the record for decision.* Unless otherwise ordered, the record for decision as defined in Rule 9(a) (48 CFR 6101.9(a)) is closed when the Board receives the final scheduled brief on the matters to be decided.

6101.25 Decisions and settlements [Rule 25].

(a) *Decisions.* The Board issues decisions in writing, except as allowed by Rule 52 (48 CFR 6101.52). The Board will send a copy of a decision to each party, requesting confirmation of receipt (see Rule 1 (48 CFR 6101.1)), and will post the decision on its website. If a decision reserves any part of a case for later proceedings, it is conclusive as to the matters it resolves, except as provided in Rules 26 and 28 (48 CFR 6101.26 and 6101.28).

(b) *Settlements.* Parties may settle a case by stipulating to an award. The Board may issue a decision making the stipulated award if:

(1) The Board is satisfied that it has jurisdiction; and

(2) The stipulation states that no party will seek reconsideration of, seek relief from, or appeal the Board's decision.

6101.26 Reconsideration [Rule 26].

(a) *Grounds.* The Board may on motion reconsider a decision or order for a reason recognized in Rule 59 of the Federal Rules of Civil Procedure. Arguments and evidence previously presented are not grounds for reconsideration.

(b) *Time limit for motion.* A party may move for reconsideration of a decision or order on an appeal or petition within 30 days after that party receives the decision or order. A party may move for reconsideration of a decision or order on an application within 7 days after receiving the decision or order. The Board does not extend these time limits.

(c) *Effect of motion.* A pending reconsideration motion does not affect any obligation to comply with a decision or order.

6101.27 Relief from decision or order [Rule 27].

(a) *Grounds.* The Board may grant relief, for a reason recognized in Rule 60 of the Federal Rules of Civil Procedure, from a decision or order that, alone or in conjunction with prior decisions or orders, resolves all of an appeal, petition, or application.

(b) *Time limit for motion.* A party may move for relief under this rule within

120 days after that party receives the decision or order at issue.

(c) *Effect of motion.* A pending motion for relief under this rule does not affect any obligation to comply with a decision or order.

6101.28 Full Board consideration [Rule 28].

(a) *By motion.* The full Board may consider a decision or order when necessary to maintain uniformity of Board decisions or if the matter is exceptionally important. Motions for full Board consideration are disfavored and are decided by a majority of the Board. A party may move for full Board consideration within 10 days after that party receives the decision or order at issue. An order granting full Board consideration will include concurring or dissenting opinions, if any.

(b) *By Board initiative.* A majority of the Board may initiate full Board consideration of any matter in a case, up to 10 days after a judge or panel issues a decision or order on that matter. The full Board will inform the parties by order of the matter or matters to be considered. The order will include concurring or dissenting opinions, if any.

(c) *Full Board decision.* The full Board decides matters by majority vote. A full Board decision will include concurring or dissenting opinions, if any.

(d) *Effect of motion.* A pending motion for full Board consideration does not affect any obligation to comply with a decision or order.

6101.29 Clerical mistakes; harmless error [Rule 29].

(a) *Clerical mistakes.* The Board may correct clerical mistakes while a case is pending, or within 60 days thereafter if a decision has not been appealed. If a Board decision is appealed, the Board may correct clerical mistakes only by leave of the appellate Court.

(b) *Harmless error.* The Board disregards errors that do not affect a substantive right of a party. No error in a ruling, order, or decision of the Board will be grounds for a new hearing or for vacating, reconsidering, modifying, or otherwise disturbing a decision or order unless refusing to correct the error will prejudice a party or work a substantial injustice.

6101.30 Award of fees and other expenses [Rule 30].

(a) *Application for fees and other expenses.* A party in an appeal may apply for an award of fees and other expenses as permitted under EAJA or any other provision that may entitle the party to such an award.

(b) *Time for filing.* A party may file an application for fees and other expenses only after the time to seek appellate review of a Board decision has expired. A party may file an application within 30 calendar days after that date.

(c) *Application requirements.* An application for fees and other expenses shall:

(1) Specify the applicant, appeal, and amount sought;

(2) Explain why the applicant is legally eligible for an award;

(3) Provide a schedule of fees and expenses with supporting documentation;

(4) Be signed by the applicant or a person appearing for the applicant, with a declaration under penalty of perjury that the information in the application is correct;

(5) Provide evidence of the applicant's small business status or net worth; and

(6) Justify any request for attorney fees exceeding the statutory rate.

(d) *Proceedings.* (1) Within 30 days after receiving an application, the respondent may file an answer with any objections to the award requested, supported by facts and legal analysis.

(2) The Board may order further proceedings if necessary for a full and fair resolution of issues arising from an application.

(e) *Decision.* The Board will issue a written decision on an application.

6101.31 Payment of award [Rule 31].

When permitted by law, Board awards under contracts may be paid from the permanent indefinite judgment fund under 31 U.S.C. 1304 and 31 CFR part 256. An EAJA award is paid from funds of the respondent.

6101.32 Appeal from Board decision [Rule 32].

(a) *Notice.* A party filing a notice of appeal with the United States Court of Appeals for the Federal Circuit (or with a district court in an admiralty case) shall provide a copy of the notice to the Board.

(b) *Record on review.* The record on appellate review is the record for decision under Rule 9(a) (48 CFR 6101.9(a)) and any other material in a case file that the appellate Court may require.

(c) *Certified list.* The Clerk will provide the clerk of the appellate Court a certified list as required by the Court's rules.

(d) *Inspection or copying of record.* The Clerk will make a record on appeal available for inspection and copying in accordance with the rules of the appellate Court.

6101.33 Remand from appellate Court [Rule 33].

If a Court remands a case to the Board for further proceedings, each party shall, within 30 days of receipt of the appellate mandate, recommend procedures to comply with the remand order. The Board will then issue an order on further proceedings.

6101.34 Ex parte communications [Rule 34].

No member of the Board or of the Board's staff will communicate with a party about any material issue in a case outside of the presence of the other party, and no one shall attempt such communications on behalf of a party. This rule does not bar such communications about the Board's administrative functions or procedures.

6101.35 Standards of conduct; sanctions [Rule 35].

(a) *Standards of conduct.* All parties and their representatives, attorneys, and any expert or consultant retained by them or their attorneys shall obey directions and orders of the Board and adhere to standards of conduct applicable to such parties and persons. Standards applying to an attorney include the rules of professional conduct and ethics of the jurisdictions in which the attorney is licensed to practice, to the extent that those rules are relevant to conduct affecting the integrity of the Board, its process, or its proceedings.

(b) *Sanctions.* If a party or its representative, attorney, expert, or consultant fails to comply with any direction or order of the Board (including an order to provide or permit discovery) or engages in misconduct affecting the Board, its process, or its proceedings, the Board may make such orders as are just, including the imposition of appropriate sanctions. Sanctions may include, but are not limited to:

(1) Taking the facts pertaining to the matter in dispute to be established for the purpose of the case in accordance with the contention of the party who is not at fault;

(2) Forbidding the challenge of the accuracy of any evidence;

(3) Refusing to allow the party to support or oppose designated claims or defenses;

(4) Prohibiting the party from introducing into evidence designated claims or defenses;

(5) Striking pleadings or parts thereof, or staying further proceedings until the order is obeyed;

(6) Dismissing the case or any part thereof;

(7) Enforcing the protective order and disciplining individuals subject to such order for violation thereof, including disqualifying a party's representative, attorney, expert, or consultant from further participation in the case;

(8) Drawing evidentiary inferences adverse to the party; or

(9) Imposing such other sanctions as the Board deems appropriate.

(c) *Denial of access to protected material.* The Board may in its discretion deny access to protected material to any person found to have previously violated a protective order, regardless of who issued the order.

(d) *Disciplinary proceedings*—(1) *Sanctions.* The Board may discipline individual party representatives, attorneys, experts, or consultants for violating any Board order, direction, or standard of conduct if the violation seriously affects the integrity of the Board, its process, or its proceedings. Sanctions may be public or private, and may include admonishment, reprimand, disqualification from a particular matter, referral to an appropriate licensing authority, or other action that circumstances may warrant.

(2) *Suspension.* The Board may suspend an individual from appearing before the Board as a party representative, attorney, expert, or consultant, if, after affording such individual notice and opportunity to be heard, a majority of the members of the full Board determine such a sanction is warranted.

6101.36 Board seal [Rule 36].

The seal of the Board is a circular logo with ''Civilian Board of Contract Appeals'' on the outer margin. The seal is a means of authenticating records, notices, orders, dismissals, opinions, subpoenas, and certificates issued by the Board.

6101.37–6101.50 [Reserved]

6101.51 Alternative procedures [Rule 51].

An appellant in an eligible case may elect the small claims procedure under Rule 52 (48 CFR 6101.52) or the accelerated procedure under Rule 53 (48 CFR 6101.53). Parties may jointly elect alternative dispute resolution under Rule 54 (48 CFR 6101.54).

6101.52 Small claims procedure [Rule 52].

(a) *Election.* The small claims procedure is available solely at an appellant's election and is limited to appeals in which there is a monetary amount in dispute and the requirements for expedited disposition set forth in the Contract Disputes Act, 41 U.S.C. 7106(b), are met. An appellant may elect the small claims procedure up to 30 days after receiving the respondent's answer.

(b) *Procedure.* The respondent may object to an election, on the grounds that Rule 52(a) (paragraph (a) of this section) is not satisfied, within 10 days after receiving the election. If the small claims procedure is used, the Board will set a schedule for timely resolution of the appeal. The schedule may restrict or eliminate pleadings, discovery, and other prehearing activities.

(c) *Decision.* The presiding judge may issue a decision in summary form. A decision is final and conclusive, shall not be set aside except for fraud, and is not precedential. If possible, the Board will resolve the appeal within 120 days after the appellant elects the small claims procedure. The Board may extend the appeal schedule if an appellant does not adhere to the established schedule.

6101.53 Accelerated procedure [Rule 53].

(a) *Election.* The accelerated procedure is available solely at an appellant's election and is limited to appeals in which there is a monetary amount in dispute and the requirements for accelerated disposition set forth in the Contract Disputes Act, 41 U.S.C. 7106(a), are met. The appellant may elect the accelerated procedure up to 30 days after receiving the respondent's answer.

(b) *Procedure.* The respondent may object to an election, on the grounds that Rule 53(a) (paragraph (a) of this section) is not satisfied, within 10 days after receiving the election. If the accelerated procedure is used, the Board will set a schedule for timely resolution of the appeal. The schedule may restrict or eliminate pleadings, discovery, and other prehearing activities.

(c) *Decision.* The presiding judge may issue a decision with the concurrence of at least one panel member. If the presiding judge and a panel member disagree, the panel will decide the appeal. If possible, the Board will resolve the appeal within 180 days after the appellant elects the accelerated procedure. The Board may extend the appeal schedule if an appellant does not adhere to the established schedule.

6101.54 Alternative dispute resolution [Rule 54].

(a) *Availability.* The CDA requires boards of contract appeals to provide to the fullest extent practicable informal, expeditious, and inexpensive resolution of disputes. Resolution of a dispute at the earliest stage feasible, by the fastest and least expensive method possible, benefits both parties. The Board provides alternative dispute resolution (ADR) services for pre-claim and pre-final decision matters, as well as appeals pending before the Board. The Board may also conduct ADR proceedings for any Federal agency. The use of ADR proceedings does not toll any statutory time limits.

(b) *Procedures for requesting ADR.* Parties may jointly ask the Board Chair to appoint a judge as an ADR Neutral. The parties may request a particular judge or judges, to include the presiding judge. To facilitate full, frank, and open participation, a Neutral will not discuss the substance of the case or the parties' conduct in ADR with other Board personnel, and a Neutral who participates in a nonbinding ADR procedure that does not resolve the dispute is recused from further participation in the matter unless the parties agree otherwise in writing and the Board concurs.

(c) *Confidentiality.* Written material prepared for use in ADR, oral presentations made in ADR, and all discussions between the parties and the Neutral are confidential, subject to 5 U.S.C. 574, and, unless otherwise specifically agreed by the parties, inadmissible as evidence in any Board proceeding, although evidence otherwise admissible before the Board is not rendered inadmissible merely because of its use in ADR.

(d) *ADR agreement.* Parties shall agree in writing to an ADR method and the procedures and requirements for implementing it. The ADR agreement shall provide that the parties and counsel will not subpoena the Neutral in any legal action or administrative proceeding of any kind to provide documents or testimony relating to the ADR.

(e) *Types of ADR.* Parties and the Board may agree on any type of binding or nonbinding ADR suited to a dispute.

PART 6102—CROP INSURANCE CASES

Sec.

Authority: 7 U.S.C. 1501 *et seq.;* 41 U.S.C. 438(c)(2).

6102.201 Scope of rules [Rule 201].

These procedures govern the Board's resolution of disputes between insurance companies and the Department of Agriculture's Risk Management Agency (RMA) involving actions of the Federal Crop Insurance Corporation (FCIC). Prior to the creation of this Board, the Department of Agriculture Board of Contract Appeals resolved this variety of dispute pursuant

to statute, 7 U.S.C. 1501 *et seq.* (the Federal Crop Insurance Act), and regulation, 7 CFR 24.4(b) and 400.169. The Board has this authority under an agreement with the Secretary of Agriculture, as permitted under section 42(c)(2) of the Office of Federal Procurement Policy Act, 41 U.S.C. 438(c)(2).

6102.202 Rules for crop insurance cases [Rule 202].

The rules of procedure for these cases are the same as the rules of procedure for Contract Disputes Act appeals, with these exceptions:

(a) *Rule 1(b)(48 CFR 6101.1(b)).* (1) The term ''appeal'' means a dispute between an insurance company that is a party to a Standard Reinsurance Agreement (or other reinsurance agreement) and the RMA, and the term ''appellant'' means the insurance company filing an appeal.

(2) A notice of appeal is filed upon its receipt by the Office of the Clerk of the Board, not when it is mailed.

(3) The terms ''petition'' and ''petitioner'' do not apply to FCIC cases.

(b) *Rule 2 (48 CFR 6101.2).* (1) Rule 2(a) (48 CFR 6101.2(a)) is replaced with the following for FCIC cases: A notice of appeal shall be in writing and shall be signed by the appellant or by the appellant's attorney or authorized representative. If the appeal is from a determination by the Deputy Administrator of Insurance Services regarding an action alleged not to be in accordance with the provisions of a Standard Reinsurance Agreement (or other reinsurance agreement), or if the appeal is from a determination by the Deputy Administrator of Compliance concerning a determination regarding a compliance matter, the notice of appeal should describe the determination in enough detail to enable the Board to differentiate that decision from any other; the appellant can satisfy this requirement by attaching to the notice of appeal a copy of the Deputy Administrator's determination. If an appeal is taken from the failure of the Deputy Administrator to make a timely determination, the notice of appeal should describe in detail the matter that the Deputy Administrator has failed to determine; the appellant can satisfy this requirement by attaching to the notice of appeal a copy of the written request for a determination it sent to the Deputy Administrator.

(2) In Rule 2(a) (48 CFR 6101.2(a)), the references to ''contracting officer'' are references to ''Deputy Administrator.''

(3) Rule 2(b) (48 CFR 6101.2(b)) does not apply to FCIC cases.

(4) In Rule 2(d)(1) (48 CFR 6101.2(d)(1)), an appeal from a determination of a Deputy Administrator shall be filed no later than 90 calendar days after the date the appellant receives that determination. The Board is authorized to resolve only those appeals that are timely filed.

(5) In Rule 2(d)(2) (48 CFR 6101.2(d)(2)), an appeal may be filed with the Board if the Deputy Administrator fails or refuses to issue a determination within 90 days after the appellant submits a request for a determination.

(c) *Rule 4 (48 CFR 6101.4).* (1) In Rule 4, the references to ''contracting officer'' are references to ''Deputy Administrator.''

(2) In Rule 4(a), paragraphs (1) through (7) (48 CFR 6101.4(a)(1) through (7)), describing materials included in the appeal file, are replaced by the following:

(i) The determination of the Deputy Administrator that is the subject of the dispute;

(ii) The reinsurance agreement (with amendments or modifications) at issue in the dispute;

(iii) Pertinent correspondence between the parties that is relevant to the dispute, including prior administrative determinations and related submissions;

(iv) Documents and other tangible materials on which the Deputy Administrator relied in making the underlying determination; and

(v) Any additional material pertinent to the authority of the Board or the resolution of the dispute.

(3) The following subsection is added to Rule 4 (48 CFR 6101.4): Media on which appeal file is to be submitted. All appeal file submissions, including the index, shall be submitted in two forms: Paper and in a text or .pdf format submitted on a compact disk. Each compact disk shall be labeled with the name and docket number of the case. The judge may delay the submission of the compact disk copy of the appeal file until the close of the evidentiary record.

(d) *Rule 5 (48 CFR 6101.5).* In Rule 5(a)(2) (48 CFR 6101.5(a)(2)), the references to ''contracting officer'' are references to ''Deputy Administrator.''

(e) *Rule 15 (48 CFR 6101.15).* In Rule 15(c) (48 CFR 6101.15(c)), the final sentence does not apply to FCIC cases.

(f) *Rule 16 (48 CFR 6101.16).* Rules 16 (b) through (h) (48 CFR 6101.16(b) through (h)) do not apply to FCIC cases. Instead, upon the written request of any party filed with the Office of the Clerk of the Board, or upon the initiative of a judge, a judge is authorized by delegation from the Secretary of Agriculture to request the appropriate United States Attorney to apply to the appropriate United States District Court for the issuance of subpoenas pursuant to 5 U.S.C. 304.

(g) *Rule 25 (48 CFR 6101.25).* In Rule 25(a) (48 CFR 6101.25(a)), the phrase, ''except as allowed by Rule 52,'' does not apply to FCIC cases.

(h) *Rule 32 (48 CFR 6101.32).* Rule 32 (a) through (c) (48 CFR 6101.32(a) through (c)) are replaced with the following for FCIC cases:

(1) *Finality of Board decision.* A decision of the Board is a final administrative decision.

(2) *Appeal permitted.* An appellant may file suit in the appropriate United States District Court to challenge the Board's decision. An appellant filing such a suit shall provide the Board with a copy of the complaint.

(i) *Rule 52 (48 CFR 6101.52).* Rule 52 does not apply to FCIC cases.

(j) *Rule 53 (48 CFR 6101.52).* Rule 53 does not apply to FCIC cases.

[FR Doc. 2018–17213 Filed 8–16–18; 8:45 am]

BILLING CODE 6820–AL–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 120815345–3525–02]

RIN 0648–XG420

Snapper-Grouper Fishery of the South Atlantic; 2018 Commercial Accountability Measure and Closure for the Other Jacks Complex

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for the Other Jacks Complex commercial sector in the exclusive economic zone (EEZ) of the South Atlantic for the 2018 fishing year through this temporary rule. The Other Jacks Complex is composed of the lesser amberjack, almaco jack, and banded rudderfish. NMFS projects that commercial landings of the Other Jacks Complex will reach the combined commercial annual catch limit (ACL) by August 22, 2018. Therefore, NMFS closes the commercial sector for this complex in the South Atlantic EEZ, on August 22, 2018, and it will remain closed until the start of the next fishing year on January 1, 2019. This closure is

necessary to protect the lesser amberjack, almaco jack, and banded rudderfish resources.

DATES: This temporary rule is effective at 12:01 a.m., local time, on August 22, 2018, until 12:01 a.m., local time, on January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes lesser amberjack, almaco jack, and banded rudderfish, which combined are the Other Jacks Complex. The Other Jacks Complex is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The combined commercial ACL for the Other Jacks Complex is 189,422 lb (85,920 kg), round weight. Under 50 CFR 622.193(l)(1)(i), NMFS is required to close the commercial sector for the Other Jacks Complex when the commercial ACL has been reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial sector for this complex is projected to reach its ACL by August 22, 2018. Therefore, this temporary rule implements an AM to close the commercial sector for the Other Jacks Complex in the South Atlantic, effective at 12:01 a.m., local time, on August 22, 2018.

The operator of a vessel with a valid commercial permit for South Atlantic snapper-grouper having lesser amberjack, almaco jack, or banded rudderfish on board must have landed and bartered, traded, or sold such species prior to 12:01 a.m., local time, on August 22, 2018. During the commercial closure, the recreational bag limit specified in 50 CFR 622.187(b)(8) and the possession limits specified in 50 CFR 622.187(c) apply to all harvest or possession of lesser amberjack, almaco jack, or banded rudderfish in or from the South Atlantic EEZ, while the recreational sector is open. These recreational bag and possession limits apply in the South Atlantic on board a vessel for which a valid Federal commercial or charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, regardless of whether such species were harvested in state or Federal waters. During the commercial closure, the sale or purchase of lesser amberjack, almaco jack, or banded rudderfish taken from the South Atlantic EEZ is prohibited.

Classification

The Regional Administrator for the NMFS Southeast Region has determined this temporary rule is necessary for the conservation and management of the fish in the Other Jacks Complex, a component of the South Atlantic snapper-grouper fishery, and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.193(l)(1)(i) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and public comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA) finds that the need to immediately implement this action to close the commercial sector for the Other Jacks Complex constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule implementing the AM itself has been subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because of the need to immediately implement this action to protect the species in the Other Jacks Complex, since the capacity of the fishing fleet allows for rapid harvest of the commercial ACL. Prior notice and opportunity for public comment would require time and would potentially result in a harvest well in excess of the established commercial ACL.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 13, 2018.

Margo B. Schulze-Haugen,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–17719 Filed 8–16–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG402

Fisheries of the Exclusive Economic Zone Off Alaska; Sablefish in the West Yakutat District of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of sablefish by vessels using trawl gear in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary because the 2018 total allowable catch of sablefish allocated to vessels using trawl gear in the West Yakutat District of the GOA will be reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), August 14, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2018 total allowable catch (TAC) of sablefish allocated to vessels using trawl gear in the West Yakutat District of the GOA is 240 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 TAC of sablefish allocated to vessels using trawl gear in the West Yakutat District of the GOA will be reached. Therefore, NMFS is requiring that sablefish caught by vessels using trawl gear in the West Yakutat District of the GOA be treated as prohibited species in accordance with § 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting the retention of sablefish by vessels using trawl gear in the West Yakutat District of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 13, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by §§ 679.20 and 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 14, 2018.

Margo B. Schulze-Haugen,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–17798 Filed 8–14–18; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG400

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the West Yakutat District of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2018 total allowable catch of Pacific ocean perch in the West Yakutat District of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), August 14, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2018 total allowable catch (TAC) of Pacific ocean perch in the West Yakutat District of the GOA is 3,371 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 TAC of Pacific ocean perch in the West Yakutat District of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,271 mt, and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the West Yakutat District of the GOA. While this closure remains effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific ocean perch in the West Yakutat District of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 13, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 14, 2018.

Margo B. Schulze-Haugen,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–17797 Filed 8–14–18; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 160
Friday, August 17, 2018

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0769; Airspace Docket No. 18–ASW–10]

RIN 2120–AA66

Proposed Amendment of VOR Federal Airways V–18, V–102, and V–278 in the Vicinity of Guthrie, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend VHF Omnidirectional Range (VOR) Federal airways V–18, V–102, and V–278 in the vicinity of Guthrie, TX. The modifications are necessary due to the planned decommissioning of the Guthrie, TX, VOR/Tactical Air Navigation (VORTAC) navigation aid (NAVAID), which provides navigation guidance for portions of the affected air traffic service (ATS) routes. The Guthrie VORTAC is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before October 1, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2018–0769; Airspace Docket No. 18–ASW–10 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2018–0769; Airspace Docket No. 18–ASW–10) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2018–0769; Airspace Docket No. 18–ASW–10.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order

7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning decommissioning activities for the Guthrie, TX, VORTAC in 2019 as one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082. Although the VOR portion of the Guthrie, TX, VORTAC NAVAID is planned for decommissioning, the Distance Measuring Equipment (DME) portion is being retained. The ATS routes effected by the Guthrie VORTAC are VOR Federal airways V–18, V–102, and V–278.

With the planned decommissioning of the Guthrie VORTAC, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, proposed modifications to V–18, V–102, and V–278 would result in gaps in the route structures. To overcome the gaps, instrument flight rules (IFR) traffic could use adjacent VOR Federal airways V–14 and V–114 between the Lubbock, TX, VORTAC and Wichita Falls, TX, VORTAC; Federal airways V–14, V–114, and V–355 between the Lubbock, TX, VORTAC and Bowie, TX, VORTAC; or Federal airways V–62 and V–66 between the Lubbock, TX, VORTAC and Millsap, TX, VORTAC to circumnavigate the affected area. Additionally, IFR traffic could file point to point through the affected area using fixes that will remain in place, or receive air traffic control (ATC) radar vectors through the area. Visual flight rules pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent VOR Federal airways or ATC services listed previously.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 by modifying VOR Federal airways V–18, V–102, and V–278. The planned decommissioning of the Guthrie, TX, VORTAC has made these actions necessary. The proposed VOR Federal airway changes are outlined below.

V–18: V–18 currently extends between the Guthrie, TX, VORTAC and the Charleston, SC, VORTAC. The FAA proposes to remove the airway segment between the Guthrie, TX, VORTAC and the Millsap, TX, VORTAC. The unaffected portions of the existing airway would remain as charted.

V–102: V–102 currently extends between the Salt Flat, TX, VORTAC and the Wichita Falls, TX, VORTAC. The FAA proposes to remove the airway segment between the Lubbock, TX, VORTAC and the Wichita Falls, TX, VORTAC. The unaffected portions of the existing airway would remain as charted.

V–278: V–278 currently extends between the Texico, NM, VORTAC and the Vulcan, AL, VORTAC. The FAA proposes to remove the airway segment between the Plainview, TX, VOR/DME and the Bowie, TX, VORTAC. The unaffected portions of the existing airway would remain as charted.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11B dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document would be subsequently published in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017 and effective September 15, 2017, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–18 [Amended]

From Millsap, TX; Glen Rose, TX; Cedar Creek, TX; Quitman, TX; Belcher, LA; Monroe, LA; Magnolia, MS; Meridian, MS; Crimson, AL; Vulcan, AL; Talladega, AL; Atlanta, GA; Colliers, SC; to Charleston, SC.

* * * * *

V–102 [Amended]

From Salt Flat, TX; Carlsbad, NM; Hobbs, NM; to Lubbock, TX.

* * * * *

V–278 [Amended]

From Texico, NM; to Plainview, TX. From Bowie, TX; Bonham, TX; Paris, TX; Texarkana, AR; Monticello, AR; Greenville, MS; Sidon, MS; Bigbee, MS; to Vulcan, AL.

Issued in Washington, DC, on August 13, 2018.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018–17767 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 876, 878, and 886

[Docket No. FDA–2018–N–3066]

Medical Devices; Classification of Accessories Distinct From Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: As required by the FDA Reauthorization Act of 2017 (FDARA), the Food and Drug Administration (FDA or Agency) has identified a list of accessories for which the Agency believes general controls alone are sufficient to provide reasonable assurance of safety and effectiveness, so the accessories could be in class I. FDA is publishing this document proposing to classify these accessories into class I and distinct from other devices, as well as seek public comment in accordance with procedures established by FDARA. This document does not represent FDA's final determination with respect to the proposed accessories listed in this document.

DATES: Submit either electronic or written comments on the document by October 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 16, 2018 The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3066 for ''Medical Devices; Classification of Accessories Distinct from Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993–0002, 301–796–5678.

SUPPLEMENTARY INFORMATION:

I. Background

On August 18, 2017, FDARA was signed into law (Pub. L. 115–52). Section 707 of FDARA amended section 513(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, among other amendments, created a process for FDA to propose a list of accessories suitable for distinct classification into class I (see section 513(f)(6)(D)(i) of the FD&C Act (21 U.S.C. 360c(f)(6)(D)(i))). Section 707 of FDARA mandated that FDA make the first such proposal within a year of enactment of FDARA, and FDA is publishing this document in accordance with this statutory mandate.

Section 201(h) of the FD&C Act defines ''device'' to include, among other articles, an ''accessory'' (see 21 U.S.C. 321(h)). As such, all articles that meet the definition of ''device'', including accessories, are regulated under the FD&C Act. Based on sections 201(h) and 513(f)(6) of the FD&C Act, we have described our current thinking on which devices we would generally consider to be accessories in the guidance document, ''Medical Device Accessories—Describing Accessories and Classification Pathways,'' available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672* (''Accessories Guidance''). That

guidance defines an accessory as a ''finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.''

Section 513 of the FD&C Act defines three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval). Some accessories may be granted marketing authorization as part of a submission for another device with which they are intended to be used and in class II or III that, if considered distinctly from another device (such as the parent device), may be suitable for classification into class I if general controls alone are sufficient to provide a reasonable assurance of safety and effectiveness of the accessory.

Section 513(h)(1) defines general controls as the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 of the FD&C Act. These controls include, but are not limited to, provisions related to adulteration and misbranding, registration and listing, records and reports on devices, and good manufacturing practices. The regulations for good manufacturing practices are under 21 CFR part 820, the Quality System regulation. Subject to the exceptions identified in § 820.30(a)(2) (21 CFR 820.30(a)(2)) for specific devices and those automated with computer software, design controls under § 820.30 do not generally apply to a class I device.

This document represents FDA's compliance with FDARA's requirement to identify the first list of accessories suitable for distinct classification into class I. As required by FDARA, we are providing you with the opportunity to provide comment. Once the comment period ends, we will consider the comments and publish in the **Federal Register** a final action classifying such suitable accessories into class I.

II. Factors for Consideration

The classification of each accessory will be based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used (see section 513(f)(6)(A) of the FD&C Act).

In general, we considered an accessory to be eligible for classification into class I distinct from another device if the accessory: (1) Is not for use in supporting or sustaining human life, or of substantial importance in preventing impairment to human health; (2) does not represent a potential unreasonable risk of illness or injury; and (3) general controls alone would be sufficient to provide a reasonable assurance of safety and effectiveness of the accessory.

Note that by regulation, design controls apply to class I devices only if the devices are automated with computer software or are listed under § 820.30(a)(2)(ii). Thus, if an accessory is not automated with computer software but would require design controls to provide reasonable assurance of safety and effectiveness, we did not consider it eligible for classification through the final action based on this document.

You may wish to propose additional accessories as suitable for distinct classification into class I using the factors described above where the accessories are otherwise eligible for classification under section 513(f)(6)(D)(i) of the FD&C Act. Should you wish to propose additional accessories, your comment should briefly explain why you think general controls alone will provide reasonable assurance of safety and effectiveness. Conversely, should you disagree with any of the proposed accessories for class I, your comments should briefly explain why additional regulatory controls, such as premarket review through a 510(k) submission or premarket approval (PMA), are necessary to provide reasonable assurance of safety and effectiveness.

III. Policy Clarification for Classification of Certain Accessories Used in Orthopedic Surgery

Certain manual orthopedic instruments that are for use with other devices in orthopedic surgery meet FDA's definition of an accessory described in the Accessories Guidance. Accordingly, we are clarifying our intended regulatory approach for certain accessories used in orthopedic surgery to distinguish which accessories may be candidates for classification per section 513(f)(6)(D)(i) of the FD&C Act.

Instruments for use in orthopedic surgery vary widely from general manual surgical instruments used to manipulate tissue to more complex accessories specifically designed for use with a parent device/system. Orthopedic manual surgical instruments are classified in § 888.4540 (21 CFR 888.4540), and many ''general use'' instruments fall within this classification. This regulation pertains to ''nonpowered hand-held device[s] intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery.'' These devices are class I, subject to general controls, and exempt from premarket notification procedures, subject to the limitations of exemptions in 21 CFR 888.9. This classification was based upon recommendations provided to FDA by the Orthopedic Device Classification Panel (the Panel) in October 1977 regarding classification of medical devices in commercial distribution before May 28, 1976. The Panel identified the following risks to health for this device type: ''Tissue damage and adverse tissue reaction: Inadequate mechanical properties, such as lack of material strength of the device, may result in device fracture and possible tissue damage and, if fragments of the fractured device remain in the tissue, an adverse tissue reaction may result'' (47 FR 29052).

FDA agreed that class I was appropriate because general controls alone were sufficient to mitigate the risk of tissue damage and adverse tissue reaction associated with inadequate mechanical properties and provide a reasonable assurance of the safety and effectiveness of these devices. Over time, manufacturers have developed and sought to market orthopedic instrumentation with designs unique to a device system, and these types of instruments may present new or different risks compared to inadequate mechanical properties. For example, certain device-specific instruments are accessories and require precise technical specifications or design characteristics to function as intended to support, supplement or augment the parent device, and if not designed appropriately, could cause implant malpositioning or migration. Accordingly, FDA considers design controls (see § 820.30) to be an important element in the regulation of device-specific accessories, among other regulatory controls, to ensure appropriate compatibility between the accessory and the parent device. In contrast, class I orthopedic manual surgical instruments do not require such controls.

Instruments that are ''device-specific,'' or designed for use with a specific parent device/system and thus are accessories, have historically been reviewed in the same premarket submission as the parent device. In an effort to ensure a common understanding as to which orthopedic accessories fall under the existing class I regulation (§ 888.4540), and which devices do not and, therefore, may be candidates for classification under section 513(f)(6)(D)(i) of the FD&C Act,

we propose the following definition: A device-specific orthopedic instrument is considered to be an accessory designed specifically for appropriate implantation or placement of the parent device, based upon unique dimensions, geometry, and/or deployment. In these cases, design specifications are critical to the proper use of the accessory in supporting, supplementing, and/or augmenting the performance of the parent device and/or a specific system. This excludes general use orthopedic instruments that are provided as a part of a system.

It is often necessary for orthopedic instruments to be described in a premarket submission (*e.g.,* 510(k), PMA) to evaluate that the parent device functions as intended. Such orthopedic instruments may be appropriately classified in an existing class I regulation (§ 888.4540) if they do not meet the definition of a device-specific orthopedic accessory above and their risk profile and necessary regulatory controls are commensurate with that of orthopedic manual surgical instruments. If they do meet the definition of a device-specific orthopedic accessory above, then such orthopedic accessories may still be eligible for classification under section 513(f)(6)(D)(ii) of the FD&C Act.

We welcome comments to help identify accessories in other product areas where the classification of the accessory relative to the parent device may be unclear and would benefit from this type of policy clarification.

IV. Proposed List of Accessories That May Be Suitable for Distinct Classification Into Class I

We are proposing the following accessories, which have been granted marketing authorization as part of a premarket submission (*i.e.,* 510(k), De Novo classification request, or PMA) for another device with which they are intended to be used, as suitable for distinct classification into class I (see Table 1). When we publish the final list of accessories based on this list and the factors in section II, we will consider those accessories classified into class I, distinct from other devices, through such action.

We would place each of these accessories in 21 CFR part 876, 878, or 886, as appropriate. Each of these accessories would be class I, exempt from the premarket notification procedures in 21 CFR part 807, subject to the applicable limitations of exemption (*i.e.,* 21 CFR 876.9, 878.9, or 886.9). We intend to make conforming changes to existing classification regulations as appropriate.

TABLE 1—PROPOSED ACCESSORIES FOR CLASSIFICATION INTO CLASS I AND DISTINCT FROM OTHER DEVICES

Current status of accessory		Proposed device type identification
Current classification regulation (21 CFR)	Device type (existing product code)	
876.1075	Gastroenterology-urology accessories to a biopsy instrument (FCG).	Accessories used to remove a specimen of tissue for microscopic examination by cutting or aspiration. This generic type of device includes a syringe for specimen aspiration and a biopsy channel adaptor. This device does not include accessories to biopsy instruments used in other medical specialty areas.
876.3350 and 876.3630	Penile implant surgical accessories (JCW and FHW).	Manual devices designed to be used for surgical procedures associated with the implantation of a penile inflatable implant or penile rigidity implant. This generic type of device includes the cylinder sizer, cylinder insertion tool, connector assembly tool, incision closing tool, corporeal dilator, tubing passer, measurement tool or tape, temporary tubing plug, and hemostat shod tubing.
876.4620	Ureteral stent accessories (FAD) ..	Accessories that aid in the insertion of the ureteral stent that is placed into the ureter to provide ureteral rigidity and allow the passage of urine. This generic type of device includes the stent positioner, wire guide, and pigtail straightener.
876.5010	Biliary stent, drain, and dilator accessories (FGE).	Manual devices that aid in the introduction and connection of biliary stents, drains, or dilators. This generic type of device includes the guiding catheter, pushing catheter, pigtail straightener, flap protector, nasal transfer tube, and drainage connecting tube.
876.5090	Suprapubic catheter accessories (KOB).	Manual devices that are used to facilitate the placement of a suprapubic catheter. This generic type of device includes the introducer, access dilator, and peel-away sheath.
876.5280	Implanted mechanical/hydraulic urinary continence device surgical accessories (EZY).	Manual devices designed to be used for surgical procedures associated with the implantation of an implanted mechanical/hydraulic urinary continence device. This generic type of device includes the measurement tool or tape, connector assembly tool, temporary tubing plug, incision closing tool, tubing passer, and hemostat shod tubing.
878.5070	Air-handling apparatus accessory (FYD).	Supplementary device that is intended to be used with an air-handling apparatus for a surgical operating room. This device provides an interface between the components of the device or can be used to switch electrical power. This generic type of device includes fittings, adapters, couplers, remote switches, and footswitches.
No corresponding CFR Section	Corneal inlay inserter handle (LQE).	Hand-held device intended to be used as an accessory to a corneal inlay inserter. The device extends the length of the inlay inserter to aid in delivering the inlay implant.

V. Paperwork Reduction Act of 1995

This document refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA

regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
"De Novo Classification Process (Evaluation of Automatic Class III Designation)".	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
"Medical Device Accessories—Describing Accessories and Classification Pathways for New Accessory Types".	Medical Device Accessories	0910–0823

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17731 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–131186–17]

RIN 1545–BO05

Proposed Removal of Temporary Regulations on a Partner's Share of a Partnership Liability for Disguised Sale Purposes; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations concerning how partnership liabilities are allocated for disguised sale purposes.

DATES: The public hearing, originally scheduled for August 21, 2018 at 10:00 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Regina Johnson of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Tuesday, June 19, 2018 (83 FR 28397) announced that a public hearing was scheduled for August 21, 2018 at 10:00 a.m. in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW, Washington, DC. The subject of the public hearing is under section 707 of the Internal Revenue Code.

The public comment period for these regulations expired on July 19, 2018. The notice of proposed rulemaking and notice of hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be discussed. The outline of topics to be discussed was due by August 3, 2018. As of August 3, 2018, no one has requested to speak. Therefore, the public hearing scheduled for August 21, 2018 at 10:00 a.m. is cancelled.

Martin V. Franks,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2018–17792 Filed 8–16–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID DOD–2016–HA–0112]

RIN 0720–AB69

TRICARE; Extended Care Health Option (ECHO) Respite Care

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: This proposed rule requests public comment on a proposed revision to the TRICARE Extended Care Health Option (ECHO) respite care benefit. Under the current program, TRICARE beneficiaries enrolled in ECHO are eligible for 16 hours of respite care per month in any month during which the beneficiary receives another ECHO authorized benefit (other than the EHHC benefit). This proposed rule seeks to eliminate the concurrent ECHO benefit requirement and allow beneficiaries enrolled in ECHO to receive a maximum of 16 hours of respite care per month, regardless of whether another ECHO benefit is received in the same month.

DATES: Written comments received at the address indicated below by October 16, 2018 will be accepted.

ADDRESSES: You may submit comments, identified by docket number or Regulatory Information Number (RIN) and title, by either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Trish Reilly, Defense Health Agency, TRICARE Clinical Policy Division, telephone (619) 236–5332.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule seeks to amend the TRICARE ECHO program regulation to expand beneficiary access to ECHO respite care services. This proposed rule, if implemented, would eliminate the concurrent ECHO benefit requirement and allow beneficiaries enrolled in ECHO to receive a maximum of 16 hours of respite care per month, regardless of whether another ECHO benefit is received in the same month.

This regulation is proposed under the authority of 5 U.S.C. 301 which allows

the Secretary of Defense to prescribe regulations for the government of DoD and 10 U.S.C. 1079(d) and (e), which directs the Secretary of Defense to establish a program to provide extended benefits for eligible active duty dependents, which may include the provision of comprehensive health care services, including case management services, to assist in the reduction of the disabling effects of a qualifying condition of an eligible dependent. The Department is authorized to provide ''respite care for the primary caregiver of the eligible dependent'' as one of the specifically enumerated extended benefits under the ECHO program pursuant to 10 U.S.C. 1079(e)(6). The ECHO program has been implemented through regulation at 32 CFR 199.5.

B. Summary of the Major Provisions of the Proposed Rule

Per 32 CFR 199.5(c)(7), ECHO beneficiaries are eligible for a maximum of 16 hours of respite care per month in any month during which the beneficiary otherwise receives an ECHO benefit(s). This requirement for a concurrent ECHO benefit was originally implemented to ensure optimal medical management of the beneficiary's ECHO-qualifying condition. TRICARE proposes to eliminate the requirement for a beneficiary to receive a concurrent ECHO benefit in order to qualify for respite care. This change will expand access to respite care services (as recommended by the Military Compensation and Retirement Modernization Commission (MCRMC)), allowing families to access those hours without receiving another ECHO benefit during the same month the respite care is received.

C. Expected Costs

The proposed rule is estimated to cost the Department of Defense $5.7 million annually (based on FY17 data). If the proposed rule is implemented, it is anticipated that 2,924 ECHO beneficiaries will participate in the respite care program at an average cost of $1,937 per beneficiary (this number does not include homebound beneficiaries who receive respite care under the ECHO Home Health Care (EHHC) program). These beneficiaries are already in ECHO and, therefore, have completed all registration requirements. This expansion of the benefit requires nothing additional from the beneficiaries and will not result in an increased burden to the public. Currently, beneficiaries may not access ECHO respite care services if they are not utilizing another ECHO benefit during the same month, and this rulemaking action will eliminate this barrier to care.

II. Discussion of the Proposed Rule

A. Background

Military families face unique challenges in caring for family members with special medical or educational needs that are complicated by frequent moves and repeated deployments. Support for these families involves a multi-faceted system coordinated across numerous functional areas within the Department of Defense and Military Services to include: The Military Health System (MHS); military personnel support services; housing programs; dependents' education programs; child and youth services; morale, welfare, and recreation activities; and community support activities, among others.

The Exceptional Family Member Program (EFMP) is designed to identify active duty military family members with special medical and/or educational needs to ensure coordination of care and continuity of benefits throughout the military assignment and relocation process. EFMP provides additional support to these active duty military families to alleviate some of the challenges associated with frequent family relocations and deployments of their sponsoring service member as required by military duties. EFMP family support services have traditionally included respite care provided by certified day care providers in order to provide temporary relief to military family members who are responsible for the regular care of dependent family members with special needs. The Office of the Under Secretary of Defense for Personnel and Readiness published a proposed rule entitled ''Exceptional Family Member Program (EFMP)'' in the **Federal Register** (80 FR 76881–76889) on December 11, 2015, that provides additional details. The Assistant Secretary of Defense for Health Affairs is tasked with advising on the availability of specialized medical services to families with special needs in the Military Health System and ensuring there is a medical case management program to support eligible beneficiaries' medical needs.

Active Duty families enrolled in EFMP may be eligible, based on qualifying conditions, for TRICARE Extended Health Care Option (ECHO) expanded benefits. ECHO is a supplemental program to the TRICARE Basic Program that provides eligible Active Duty Family Members extended benefits to include comprehensive health care services (including services necessary to maintain, or minimize or prevent deterioration of function of the patient) and case management services with respect to the qualifying condition which include serious physical disabilities and extraordinary physical or psychological conditions as defined in 32 CFR 199.2. The purpose of ECHO is to provide an additional financial resource for an integrated set of services and supplies designed to assist in the reduction of the disabling effects of the beneficiary's qualifying condition. The ECHO program provides coverage for medical, habilitative, and rehabilitative services and supplies not covered under the TRICARE Basic Program; durable medical equipment, including adaptation and maintenance; assistive technologies devices and training to use the devices; comprehensive home health care services (*e.g.*, ventilator support, medication administration); and other services to support eligible family members.

The final rule implementing the ECHO Program (which was previously called the Program for Persons with Disabilities (PFPWD) from 1997–2004, and before that the Program for the Handicapped (PFTH) from origination in 1966–1997), amended the TRICARE regulations governing the PFPWD and was published in the **Federal Register** (69 FR 44947) on July 28, 2004.

ECHO-registered beneficiaries who are not receiving ECHO Home Health Care (EHHC) services currently are eligible to receive a maximum of 16 hours of respite care in any calendar month in which they also receive any other ECHO authorized benefit other than the EHHC benefit. Respite care consists of providing skilled and non-skilled health care services for the covered beneficiary such that in the absence of the primary caregiver, management of the beneficiary's ECHO qualifying condition and safety are provided. In order to assure the quality of care for beneficiaries enrolled in ECHO, all ECHO respite care services must be provided by Medicare or Medicaid certified Home Health Agencies (HHAs) who have in effect at the time of services a valid agreement to participate in the TRICARE program. The ECHO respite care program (which provides health care services by a home health agency) should not be considered a substitute for EFMP respite care (which provides day care services by a certified day care provider), because not all EFMP family members qualify for ECHO or require specific health care services in the absence of the primary caregiver. The goal is to ensure that these families have access to the appropriate services to meet their specific needs while still ensuring

fiscally prudent expenditures of appropriated funds.

In addition to EFMP respite care and ECHO respite care, there is a third type of respite care, EHHC respite care. The EHHC benefit provides coverage of home health care services and respite care services for ECHO eligible beneficiaries who require more than intermittent or part-time home health services covered under the TRICARE Basic Program. This would include ventilator-dependent beneficiaries and others with extraordinary physical conditions. EHHC beneficiaries whose plan of care includes frequent interventions by the primary caregiver(s) (*e.g.,* frequent suctioning, tube feeding, medication administration etc.) are eligible for respite services under EHHC in lieu of the ECHO general respite benefit. EHHC respite care may include a maximum of 8 hours per day, 5 days per week, by a TRICARE-authorized home health agency. The Department is not proposing any changes to the robust EHHC respite care benefit as part of this proposed rule, but includes a description of the program in order to clarify the full spectrum of respite care programs available to active duty military families with special needs.

B. Proposed Change to the ECHO Respite Care Benefit

The Department of Defense remains committed to supporting Service members and their family members with special needs. Together, the Office of Community Support for Military Families with Special Needs, the Services, and the MHS, are working to enhance and improve support for these families, including everything from complex medical management to non-clinical case management and family support services. The Department is also committed to eliminating unnecessary requirements that act as barriers to care. Consistent with these principles, the Department is proposing this specific amendment to the existing regulations governing the ECHO program.

The requirement to receive a concurrent ECHO benefit in order to be entitled to ECHO respite care was originally imposed as a medical management tool. We now conclude that this specific requirement is no longer necessary and may serve as an inappropriate barrier to receipt of respite services for some families. Even in those months where no other ECHO services are provided (where all needed care may already be covered under the Basic Program or under demonstration authority), there may still be some health care services rendered to the beneficiary enrolled in ECHO by the primary caregiver for which respite care provided by a home health agency is warranted.

We note that the January 2015 Report of the MCRMC cited a need to improve support for military members with special needs dependents and made a number of recommendations. We have already implemented or are taking steps to implement several of their specific recommendations, including the recommendation to allow families to access ECHO respite care without receiving another ECHO benefit during the same month that respite care is received which is proposed in this rule. The Department is still studying some of the other recommendations that were made in order to identify and implement, as appropriate, ECHO enhancements that will be of greatest benefit to our beneficiaries. Finally, we believe some of the recommendations fall outside the purview of the ECHO program specifically, and the Military Health System in general, and are more appropriately directed to the Office of Community Support for Military Families with Special Needs, including the provision of respite care that does not involve health care services (*i.e.,* EFMP respite).

We propose that elimination of the requirement for a simultaneous ECHO benefit will provide maximum flexibility to families without sacrificing the goal of ensuring the safe and effective management of the beneficiary's ECHO qualifying condition. First, we note that TRICARE beneficiaries with complex medical needs may receive case management services including medical management, disease management and chronic care coordination, under the TRICARE Basic Program, regardless of whether the beneficiary is an ECHO eligible beneficiary. As the TRICARE program has evolved over time, continuing to require an ECHO eligible beneficiary to receive a concurrent ECHO benefit as a medical management tool is no longer necessary. Based on our current program structure, beneficiaries should already be receiving medical management services and the receipt of any ECHO benefit, including ECHO respite care, provides an additional opportunity to ensure the safe and effective management of the beneficiary's qualifying condition. Furthermore, in accordance with 32 CFR 199.5(h)(3), all ECHO benefits, including ECHO respite care, require authorization prior to receipt of such benefits. Paragraph (i) discusses required documentation as a prerequisite to authorizing ECHO benefits. As a practical matter, the home health agency providing the respite services must document the health care services needed by the ECHO beneficiary in the absence of the family caregiver and the schedule for the services during the provision of respite care in order to ensure an appropriately trained provider is sent and the beneficiary's needs are met. If this regulatory change is enacted, after public comment, additional details regarding required documentation to be provided to the Managed Care Support Contractor and home health agency for authorization of ECHO respite services will be published in the TRICARE Policy Manual available at *http://manuals.tricare.osd.mil.* We believe that this approach will provide greater flexibility and eliminate unnecessary barriers for families to access to ECHO respite care services while still ensuring the safe and effective medical management of the beneficiary's medical condition(s).

III. Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year). This rulemaking is neither ''economically significant'' as measured by the $100 million threshold, nor is it otherwise significant.

Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs''

This proposed rule is not expected to be an E.O. 13771 regulatory action because it is not significant under E.O. 12866.

Congressional Review Act, 5 U.S.C. 804(2)

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule.

A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. This proposed rule is not a major rule under the Congressional Review Act.

Public Law 96–354, ''Regulatory Flexibility Act'' (RFA), (Title 5, U.S.C., Sec. 601)

The Regulatory Flexibility Act requires that each Federal agency analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This proposed rule is not an economically significant regulatory action, and it will not have a significant impact on a substantial number of small entities. Therefore, this rule is not subject to the requirements of the RFA.

Public Law 104–4, Sec. 202, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $140 million. This final rule will not mandate any requirements for state, local, or tribal governments or the private sector.

Public Law 96–511, ''Paperwork Reduction Act'' (Title 44, U.S.C., Chapter 35)

This rule will not impose significant additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3502–3511). Existing information collection requirements of the TRICARE and Medicare programs will be utilized. TRICARE ECHO respite care providers will be coding and filing claims in the same manner as they currently are with TRICARE.

Executive Order 13132, ''Federalism''

This rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of powers and responsibilities among the various levels of Government. Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is proposed to be amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Revise § 199.5(c)(7) introductory text to read as follows:

§ 199.5 TRICARE Extended Care Health Option (ECHO).

* * * * *

(c) * * *

(7) *Respite care.* TRICARE beneficiaries enrolled in ECHO are eligible for a maximum of 16 hours of respite care per month. Respite care in defined is § 199.2. Respite care services will be provided by a TRICARE-authorized home health agency and will be designed to provide health care services for the covered beneficiary, and not baby-sitting or child-care services for other members of the family. The benefit will not be cumulative, that is, any respite hours not used in one month will not be carried over or banked for use on another occasion.

* * * * *

Dated: August 9, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–17463 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0577]

RIN 1625–AA08

Special Local Regulation; Choptank River, Talbot and Dorchester Counties, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish special local regulations for certain navigable waters of the Choptank River. This action is necessary to provide for the safety of life on these waters near Oxford, MD, from October 7, 2018, through October 15, 2018, during a sailboat regatta. This proposed rule would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or the Coast Guard Patrol Commander. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before September 17, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0577 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Ronald Houck, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
PATCOM Patrol Commander
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On February 13, 2018, the Tred Avon Yacht Club of Oxford, MD, notified the Coast Guard through submission of a marine event application that it is planning to conduct a sailboat regatta from October 5, 2018, through October 15, 2018, the 2018 Star World Championship. Race activities on navigable waters are planned each afternoon of the regatta beginning on October 7th. The regatta consists of approximately 100 2-person, 23-foot long International Star Class sailboats. These vessels will operate along a designated and marked 2.5 nautical mile long course. The course is located on the Choptank River, in Talbot and Dorchester Counties, near Oxford, MD. Hazards from the sailboat regatta include participants operating within and adjacent to a designated navigation channel and interfering with vessels intending to operate within that channel, as well as injury to persons and damage to property that involve

vessel mishaps during sailboat regattas conducted on navigable waters. The Captain of the Port Maryland-National Capital Region (COTP) has determined that potential hazards associated with the sailboat regatta would be a safety concern for anyone intending to operate in or near the race area.

The purpose of this rulemaking is to protect event participants, spectators, and transiting vessels on waters in and near the race area before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1233, which authorizes the Coast Guard to establish special local regulations to promote the safety of life on navigable waters during regattas or marine parades.

III. Discussion of Proposed Rule

The COTP Maryland-National Capital Region is proposing to establish special local regulations that would be enforced from 11:30 a.m. until 5:30 p.m., each day, from October 7, 2018, through October 15, 2018. The proposed regulated area is rectangular in shape, measuring approximately six nautical miles in length by four nautical miles in width. The area would cover all navigable waters of the Choptank River, within an area bounded by the following coordinates: commencing at latitude 38°41′39.02″ N, longitude 076°11′19.18″ W, thence south to latitude 38°37′28.68″ N, longitude 076°11′19.18″ W, thence west to latitude 38°37′28.68″ N, longitude 076°18′18.35″ W, thence north to latitude 38°41′39027″ N, longitude 076°18′18.35″ W, thence east to point of origin, located near Oxford, MD.

This proposed rule provides additional information about an area within the regulated area, the ''Race Area'', and its definition.

The proposed duration of the special local regulations and size of the regulated area are intended to ensure the safety of life on these navigable waters before, during, and after races, scheduled from noon until 5 p.m. on October 7, 8, 9, 10, 11, 12, 13, 14, and 15, 2018. The COTP and PATCOM would have authority to forbid and control the movement of vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area would be required to immediately comply with directions given by the COTP or PATCOM. If a person or vessel fails to follow such directions, the Coast Guard may expel them from the area, issue them a citation for failure to comply, or both.

Except for 2018 Star World Championship participants, a vessel or person would be required to get permission from the COTP or PATCOM before entering the regulated area. Vessel operators can request permission to enter and transit through the regulated area by contacting the PATCOM on VHF–FM channel 16. Vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so. A person or vessel not registered with the event sponsor as a participant or assigned as official patrols would be considered a spectator. Official Patrols are any vessel assigned or approved by the Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

If permission is granted permission by the COTP or PATCOM, a person or vessel would be allowed to enter the regulated area or pass directly through the regulated area as instructed. Vessels would be required to operate at a safe speed that minimizes wake while within the regulated area. Official patrol vessels will direct spectator vessels while within the regulated area. Vessels would be prohibited from loitering within the navigable channel.

The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, duration and location of the regulated area. Vessel traffic would be able to safely transit around this regulated area, which would impact a small designated area of the Choptank River for 54 hours. The Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the status of the regulated area. Moreover, the rule would allow vessels to seek permission to enter the regulated area, and vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves implementation of regulations within 33 CFR part 100 applicable to organized marine events on the navigable waters of the United States. The temporary regulated area that would be enforced daily during a nine-day period during the sailboat regatta.. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Memorandum For Record for Categorically Excluded Actions supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 33 CFR 1.05–1.

■ 2. Add § 100.501T05–0577 to read as follows:

§ 100.501T05–0577 Special Local Regulation; Choptank River, Talbot and Dorchester Counties, MD.

(a) *Definitions.* As used in this section:

Captain of the Port (COTP) Maryland-National Capital Region means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region or any Coast Guard commissioned, warrant or petty officer who has been authorized by the COTP to act on the COTP's behalf.

Coast Guard Patrol Commander (PATCOM) means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Commander, Coast Guard Sector Maryland-National Capital Region.

Official Patrol means a vessel assigned or approved by the Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

Participant means a person or vessel registered with the event sponsor as participating in the 2018 Star World Championship regatta or otherwise designated by the regatta's sponsor as having a function tied to the event.

Spectator means a person or vessel not registered with the event sponsor as a participant or assigned as an official patrol.

(b) *Locations.* All coordinates reference Datum NAD 1983.

(1) *Regulated area.* All navigable waters of the Choptank River, bounded by a line connecting the following coordinates: Commencing at latitude 38°41′39.02″ N, longitude 076°11′19.18″ W, thence south to latitude 38°37′28.68″ N, longitude 076°11′19.18″ W, thence west to latitude 38°37′28.68″ N, longitude 076°18′18.35″ W, thence north to latitude 38°41′39027″ N, longitude 076°18′18.35″ W, thence east to point of origin, located near Oxford, MD. The

following location is within the regulated area:

(2) *Race Area.* The race area is a circle in shape with its center located at position latitude 38°39′48.00″ N, longitude 076°15′03.42″ W. The area is bounded by a line measuring approximately 2.5 nautical miles in diameter.

(c) *Special local regulations:* (1) The COTP Maryland-National Capital Region or PATCOM may forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area must immediately comply with the directions given by the patrol. Failure to do so may result in the Coast Guard expelling the person or vessel from the area, issuing a citation for failure to comply, or both. The COTP Maryland-National Capital Region or PATCOM may terminate the event, or a participant's operations at any time the COTP Maryland-National Capital Region or PATCOM believes it necessary to do so for the protection of life or property.

(2) Except for participants and vessels already at berth, a person or vessel within the regulated area at the start of enforcement of this section must immediately depart the regulated area.

(3) A spectator must contact the PATCOM to request permission to either enter or pass through the regulated area. The PATCOM, and official patrol vessels enforcing this regulated area, can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz) and channel 22A (157.1 MHz). If permission is granted, the spectator may enter the regulated area or pass directly through the regulated area as instructed by PATCOM. A vessel within the regulated area must operate at a safe speed that minimizes wake. A spectator vessel must not loiter within the navigable channel while within the regulated area.

(4) Only participant vessels and official patrol vessels are allowed to enter the race area.

(5) A person or vessel that desires to transit, moor, or anchor within the regulated area must first obtain authorization from the COTP Maryland-National Capital Region or PATCOM. A person or vessel seeking such permission can contact the PATCOM on Marine Band Radio, VHF–FM channel 16 (156.8 MHz).

(6) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio announcing specific event date and times.

(d) *Enforcement periods.* This section will be enforced during each of the following times:

(1) From 11:30 a.m. until 5:30 p.m. on October 7, 2018.

(2) From 11:30 a.m. until 5:30 p.m. on October 8, 2018.

(3) From 11:30 a.m. until 5:30 p.m. on October 9, 2018.

(4) From 11:30 a.m. until 5:30 p.m. on October 10, 2018.

(5) From 11:30 a.m. until 5:30 p.m. on October 11, 2018.

(6) From 11:30 a.m. until 5:30 p.m. on October 12, 2018.

(7) From 11:30 a.m. until 5:30 p.m. on October 13, 2018.

(8) From 11:30 a.m. until 5:30 p.m. on October 14, 2018.

(9) From 11:30 a.m. until 5:30 p.m. on October 15, 2018.

Dated: August 13, 2018.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2018–17762 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0225]

RIN 1625–AA08

Special Local Regulation; Breton Bay, Leonardtown, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish special local regulations for certain waters of the Breton Bay. This action is necessary to provide for the safety of life on these navigable waters of Breton Bay, at Leonardtown, MD, on October 6, 2018 and October 7, 2018. This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before September 17, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0225 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST2 Dane Grulkey, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2570, email *Dane.M.Grulkey@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On January 22, 2018, the Southern Maryland Boat Club notified the Coast Guard that they will be conducting their fall regatta from 8 a.m. to 5 p.m. on October 6, 2018, and October 7, 2018. The regatta consists of approximately 40 boats, participating in an exhibition of vintage outboard racing V-hull boats; the regatta is not a competition but rather a demonstration of the vintage race craft. Hazards from the regatta include vessels reaching speeds of 90 mph and include risks of injury or death resulting from near or actual contact among participant vessels and spectator vessels or waterway users if normal vessel traffic were to interfere with the event. The COTP Maryland-National Capital Region has determined that potential hazards associated with the regatta would be a safety concern for anyone intending to operate within specified waters.

The purpose of this rulemaking is to protect marine event participants, spectators and transiting vessels on specified waters of Breton Bay before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1233, which authorize the Coast Guard to establish and define special local regulations.

III. Discussion of Proposed Rule

The COTP Maryland-National Capital Region proposes to establish special local regulations to be enforced from 7:30 a.m. to 5:30 p.m. on October 6, 2018, and from 7:30 a.m. to 5:30 p.m. on October 7, 2018. The regulated area would include all navigable waters within Breton Bay, from shoreline to shoreline, within an area bound by a line drawn along latitude 38°16′43″ N;

and bounded to the west by a line drawn along longitude 76°38′29.5″ W, located at Leonardtown, MD. This rule provides additional information about designated areas within the regulated area, including ''Race Area'', ''Buffer Zone'' and ''Spectator Area(s).'' The duration of the regulated area is intended to ensure the safety of event participants and vessels within the specified navigable waters before, during, and after the regatta, scheduled to occur between 8 a.m. to 5 p.m. each day of the event. Except for participants, no vessel or person would be permitted to enter the regulated area without obtaining permission from the COTP Maryland-National Capital Region or the Coast Guard Patrol Commander.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size and duration of the regulated area, which would impact a small designated area of Breton Bay during October 6–7, 2018, for a total of 18 hours. The Coast Guard would issue a Broadcast Notice to Mariners via marine band radio VHF–FM channel 16 about the status of the regulated area. Moreover, the rule would allow vessel operators to request permission to enter the regulated area for the purpose of safely transiting the regulated area if deemed safe to do so by the Coast Guard Patrol Commander.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV–A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the creation of a special local regulation to be enforced a total of 18 hours over two days. This category of marine event water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, canoe and sail board racing. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Memorandum For Record for Categorically Excluded Actions is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER**

INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.501T05–0225 to read as follows:

§ 100.501T05–0225 Special Local Regulation; Breton Bay, Leonardtown, MD.

(a) *Definitions.* (1) *Captain of the Port Maryland-National Capital Region* means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region or a Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Commander, Coast Guard Sector Maryland-National Capital Region.

(3) *Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(4) *Spectator* means any person or vessel not registered with the event sponsor as a participant or an official patrol vessel.

(5) *Participant* means any person or vessel participating in the Southern Maryland Boat Club Fall Regatta event under the auspices of the Marine Event Permit issued to the event sponsor and approved by Commander, Coast Guard Sector Maryland-National Capital Region.

(b) *Regulated area.* All coordinates reference Datum NAD 1983.

(1) *Coordinates:* The following location is a regulated area: All navigable waters within Breton Bay, MD, immediately adjacent to Leonardtown, MD shoreline, from shoreline to shoreline, within an area bounded to the east by a line drawn along latitude 38°16′43″ N and bounded to the west by a line drawn along longitude 076°38′29.5″ W, located at Leonardtown, MD.

(2) *Race area:* Located within the waters of Breton Bay, MD in an area bound by a line commencing at position latitude 38°17′07.2″ N, longitude 076°38′17.3″ W, thence southeast to latitude 38°16′55.3″ N, longitude 076°37′48″ W, thence southwest to latitude 38°16′50.1″ N, longitude 076°37′51.3″ W, thence northwest to latitude 38°17′01.9″ N, longitude 076°38′21″ W, thence northeast to point of origin.

(3) *Buffer zone:* Located within the waters of Breton Bay, MD. The area surrounds the entire race area described in the preceding paragraph of this section. This area is rectangular in shape and provides a buffer of approximately 125 yards around the perimeter of the race area. The area is bounded by a line commencing at position latitude 38°17′12″ N, longitude 076°38′19.6″ W; thence southeast to latitude 38°16′57″ N, longitude 076°37′40.5″ W; thence southwest to latitude 38°16′44.8″ N, longitude 076°37′48.2″ W; thence northwest to latitude 38°17′00.2″ N, longitude 076°38′27.8″ W; thence northeast to point of origin.

(4) *Spectator areas:* (i) *Spectator area A.* The area is bounded by a line commencing at position latitude 38°16′52.1″ N, longitude 076°38′14.2″ W; thence northeast to latitude 38°16′54″ N, longitude 076°38′12.5″ W; thence southeast to latitude 38°16′48.6″ N, longitude 076°37′59.3″ W; thence south to latitude 38°16′47.4″ N, longitude 076°37′59.3″ W; thence northwest along the shoreline to point of origin.

(ii) *Spectator area B.* The area is bounded by a line commencing at position latitude 38°16′59.1″ N, longitude 076°37′45.6″ W; thence southeast to latitude 38°16′57.1″ N, longitude 076°37′40.2″ W; thence southwest to latitude 38°16′54.3″ N, longitude 076°37′41.9″ W; thence southeast to latitude 38°16′51.8″ N, longitude 076°37′36.4″ W; thence northeast to latitude 38°16′55.2″ N, longitude 076°37′34.2″ W; thence northwest to latitude 38°16′59.2″ N, longitude 076°37′37.2″ W; thence west to latitude 38°17′01.7″ N, longitude 076°37′43.7″ W; thence south to point of origin.

(iii) *Spectator area C.* The area is bounded by a line commencing at position latitude 38°16′47.2″ N, longitude 076°37′54.8″ W; thence south to latitude 38°16′43.3″ N, longitude 076°37′55.2″ W; thence east to latitude 38°16′43.2″ N, longitude 076°37′47.8″ W; thence north to latitude 38°16′44.7″ N, longitude 076°37′48.5″ W; thence northwest to point of origin.

(c) *Special local regulations:* (1) The Captain of the Port Maryland-National Capital Region or the Coast Guard Patrol Commander may forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area shall immediately comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(2) The operator of any vessel in the regulated area shall:

(i) Stop the vessel immediately when directed to do so by any Official Patrol and then proceed only as directed.

(ii) All persons and vessels shall comply with the instructions of the Official Patrol.

(iii) When authorized to transit the regulated area, all vessels shall proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the race course.

(3) The Coast Guard Patrol Commander may terminate the event, or the operation of any participant, at any time it is deemed necessary for the protection of life or property.

(4) The Race Area is an area described by a line bounded by coordinates provided in latitude and longitude that outlines the boundary of a Race Area within the regulated area defined in paragraph (b)(2) of this section. The actual placement of the race course will be determined by the marine event sponsor but must be located within the designated boundaries of the Race Area. Only participants and official patrol vessels are allowed to enter the Race Area.

(5) The Buffer Zone is an area that surrounds the perimeter of the Race Area within the regulated area defined in paragraph (b)(3) of this section. The purpose of a Buffer Zone is to minimize potential collision conflicts with participants and spectators or nearby transiting vessels. This area provides separation between the Race Area and Spectator Area or other vessels that are operating in the vicinity of the regulated area defined in paragraph (b)(1) of this section. Only participants and official patrol vessels are allowed to enter the Buffer Zone.

(6) The Spectator Area is an area described by a line bounded by coordinates provided in latitude and longitude that outlines the boundary of a spectator area within the regulated area defined in paragraph (b)(4) of this section. Spectators are only allowed inside the regulated area if they remain within the Spectator Area. All spectator vessels shall be anchored or operate at a no-wake speed while transiting within the Spectator Area. Spectators may contact the Coast Guard Patrol Commander to request permission to either enter the Spectator Area or pass through the regulated area. If permission is granted, spectators must enter the Spectator Area or pass directly through the regulated area as instructed at safe speed and without loitering.

(7) The Coast Guard Patrol Commander and official patrol vessels enforcing this regulated area can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz) and channel 22A (157.1 MHz). Persons and vessels desiring to transit, moor, or anchor within the regulated area must obtain authorization from Captain of the Port Maryland-National Capital Region or Coast Guard Patrol Commander. The Captain of the Port Maryland-National Capital Region can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard Patrol Commander can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz).

(8) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio.

(d) *Enforcement periods.* This section will be enforced from 7:30 a.m. to 5:30 p.m. on October 6, 2018 and from 7:30 a.m. to 5:30 p.m. on October 7, 2018.

Dated: August 13, 2018.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2018–17763 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–0AR–2018–0530; FRL–9982–03—Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Colorado; Motor Vehicle Inspection and Maintenance Program and Associated Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of two State Implementation Plan (SIP) revisions submitted by the State of Colorado. The revisions involve amendments to Colorado's Regulation Number 11, ''Motor Vehicle Emissions Inspection Program.'' The revisions enhance the use of Regulation Number 11's Clean Screen Program, allow self-inspecting vehicle fleets to use the On-Board Diagnostics (OBD) testing procedure, provide corrections to the Low Emitter Index (LEI) component of the Clean Screen Program, clarify existing provisions, correct administrative errors, delete obsolete language, establish inspection procedures for when emission control equipment tampering is detected, and make several other minor associated revisions. These actions are being taken under section 110 of the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 17, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2018–0530, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. The EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Tim Russ, Air Program, EPA, Region 8, Mail-code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6479, or *russ.tim@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

I. Background

Colorado's Regulation Number 11 (hereafter ''Reg. No. 11'') addresses the implementation of the State's motor vehicle inspection and maintenance (I/M) program. The I/M program consists of an ''enhanced'' component that

utilizes a dynamometer-based EPA IM240 [1] test for 1982 and newer light-duty gasoline vehicles and a two-speed idle test (TSI) [2] for 1981 and older light-duty gasoline vehicles. To improve motorist convenience and reduce program implementation costs, the State also administers a remote sensing-based ''Clean Screen'' component of the I/M program. Remote sensing is a method for measuring vehicle emissions, while simultaneously photographing the license plate, when a vehicle passes through infrared or ultraviolet beams of light. Owners of vehicles meeting the Clean Screen criteria are notified by the County Clerk that their vehicles have passed the motor vehicle inspection process and are exempt from their next regularly scheduled IM240 test.

The Clean Screen program component of Colorado's Reg. No. 11 was originally approved, for implementation in the Metro-Denver area, with the Denver carbon monoxide redesignation to attainment and maintenance plan (see: 66 FR 64751, December 14, 2001). The Clean Screen criteria that was approved in 2001 by the EPA required two valid passing remote sensing readings on different days or from different sensors, that met the applicable emissions reading requirements in Part F of Reg. No. 11, within a 12-month period to clean-screen a vehicle (see 66 FR 44097, August 22, 2001).

Colorado revised Reg. No. 11 to expand the definition and requirements for a ''clean-screened vehicle'' to also include vehicles identified as low emitting vehicles in the state-determined LEI which have one passing remote sensing reading prior to the vehicle's registration renewal date. As part of the LEI process, the Colorado Department of Public Health and Environment, Air Pollution Control Division (APCD) develops an LEI on or before July 1 of each year. The LEI is based on a tabulation of the previous calendar year's IM240 inspection program results for specific make, model, and model year vehicles that passed IM240 vehicle inspections the previous year at a minimum rate of 98%.

Beginning in January 2015, Colorado also began implementing an OBD test for certain model year vehicles. An OBD I/M test essentially means the electronic retrieval, by connecting an OBD test analyzer to the computer port data link in the vehicle, of information from a vehicle's computer system. The electronic information retrieved includes stored readiness status, diagnostic trouble codes (DTC), malfunction indicator light (MIL) illumination and other data. If emission related DTCs are present or the MIL is commanded on, that would indicate an emissions related malfunction.[3]

In addition, Colorado also extended the Reg. No. 11 exemption from I/M testing for new vehicles from 4 years to 7 years. This revision was based on Colorado's gathering of emissions testing information over a period of several years, which demonstrated that historically new and newer vehicles typically did not fail the IM240 or OBD emissions test within the first seven years of the vehicle's life.

II. What action is the Agency taking?

As explained below, the EPA is proposing to approve various revisions to Colorado's Reg. No. 11 that the State submitted to the EPA on February 20, 2015, and on May 14, 2018. Most of the revisions involve minor updates to several sections of Reg. No. 11 and the deletion of obsolete language. More specifically, the substantive SIP revisions involve:

a. Addition of a definition of ''Tampering'' to Part A.II.

b. Revisions to Part B.IV.B to require span gases to be labelled in accordance with Attachment VI of Appendix A.

c. Revisions to Part A.II.16 and Part C.XII. (A.3 and C.2) to increase clean screening efficiency by removing the requirement that two qualifying clean screen observations must be made on different days or at different locations.

d. Revisions to Part C.II.B.4 to remove incomplete and obsolescent qualifying criteria for certain vehicles that are unable to be tested on the IM240 chassis dynamometer.

e. Revisions to Part C.II.C to allow self-inspecting gasoline vehicle fleets to utilize the more effective and more convenient OBD II testing procedure on all 1996 model year and newer vehicles.

f. Revisions to Part C.II.C.3 regarding acceptable readiness criteria for OBD sensors and monitors.

g. Revisions to Part C.II.C.9 and C.10 regarding I/M240 tests and tampering associated with OBD tests.

h. Revisions to Part C.VIII and IX to clarify and modernize provisions for issuance of emissions repair, diagnostic and economic hardship waivers.

i. Revisions to Part D.I.B. 5, 6, and 7 to remove obsolete language regarding dwell meters, timing lights, and idle adjustment.

j. Revisions to Part F.VI.B, the roadside remote sensing clean screen LEI, to allow for greater utilization of this component of the I/M program.

k. Revisions to Part F.VII with regard to OBD testing criteria.

l. Revisions to Appendix A, Attachment IV, Section 2.2, and the deletion of Appendix B in its entirety such as to remove obsolete specifications and procedures for vehicle inspection analyzer calibration gasses.

m. Corrections of typographical, grammatical, and formatting errors throughout Reg. No. 11.

We note that the specific basis for our proposed action and our analyses and findings are discussed in this proposed rulemaking. Technical information that we relied upon in this proposal is contained in the docket, available at *http://www.regulations.gov,* Docket No. EPA–R08–OAR–2018–0530.

III. What was the State's process?

Section 110(a)(2) of the CAA requires that a state provide reasonable notice and public hearing before adopting a SIP revision and submitting it to us.

The State's February 20, 2015 SIP Submittal

On October 16, 2014, the Colorado Air Quality Control Commission (AQCC) conducted a public hearing to consider the adoption of revisions and additions to the Colorado SIP. The revisions affecting the SIP involved the Reg. No. 11 revisions noted above and as discussed below in section IV. There were no public comments. After conducting a public hearing, the AQCC adopted the proposed revisions to Reg. No 11 on October 16, 2014. The SIP revisions became State effective on November 30, 2014.

We evaluated the State's February 20, 2015 SIP submittal for Reg. No. 11 and determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2)

[1] See 40 CFR part 51, subpart S for a complete description of EPA's IM240 test. The IM240 test is essentially an enhanced motor vehicle emissions test to measure mass tailpipe emissions while the vehicle follows a computer generated driving cycle trace for 240 seconds and while the vehicle is on a dynamometer.

[2] See 40 CFR part 51, subpart S for a complete description of EPA's two-speed idle test. The two-speed idle test essentially measures the mass tailpipe emissions of a stationary vehicle; one reading is at a normal idle of approximately 700 to 800 engine revolutions per minute (RPM) and one reading at 2,500 RPM.

[3] The EPA required that OBD II testing requirements be in place by January 1, 2002 (66 FR 18156; April 5, 2001). All 1996 and newer model year light duty gasoline and alternate fuel passenger cars and trucks are required to have OBD II systems. OBD–II is an improvement over OBD–I in both capability and standardization. The OBD–II standard specifies the type of diagnostic connector and its pinout, the electrical protocols available, and the messaging format. The OBD–II standard provides a list of standardized DTCs. OBD–II standardization was prompted to simplify diagnosis of increasingly complicated emissions equipment.

of the CAA. By operation of law under section 110(k)(1)(B) of the CAA, the State's February 20, 2015 submittal was deemed complete on August 20, 2015.

The State's May 14, 2018 SIP Submittal

On May 17, 2017, the AQCC conducted a public hearing to consider the adoption of revisions and additions to the Colorado SIP. The revisions affecting the SIP involved the Reg. No. 11 revisions noted above and as discussed below in section V. There were no public comments. After conducting a public hearing, the AQCC adopted the proposed revisions to Reg. No. 11 on May 17, 2017. The SIP revisions became State effective on September 30, 2017.

We evaluated the State's May 14, 2018 SIP submittal for Reg. No. 11 and determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the CAA. In addition, our evaluation of the SIP revisions submittal also concluded that it met the minimum ''completeness'' criteria found in 40 CFR part 51, Appendix V.

IV. EPA's Evaluation of the State's 2015 Revisions to Part A, Part B, Part C, Part F, Appendix A and Appendix B

The sections of Reg. No. 11 that were revised with the State's February 20, 2015 submittal were as follows:

1. *Part A, section II:* Add a new definition number 50, ''Tampering.'' Renumber definitions number 51 and higher. The new definition is consistent with the prohibitions in CAA section 203(a)(3)(A).

2. *Part B, section IV:* Modify section IV.B to require span gases to be labelled in accordance with Attachment VI of Appendix A and to require span and calibration gas suppliers to be approved by the Colorado Automobile Inspection and Readjustment (AIR) Program Standards Lab.

3. *Part C, section II:* Modify section II.B.4 to replace specific criteria for eligibility for an alternative test to the IM240 test with an eligibility list that is maintained in the Colorado APCD Emission Technical Center Procedures Manual.

4. *Part C, section II:* Modify section II.C to indicate that effective July 1, 2015, 1996 and newer light duty vehicles that are owned by a fleet that operates a Fleet Inspection Station shall administer an OBD test as specified in 40 CFR 85.2222.

5. *Part C, section VIII:* Modify sections VIII.B.1 to require, as part of eligibility for an emissions test waiver, there are no visible smoke emissions from the vehicle's exhaust, there has been no tampering, and VIII.B.3 (renumbered to VIII.B.2) to clarify requirements for expenditures needed to qualify for an emissions test waiver. Remove prior sections VIII.B.2, VIII.B.4, and VIII.B.5. We note that section VIII.B.2 involved certain aspects of the basic I/M program that are obsolete and sections VIII.B.4 and VIII.B.5 contained emissions reduction and operating parameter requirements that are not required under 40 CFR 51.360 for waivers.

6. *Part C, section VIII:* Modify section VIII.C to require a vehicle to be evaluated via an IM240 test if the OBD MIL remains illuminated even after the maximum expenditure for repairs has been met.

7. *Part C, section VIII:* Modify section VIII.D.1 to add failure for an OBD test.

8. *Part C, section VIII:* Modify section VIII.F to remove unnecessary language regarding the generation of an emissions sticker and removal of the prior emissions sticker by an emissions inspector.

9. *Part C, section IX:* Remove this section in its entirety to delete obsolete language regarding engine and emissions equipment adjustment procedures. These procedures are no longer performed by inspectors; instead, if a vehicle does not pass the owner must have the necessary repairs done before the vehicle is retested.

10. *Part C, section X:* Modify section X.A and X.B to include provisions for emissions related repairs that are necessary to extinguish the OBD MIL light.

11. *Part C, section X:* Modify section X.C to state the specific requirements to meet the emissions maximum expenditure for repairs cost limit, with respect to an OBD test, in order for a vehicle to be eligible to apply for a waiver.

12. *Part F, section VI:* The State modified section VI.B.3 to remove a 98% passing criteria for Clean Screen vehicles and instead indicate the passing criteria would be based on sound scientific evidence. The EPA is not acting on this revision in the State's February 20, 2015 SIP submittal, as it has been superseded by the 2018 revisions.

13. *Part F, section VI:* The State added section VI.B.4 to include that the State would establish the low emitting vehicle index, without review by the EPA or the public, and would retain the low emitting vehicle index in the State's Emission Technical Center Procedures Manual. The EPA is not acting on this revision in the State's February 20, 2015 SIP submittal, as it has been superseded by the May 14, 2018 submitted revisions.

14. *Appendix A, Technical Specifications:* Modify section 2.11 to remove a reference to gas blender specifications in the obsolete Appendix B and change to indicate as approved by the Colorado APCD.

15. *Appendix A, Technical Specifications, Attachment IV:* Modify section IV.2.2 to indicate that the Colorado97 procedure shall use two tri-blend span gas blends that meet the California BAR97 span gas low (blend 31) and high (blend 34) specifications.

16. *Appendix A, Technical Specifications, Attachment IV:* Modify section IV.2.3 to indicate that audit gases shall meet the California BAR97 audit gas specification.

17. *Appendix A, Technical Specifications, Attachment VI:* Modify section VI to revise the label figure to indicate that it represents the Colorado-approved calibration span gas.

18. *Appendix B, Standards and Specifications for Calibration/Span Gas Suppliers:* Appendix B was removed by the State in its entirety as it contained obsolete specifications and procedures for inspection analyzer calibration gases.

V. EPA's Evaluation of the State's 2018 Revisions to Part C, Part D, Part F and Appendix A

The sections of Reg. No. 11 that were revised with the State's May 14, 2018 submittal were as follows:

1. *Part C, section II:* Modify section II.C.3.a to replace the existing monitor readiness evaluation with a monitor readiness evaluation that ensures that the oxygen sensor and/or heated oxygen sensor monitor(s) shall be ready if supported, the catalyst monitor shall be ready if supported, 2001 and newer vehicles shall only be allowed to have one supported monitor in a not ready status, and 2000 and older vehicles shall only be allowed to have two supported monitors in a not ready status. In addition, if the above criteria are not met and the vehicle's MIL light is commanded off, then the vehicle will be required to be evaluated via an IM240 test.

2. *Part C, section II:* Modify section II.C.9 to indicate that for the 5 percent vehicles that are selected at random from the OBD test for a subsequent IM240 test, the IM240 test shall be the pass/fail determination for these vehicles.

3. *Part C, section II:* New section II.C.10 that states if the vehicle's OBD responds that the catalyst readiness monitor is not supported and that all readiness monitors are supported, or if any other OBD tampering indicators are present, then the OBD test will be failed.

4. *Part D, section I:* Modify sections I.B to remove sections I.B.5, I.B.6 and I.B.7 to delete obsolete terms and renumber the remaining sections in I.B.

5. *Part D, section I:* Modify renumbered section I.B.10 to indicate that renumbered sections I.B.5 and I.B.6 are not required for licensing as an inspection-only station or inspection-only facility.

6. *Part D, section I:* Remove prior numbered section I.B.15 as it contains obsolete language.

7. *Part F, section VI:* Modify section VI.B.1 to remove the restricting term ''IM240'' which then allows all types of test results to be evaluated.

8. *Part F, section VI:* Modify section VI.B.2 to remove the unnecessary term ''exhaust.''

9. *Part F, section VI:* Modify section VI.B.3 to remove the minimum 98% passing rate criteria for the LEI and instead require that the passing rate criteria ensures equivalent air quality benefits as a second remote sensing test.

10. *Part F, section VI:* Modify section VI.B.4 to remove prior language and to add that the passing rate criteria for the LEI, as established by the APCD, will be maintained and contained in the APCD's Emissions Technical Center Procedures Manual, and will be submitted to the EPA on or before July 1 of each year.

11. *Part F, section VII:* Modify section VII to remove the obsolete sections VII.E and VII.F.

12. *Appendix A, Technical Specifications, Attachment V:* Modify Attachment V ''Specifications for Colorado On-Board Diagnostic (OBD) Stand-Alone Analyzer'' to remove the obsolete language regarding readiness criteria for a vehicle's oxygen sensor, catalyst sensor and the allowable number of not-ready sensors for 2001 and newer vehicles and 2000 and older vehicles. The revised language now contains overall requirements for OBD readiness such that if the readiness evaluation indicates that a vehicle has more than one unset (not ready) readiness monitor, and the MIL is commanded off, then the inspection is automatically aborted with the reason printed out on the Vehicle Inspection Report.

VI. Conclusion

Our review of the State's Reg. No. 11 revisions, as presented above in sections IV and V, involved numerous revisions to Reg. No. 11 Parts A, B, C, D, F, Appendix A, the deletion of Appendix B, and overall formatting, correction of typographic errors and other non-substantive changes. Based on our review and evaluation discussed above, we propose that the Reg. No. 11 SIP revisions, submitted by the State in letters dated February 20, 2015, and May 14, 2018, sufficiently address applicable provisions in 40 CFR part 51, subpart S, 40 CFR part 85, subpart W, and that our approval is warranted.

VII. Consideration of Section 110(1) of the Clean Air Act

Section 110(1) of the CAA states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress towards attainment of a National Ambient Air Quality Standard or any other applicable requirement of the CAA. In view of the evaluations presented in sections IV and V above, the EPA proposes that the revisions to Colorado's Reg. No. 11 that are contained in the State's SIP submittals dated February 20, 2015, and May 14, 2018 will not interfere with attainment, reasonable further progress, or any other applicable requirement of the CAA.

VIII. Proposed Action

The EPA is proposing approval of the February 20, 2015, submitted SIP revisions to Colorado's Regulation Number 11, Part A, Part B, Part C, Part F, Appendix A and the deletion of Appendix B. The EPA notes that revisions to Part F, sections VI.B.3 and VI.B.4 were also provided with the State's February 20, 2015 submittal. The EPA is not proposing action on these sections of Part F for the reasons noted above in section IV of this action.

In addition, the EPA is proposing approval of the May 14, 2018, submitted SIP revisions to Regulation Number 11, Part C, Part D, Part F and Appendix A.

IX. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the amendments described in sections IV and V, above. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

X. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, and Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 13, 2018.

Douglas Benevento,

Regional Administrator, EPA Region 8.

[FR Doc. 2018–17805 Filed 8–16–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2017–0414; FRL–9981–82]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 27 chemical substances which were the subject of premanufacture notices (PMNs). The chemical substances are subject to Orders issued by EPA pursuant to section 5(e) of TSCA. This action would require persons who intend to manufacture (defined by statute to include import) or process any of these 27 chemical substances for an activity that is designated as a significant new use by these rules to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notification, and has taken such actions as are required with that determination. In addition to this notice of proposed rulemaking, EPA is issuing the action as a direct final rule elsewhere in this issue of the **Federal Register**.

DATES: Comments must be received on or before September 17, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0414, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION: In addition to this Notice of Proposed Rulemaking, EPA is issuing the action as a direct final rule elsewhere in this issue of the **Federal Register**. For further information about the proposed significant new use rules, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this issue of the **Federal Register**.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: August 3, 2018.

Mark A. Hartman,

Acting Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2018–17349 Filed 8–16–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 019—Irritable Bowel Syndrome; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Denial of petition for addition of a health condition.

SUMMARY: On May 17, 2018, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 019) to add irritable bowel syndrome (IBS) to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add IBS to the List. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of August 17, 2018.

ADDRESSES: Visit the WTC Health Program website at *https://www.cdc.gov/wtc/received.html* to review Petition 019.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113), added Title XXXIII to the Public Health Service (PHS) Act,[1] establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.15. Within 90 days after receipt of a valid petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) of the PHS Act and § 88.16(a)(2) of the Program regulations: (1) Request a recommendation of the STAC; (2) publish a proposed rule in the **Federal Register** to add such health condition; (3) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (1) through (3) above.

B. Procedures for Evaluating a Petition

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions,[2] as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.[3]

A valid petition must include sufficient medical basis for the association between the September 11, 2001, terrorist attacks and the health condition to be added; in accordance with WTC Health Program policy, reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors may demonstrate the required medical basis.[4] Studies linking 9/11 agents to the petitioned health condition may also provide sufficient medical basis for a valid petition.

After the Program has determined that a petition is valid, the Administrator must direct the Program to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the health condition to the List.[5] The literature review includes a search for peer-reviewed, published, epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) about the health condition among 9/11-exposed populations. The Program evaluates the scientific quality of each peer-reviewed, published, epidemiologic study of the health condition identified in the literature search; the Program then compiles the scientific results of each study to assess whether a causal relationship between 9/11 exposures and the health condition is supported, and evaluates whether the results of the studies are representative of the 9/11-exposed population of responders and survivors. A health condition may be added to the List if peer-reviewed, published, epidemiologic studies provide support that the health condition is substantially likely[6] to be causally associated with 9/11 exposures. If the evaluation of evidence provided in peer-reviewed, published, epidemiologic studies of the health condition in 9/11 populations demonstrates a high, but not substantial, likelihood of a causal association between the 9/11 exposures and the health condition, then the Administrator may consider additional highly relevant scientific evidence regarding exposures to 9/11 agents[7] from sources using non-9/11-exposed populations. If that additional assessment establishes that the health condition is substantially likely to be causally associated with 9/11 exposures among 9/11-exposed populations, the health condition may be added to the List.

C. Petition 019

On May 17, 2018, the Administrator received a petition (Petition 019) from a WTC survivor who was caught in the dust cloud near Ground Zero, requesting the addition of ''irritable bowel syndrome (IBS)'' to the List.[8] The petition included one scientific article, by Marynowski *et al.* [2015],[9] reviewing the findings of peer-reviewed, published epidemiologic studies concerning the association of IBS with environmental pollution (including particulate matter, a 9/11 agent). Although the Marynowski article on its own did not provide a sufficient medical basis for the submission to be considered a valid petition, the article referenced a peer-reviewed, published study by Kaplan *et al.* [2012][10] regarding IBS symptoms in non-9/11-exposed populations. Kaplan *et al.* conducted an epidemiologic study to evaluate the association between daily concentrations of air pollutants, including particulate matter, with emergency department visits for non-specific abdominal pain, a symptom necessary for a diagnosis of IBS. The inclusion of a reference to this study provides sufficient medical basis for the submission to be considered a valid petition.

D. Review of Scientific and Medical Information and Administrator Determination

In response to Petition 019, and pursuant to the Program policy on the

[1] Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the James Zadroga 9/11 Health and Compensation Act of 2010 found in Titles II and III of Public Law 111–347 do not pertain to the WTC Health Program and are codified elsewhere.

[2] *See* WTC Health Program [2014], *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions,* May 14, 2014, *http://www.cdc.gov/wtc/pdfs/WTCHPPPPetitionHandlingProcedures14May2014.pdf.*

[3] *See* WTC Health Program [2017], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* February 14, 2017, *https://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_14_February_2017.pdf.*

[4] *See supra* note 2.

[5] *See supra* note 3.

[6] The ''substantially likely'' standard is met when the scientific evidence, taken as a whole, demonstrates a strong relationship between the 9/11 exposures and the health condition.

[7] 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites.

[8] *See* Petition 019, WTC Health Program: Petitions Received, *http://www.cdc.gov/wtc/received.html.*

[9] Marynowski M, Likońska A, Zatorski H, Fichna J [2015], *Role of Environmental Pollution in Irritable Bowel Syndrome,* World J Gastroentero 21(40):11371–11378.

[10] Kaplan GG, Szyszkowicz M, Fichna J, Rowe BH, Porada E, Vincent R, Madsen K, Ghosh S, Storr M [2012], *Non-Specific Abdominal Pain and Air Pollution: A Novel Association,* PLOS ONE 7(10).

addition of non-cancer health conditions to the List,[11] the Program conducted a review of the scientific literature on IBS.[12] The Program was unable to identify any references to the petitioned health condition, IBS, in 9/11-exposed populations for further scientific evaluation based on the literature search. Since Kaplan *et al.* [2012] is not an epidemiologic study of IBS in 9/11-exposed populations, it does not meet the threshold for evaluation established in Program policy; therefore, the article was not further reviewed.

E. Administrator's Final Decision on Whether To Propose the Addition of IBS to the List

The Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of IBS to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.16(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.16(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the Petition 019 request to add IBS to the List of WTC-Related Health Conditions is denied.

F. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or his designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Robert Redfield M.D., Director, CDC, and Administrator, ATSDR, approved this document for publication on August 10, 2018.

Dated: August 10, 2018.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Delegated the duties of the Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2018–17711 Filed 8–16–18; 8:45 am]

BILLING CODE 4163–18–P

[11] *Supra* note 3.

[12] Databases searched include: CINAHL, Embase, NIOSHTIC–2, ProQuest Health & Safety, PsycINFO, PubMed, Scopus, and Toxicology Abstracts/TOXLINE.

Notices

Federal Register
Vol. 83, No. 160
Friday, August 17, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket No. AMS–LPS–17–0046]

United States Standards for Grades of Pork Carcasses

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: This Notice informs the public that the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) will not proceed with revisions to the United States Standards for Grades of Pork Carcasses (pork standards) at this time.

DATES: August 17, 2018.

ADDRESSES: USDA, AMS, Livestock and Poultry Program (LP), Quality Assessment Division (QAD); 1400 Independence Ave. SW; Room 3932–S, STOP 0258; Washington, DC 20250–0258.

FOR FURTHER INFORMATION CONTACT: David Bowden, Chief, Standardization Branch; USDA, AMS, LP, QAD; 1400 Independence Avenue SW; Room 3932–S, STOP 0258; Washington, DC 20250–0258; phone (202) 690–3148; or via email at *David.Bowden@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Official USDA grade standards and associated voluntary, fee-for-service grading programs are authorized under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*) (the Act). Specifically, section 203(c) of the Act directs and authorizes the Secretary of Agriculture ''to develop and improve standards of quality, condition, quantity, grade, and packaging and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices'' (7 U.S.C. 1622(c)). AMS is committed to carrying out this authority in a manner that facilitates the marketing of agricultural products. Accordingly, the primary purpose of USDA grade standards is to divide the population of a commodity into uniform groups (of similar quality, yield, value, etc.) to facilitate marketing. Currently, AMS maintains standards for a wide variety of commodities and in many cases, applies those standards to commodities on a fee-for-service basis.

AMS recognizes that the pork standards must be relevant to be of value to stakeholders and, therefore, recommendations for changes in the standards may be initiated by AMS or by interested parties at any time to achieve that goal. AMS originally posted this Notice seeking comment on the revised pork standards on October 23, 2017, with a closing date of December 22, 2017. Subsequently, AMS reopened the Notice for an additional 60-day comment period, ending March 19, 2018.

Comments

In all, 47 comments were received: There were 19 comments in favor of updating the pork standards, while 24 were opposed; 2 only requested extending the comment period; and 2 commenters did not clearly state a position. Responses received were representative of the pork industry and stakeholders, with the most comments coming from pork industry associations, packers, and producers.

The 19 commenters in support of revised pork standards said that changes were needed in the pork industry to revitalize domestic consumer demand and that the updated standards may be helpful in addressing the decline in purchases of fresh pork products, citing data that the average American consumer buys fresh pork only seven times a year. Some commenters expressed that a revised standard could lead to a USDA fee-for-service grading program, which would enhance uniformity of pork quality and build consumer confidence in pork purchasing decisions. Commenters also said that the revisions were scientifically sound and applicable to pork quality attributes that are consumer-recognized and tied to an improved eating experience. While some recognized the challenge of implementing the proposed standards revisions via a grading program in the modern processing environment, they expressed support for a standardized, objective carcass grading system focused more on quality than percent lean.

Most of the 24 comments against the proposed revisions were similar in nature and asserted the new grades would not add value for pork producers. Some commenters noted that the pork industry and individual companies have worked for many years to improve product quality attributes and promote their efforts through product branding and ''niche'' marketing, and the revised pork standards would endanger these efforts. Further, some commenters noted that proposed nomenclature of Prime, Choice, and Select, if implemented for pork, could result in devaluation of the established beef grading system. Pork packers and processors expressed concern that implementation of the revised pork standards would be impractical, in part because the technology available to accurately assess quality factors for pork is not yet effective while maintaining today's processing line speeds. Commenters opposed to the revisions also expressed concern that implementation at this time would cause disruption to existing producer-packer relationships and established logistics. Others were concerned that application of the standard specifically to the loin primal without positive correlation with the remaining carcass parts would be misleading, and that any premium generated by applying the standards would not offset the cost of implementing a USDA fee-for-service grading program in the plant.

A few commenters provided responses that were both for and against the revisions, outlining opportunities and challenges similar to those discussed above. All comments are available at the following website: *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=AMS-LPS-17-0046.*

Based on the responses received from the Notices, AMS will not pursue any revisions to the pork standards at this time. AMS stands ready to assist agricultural industries in establishing voluntary standards and grading programs for commodities for which it has authority to do so; the pork industry retains this option should the need arise.

Dated: August 13, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018–17725 Filed 8–16–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Supplemental Nutrition Assistance Program (SNAP), Store Applications, Forms FNS–252, FNS–252–E, FNS–252–FE, FNS–252–R, FNS–252–2 and FNS–252–C

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on the proposed collection. This is a revision of a currently approved collection in the Supplemental Nutrition Assistance Program and concerns Retail Store Applications (Forms FNS–252; FNS–252–E; FNS–252–FE; FNS–252–R; FNS–252–2; and FNS–252–C).

DATES: Written comments must be received on or before October 16, 2018.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments may be sent to: Nicole Budzius, Chief, Retailer Administration Branch, Supplemental Nutrition Assistance Program, Retailer Policy and Management Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 422, Alexandria, VA 22302. Comments may be faxed to the attention of Ms. Budzius at (703) 305–1863 or via email to: *RPMDHQ-WEB@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically. All written comments will be open for public inspection at the FNS office located at 3101 Park Center Drive, Room 422, Alexandria, Virginia 22302, during regular business hours (8:30 a.m. to 5 p.m. Monday through Friday).

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Nicole Budzius at *RPMDHQ-WEB@fns.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Supplemental Nutrition Assistance Program (SNAP)—Store Applications.

Form Number: FNS–252; 252–E; 252–FE; 252–R; 252–2; and 252–C.

OMB Number: 0584–0008.

Expiration Date: January 31, 2021.

Type of Request: Revision of a currently approved collection of information.

Abstract: Section 9(a) of the Food and Nutrition Act of 2008, as amended, (the Act) (7 U.S.C. 2011 *et seq.*) requires that FNS determine the eligibility of retail food stores and certain food service organizations to accept SNAP benefits and to monitor them for compliance and continued eligibility and to ensure Program integrity.

FNS is also responsible for requiring updates to application information and reviewing retail food store applications at least once every five years to ensure that each firm is under the same ownership and continues to meet eligibility requirements. The Act specifies that only those applicants whose participation will ''effectuate the purposes of the program'' should be authorized.

There are six forms associated with this approved Office of Management and Budget (OMB) information collection number 0584–0008—the Supplemental Nutrition Assistance Program Application for Stores, Forms FNS–252 (English and Spanish) and FNS–252–E (paper and online version respectively); Farmer's Market Application, Form FNS–252–FE; Meal Service Application, Form FNS–252–2; Reauthorization Application, Form FNS–252–R; and the Corporation Supplemental Application, Form FNS–252–C used for individual (chain) stores under a corporation. For new authorizations, the majority of applicants use form FNS–252 or FNS–252–E (paper or online, respectively). FNS is responsible for reviewing retail food store applications at least once every five years to ensure that each firm is under the same ownership and continues to meet eligibility guidelines. In order to accomplish this regulatory requirement, form FNS–252–R is used for reauthorization. In addition to these forms, during authorization or reauthorization, FNS may conduct an on-site store visit of the firm. The store visit of the firm helps FNS confirm that the information provided on the application is correct. An FNS representative or store visit contractor obtains permission to fill in the store visit checklist, photograph the store and asks the store owner or manager about the continued ownership of the store.

Applicants using form FNS–252–E or FNS–252–FE must also first self-register for a Level 1 access account through the USDA eAuthentication system in order to start an online application. USDA eAuthentication facilitates the electronic authentication of an individual.

The Agricultural Act of 2014 (2014 Farm Bill) amended the Food and Nutrition Act of 2008 (the Act) and the Supplemental Nutrition Assistance Program (SNAP) revised all retailer application forms (paper and electronic) in January, 2018, as a result of regulatory changes required by the Act and amended by the 2014 Farm Bill. Such changes to the Act amended the definition of ''retail food store'' to clarify when a retailer is a restaurant rather than a retail food store. Among the changes made to the SNAP retailer application form(s), the Food and Nutrition Service (FNS) added a new question, Question 18, concerning restaurant licensing, and revised Question 22, regarding total retail sales on Form FNS–252. Currently, respondents select a Yes or No response if they have or are applying for a restaurant license for their store in Question 18. Question 22 currently asks retailers to enter their total retail sales by category in dollars for a one year period. Sales categories include gasoline, lottery, tobacco, alcohol, other nonfood, and hot foods, cold prepared foods, accessory foods, and staple foods. Due to concern with the manner in which FNS is currently asking for retailer sales data, FNS is updating the retailer application question regarding sales. FNS is also removing the question concerning restaurant licensing and the requirement for businesses located in community property states to provide spousal information for each owner. Question 22 will revert back to asking

for percentages for each category as opposed to exact dollar amounts. FNS will also change from asking for individual sales amounts for each non-food category to asking for the percentage of total sales in gasoline and an aggregate percentage of all other total non-foods sold by the firm.

FNS intends to (1) rename Question 3, ''Doing Business As (if different from Store Name)'' to ''Legal Business Name (if different from Store Name)'', (2) update Question 14 to remove the sentence requiring spousal information for businesses located in community property states, and in the Business Title section remove the word ''spouse'' in questions 14a–14d, (3) delete Question 18 regarding restaurant licensing, (4) revise Question 22 concerning total retail sales in the following manner: (a) Respondents will provide a response for either estimated or actual sales for a one year period. If actual sales are provided, the respondent will indicate the applicable tax year for this information. FNS also added back in the option to provide estimated retail sales per day, week, month, or year for total retail sales in Question 22b, and (b) provide a percentage of total retail sales for each category of product sold: Staple foods; accessory foods; hot foods, cold foods prepared on site; gasoline, and other non-food items, (5) add a new sentence to the Certification and Signature Statement to more clearly outline the risk for owners that are disqualified or fined for violation of Program rules; and (6) where appropriate, re-number the questions and update assistance material such as the General and Specific Instructions sections and on-line help screens. With the exception of the question identified in 4(b) above, no new questions or data information is being asked.

A draft of the proposed revision to Question 22 is provided in Attachment A. FNS also shared a draft of the proposed changes with our stakeholders. The proposed revision incorporates the feedback FNS received with the exception of any changes that would render FNS unable to make an eligibility decision or complete retailer monitoring activities. FNS would like to take this opportunity to clarify that while cold foods prepared on-site, such as at an in-store deli or salad bar, are eligible for purchase with SNAP benefits, collection of the percentage sales information is still necessary for FNS to make a restaurant determination. Additionally, all information provided on the application is information ''provided by the retailer'' and is protected under Section 9(c) of the Food and Nutrition Act of 2008, as amended, (the Act) (7 U.S.C. 2011 *et seq.*) and as such, not subject to release under the Freedom of Information Act (FOIA). The feedback FNS incorporated includes asking for sales percentages as opposed to an exact sales amount for each category, removing the requirement to provide individual sales figures for lottery, tobacco, and alcohol, rewording ''cold prepared foods'' to ''cold food prepared on site,'' continuing to separate hots foods from cold foods, and clarifying the instructions for Question 22. The aggregated percentages of non-food sales, of accessory sales, and of gas sales, in particular, will provide FNS with an indicator as to whether a criteria B eligibility or restaurant assessment are necessary.

FNS estimates that the hourly burden time per response associated with this information collection for respondents remains unchanged from our previous submission. The revisions to the application(s) are due to program adjustments and the update to Question 3, the removal of a sentence in Question 14, the deletion of Question 18, the reformatting of information collected in Question 22; and the revision to the Certification and Signature Statement.

FNS used FY 2017 data in our calculation of burden estimates associated with this information collection as this was the most complete data available to us at this time. Table A below clarifies the burden of this information collection.

As currently approved by OMB, the hourly burden rate per response varies by the type of application used and the response time per respondent varies from 1 minute to 19 minutes. We estimate the new burden, on average, to be 9.13 minutes per respondent. There is no recordkeeping burden associated with these forms.

Affected Public: Business for Profit; Retail food stores; Farmers' Markets, Military Commissaries and Meal Services.

Estimated Number of Respondents: The total estimated number of respondents is 143,354 annually.

Estimated Number of Responses per Respondent: Respondents complete either 1 application form at initial authorization or 1 reauthorization application, as appropriate, for a total of 1 response each.

Estimated Total Annual Responses: 143,354.

Estimated Time per Response: 9.13 minutes (0.1534941). The estimated time response varies from 1 minute to 19 minutes depending on respondent group, as shown in the table below:

TABLE A—REPORTING ESTIMATE OF HOUR BURDEN

[Summary of burden—#0584–0008]

Affected public	Respondent type	(a) Description of collection activity	(b) Form No.	(c) Number of respondents	(d) Number of responses per respondent	(e) Total annual responses (cxd)	(f) Hours per response	(g) Total burden (exf)
Reporting								
Farms, Business for not for profit.	SNAP Retailer, Farmers' Market, and Meal Service.	Applications Received.	252	1,381	1	1,381	0.3167	437.36
		Applications Received.	252–E	31,480	1	31,480	0.25	7,870
		E-Authentication	252–E and FNS–252–FE.	33,213	1	33,2139	0.1336	4,437.25
		Applications Received.	252–FE	1,730	1	1,730	0.25	432.50
		Applications Received.	252–2	386	1	386	0.25	96.50
		Applications Received.	252–C	5,658	1	5,658	0.25	1,414.50
		Store Visits		43,126	1	43,126	0.0167	720.20
		Reauthorization	252–R	26,377	1	26,377	0.25	6,594.25

TABLE A—REPORTING ESTIMATE OF HOUR BURDEN—Continued
[Summary of burden—#0584–0008]

Affected public	Respondent type	(a) Description of collection activity	(b) Form No.	(c) Number of respondents	(d) Number of responses per respondent	(e) Total annual responses (cxd)	(f) Hours per response	(g) Total burden (exf)
Sub-Total For Farm & Business				143,351	1	143,351	0.1534873	22,002.56
Federal	Military Commissaries.	Applications Received.	252–E	3	1	3	0.3167	0.95
		Reauthorization	252–R	0	1	0	0.25	0
Sub-Total For Federal Respondents				3	1	3	0.3167	0.95
Grand Total Reporting Burden				143,354	1	143,354	0.1534907	22,003.51
SUMMARY OF BURDEN FOR THIS COLLECTION				143,354	1	143,354	0.1534941	22,004

* **Note:** The respondents for the 252–E and the 252–FE are the same respondents for e-Authentication and therefore not double counted in the total number of respondents.

Attachment A: Draft FNS–252.

Dated: August 8, 2018.

Brandon Lipps,

Administrator, Food and Nutrition Service.

[FR Doc. 2018–17722 Filed 8–16–18; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Humboldt-Toiyabe National Forest; Clark Counties, Nevada; Lee Canyon Notice of Availability

AGENCY: Forest Service, USDA.

ACTION: Notice of Availability of the Draft Environmental Impact Statement for the Lee Canyon Ski Area Master Development Plan Phase I and Public Comment Period for the Associated Forest Plan Amendment.

SUMMARY: The Humboldt-Toiyabe National Forest is issuing this notice to advise the public of the 45-day public comment period for the Draft Environmental Impact Statement (EIS) for the Lee Canyon Ski Area Master Development Plan Phase I (Lee Canyon Project) and the addition of a proposed project-specific amendment to the Toiyabe National Forest Land and Resource Management Plan (Forest Plan) for the Proposed Action and alternatives other than the No Action alternative. The Notice of Intent for the Lee Canyon Project was published in the **Federal Register** on March 23, 2017 (82 FR 14865). Today's notice has been published to ensure all persons and entities interested in the Lee Canyon Project are aware of the addition of the proposed amendment and to identify the Forest Service planning rule provisions likely to be directly related and, therefore, applicable to the Forest Plan amendment. The public is advised that during the 45 day comment period for the Lee Canyon Project Draft EIS, comments may also be submitted regarding the substantive requirements that are likely to be directly related to the amendment and the scope and scale to which the substantive requirements would apply. Comments will be considered in the preparation of the Final EIS and Draft Record of Decision for the Lee Canyon Project.

DATES: The comment period ends 45 days after today's Notice of Availability or 45 days after the Environmental Protection Agency's Notice of Availability is published in the **Federal Register**, whichever is later. All relevant comments received during the public comment period related to the substantive requirements that would likely be directly related to the proposed Forest Plan amendment and the scope and scale of the proposed Forest Plan amendment will be considered in the preparation of the Final EIS and Draft Record of Decision (ROD).

ADDRESSES: Comments may be submitted by any one of the following methods:

- *Electronic Submissions:* Comments can be filed electronically at: *leecanyoneis@fs.fed.us.* Electronic comments must be submitted as part of the email message or as an attachment in plain text (.txt), Microsoft Word (.doc), rich text format (.rtf), or portable document format (.pdf). Emails submitted to addresses other than the one listed above, or in formats other than those listed or containing viruses, will be rejected.
- *Mail:* Written, specific comments must be submitted to Donn Christiansen, Area Manager, Spring Mountains National Recreation Area, 701 Torrey Pines Dr., Las Vegas, NV 89130.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by the Forest. All comments received are part of the public record and will generally be posted for public viewing without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible.

FOR FURTHER INFORMATION CONTACT: Chris Linehan, Interdisciplinary Team Leader, at (702) 515–5401, or via email at *clinehan@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday. Information about the Lee Canyon Project may be found on the Forest Service website at *http://www.fs.usda.gov/project/?project=50649.*

SUPPLEMENTARY INFORMATION: The purpose and need for the proposed Lee Canyon Project, as described in the Notice of Intent, is to address the length of time since the resort's facilities have been upgraded and emerging trends in winter recreation. Specific details of these needs are described in Draft EIS. The purpose and need for the proposed plan amendment is to ensure consistency between the Forest Plan and the proposed Lee Canyon Project. As described in the Draft EIS, the need was identified for exempting the Lee Canyon Project from the following Standards of the 1996 Spring Mountains National Recreation Area (SMNRA) General

Management Plan (GMP) (Amendment five of the Forest Plan):

SMNRA-wide Standards and Guidelines: (GMP Standard 0.31) New roads, administrative facilities, and developed recreation sites other than low-impact facilities (trails, trailhead parking, signs, restrooms, etc.) will be outside a 100-yard buffer zone around known Clokey's eggvetch and rough angelica populations or potential habitat, and outside biodiversity hotspots (defined as areas of particular diversity or sensitivity).

The need for this Forest Plan amendment is that in the Lee Canyon Proposed Action new service roads, and ski area facilities would occur within the 100-yard buffer zone established around known Clokey's eggvetch and rough angelica populations or potential habitat. These areas have been thoroughly inventoried for these species and none were found within the project foot print. This project-specific Forest Plan amendment will allow development within the 100-yard buffer zones for these two-species established in the Standard GMP 0.31 (p. 18) to allow for construction of service roads and ski area facilities.

Under the Proposed Action and other action alternatives, Standard GMP 0.31 would be amended to allow new service roads and developed recreation sites to be placed within the 100-yard buffer zone around known Clokey's eggvetch and rough angelica populations or potential habitat, and within biodiversity hotspots in the Lee Canyon Special Use Permit Boundary.

Management Area 11: (11.57) Allow limited expansion of ski area in Lee Canyon and enhancement of skiing opportunities and facilities within the scope of an approved master development plan and under the following constraints:

1. Expansion occurs within the existing sub-basin.
2. Does not impact any threatened, endangered, or sensitive species or species of concern or its habitat.
3. Expansion is commensurate with development of additional parking in the lower Lee Canyon area and shuttle services.
4. Expansion incorporates defensible space design and fire safe facilities.
5. Where consistent with other standards and guidelines.

The need for this Forest Plan amendment is that the Proposed Action and other action alternatives include development of ski runs, mountain coasters, zip lines, mountain bike trails, parking areas, and access roads within the Lee Canyon Ski Area permitted boundary. As the Mount Charleston Blue Butterfly was listed as a endangered species in 2015 and the designated critical habitat for the butterfly includes portions of the Lee Canyon Ski Area, Constraint #2 from the standard cannot be met. The Proposed Action and other action alternatives also include the addition of a 500 vehicle parking lot at the ski area to accommodate increased visitor use without the development of additional parking in lower Lee Canyon or shuttle services. The project-specifc Forest Plan Amendment would exempt the project from the requirements under Constraint #2 and Constraint #3.

The substantive requirements of the 2012 Planning Rule (36 CFR part 219) likely to be directly related and, therefore, applicable to the Forest Plan amendment for the Lee Canyon Project are in 36 CFR 219.9(b) regarding threatened and endangered species and 36 CFR 219.10(a)(1), (3), and (7) regarding integrated resource management for multiple use. The scope and scale to which these substantive requirements would apply are the scope and scale of the Lee Canyon Project. The amendment would not apply to any other projects or activities.

Responsible Official

The Responsible Official for the Lee Canyon Project and the Forest Plan amendment is William A. Dunkelberger, Forest Supervisor, Humboldt-Toiyabe National Forest Supervisor's Office, 1200 Franklin Way, Sparks, Nevada 89431, phone (775) 355–5310.

Decision To Be Made

In consideration of the stated purpose and need and the analysis of environmental effects documented in this EIS, the Responsible Official will review the proposed action and alternatives in order to make the following decisions:

- Whether to authorize the proposed action or an alternative, including the required no-action alternative, all or in part;
- What design criteria and mitigation measures to require as a condition of the authorization;
- What evaluation methods and documentation to require for monitoring project implementation and mitigation effectiveness; and
- Whether to amend the Forest Plan to exempt the project from Standard GMP 0.31 and from Constraints #2 and #3 of Standard GMP Management Area 11.57.

Administrative Review

The Lee Canyon Project and the Forest Plan amendment will be subject to objection under 36 CFR part 218.

Dated: May 7, 2018.

Chris French,

Associate Deputy Chief, National Forest System.

[FR Doc. 2018–17730 Filed 8–16–18; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Housing Service

Rural Utilities Service

Rural Development Cooperative Agreement Program

AGENCY: Rural Development USDA.

ACTION: Notice.

SUMMARY: The Assistant to the Secretary for Rural Development (Agency) is seeking applications to support regional economic development planning efforts in rural communities under the Rural Economic Development Innovation (REDI) initiative. This funding opportunity will be administered by the Rural Development Innovation Center, in partnership with the Rural Business-Cooperative Service. The Agency is announcing up to $750,000 in competitive cooperative agreement funds in fiscal year (FY) 2018. Rural Development Agency may select one, multiple, or no award recipients. The Agency reserves the right to withhold the awarding of any funds if no application receives a score of at least 60 points.

This Notice lists the information needed to submit an application for these funds. This Notice announces that the Agency is accepting FY 2018 applications to support REDI.

DATES: The deadline for receipt of a complete application is midnight Eastern Standard Time on Wednesday, September 5, via *www.grants.gov.* The Agency will not consider any application received after the deadline. After an applicant submits an application via *grants.gov*, all applicants must email *RD.Innovation@osec.usda.gov* to confirm application and receipt of the application package. Applicants who have been selected for funding will receive a letter of official notification and will be awarded a cooperative agreement authorized under 7 U.S.C. 2204b(b)(4). Pending funding availability, all awards will be made no later than September 30, 2018.

Applicants should plan their projects based on a start date of September 30, 2018 and must be completed within 24 months.

ADDRESSES: The deadline for receipt of an application is midnight Eastern Standard Time on Wednesday, September 5, 2018. Applications may be submitted electronically through the *Grants.gov* system or through email to *RD.Innovation@osec.usda.gov.* Note that there are registration requirements for submitting applications using the *Grants.gov* system. We recommend that you review the instructions for registering as soon as possible, but at least two weeks before you plan to submit your application. The requirements can be viewed at: *http://grants.gov/applicants/organization_registration.jsp.* Your application will be rejected by *Grants.gov* if you miss the deadline and the Agency will not consider any application received after the deadline.

FOR FURTHER INFORMATION CONTACT: Question about this announcement can be directed to Christine Sorensen, Regional Coordinator, via 202–568–9832 or *Christine.Sorensen@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Preface

The Agency encourages applications that will support recommendations made in the Rural Prosperity Task Force report to help improve life in rural America (*www.usda.gov/ruralprosperity*). Applicants are encouraged to consider projects that provide measurable results in helping rural communities build robust and sustainable economies through strategic investments in infrastructure, partnerships, and innovation. Key strategies include:

- Achieving e-Connectivity for Rural America.
- Developing the Rural Economy.
- Harnessing Technological Innovation.
- Supporting a Rural Workforce.
- Improving Quality of Life.

Paperwork Reduction Act

It is anticipated that the anticipated number of respondents affected by this information collection is less than 10 entities and therefore, this Notice contains no reporting or recordkeeping provisions requiring Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Overview

Federal Agency Name: U.S. Department of Agriculture, Rural Development.

Funding Opportunity Title: Rural Development Cooperative Agreement Program.

Announcement Type: Notice of Funding Availability (NOFA).

Catalog of Federal Domestic Assistance (CFDA) Number: 10.890.

Application Due Date: All required application documents must be submitted by midnight Eastern Standard Time on Wednesday, September 5 electronically via *www.grants.gov.* Applicants submitting proposals must also confirm receipt and email *RD.Innovation@osec.usda.gov* to confirm application and receipt of the application package. Applicants who have been selected for funding will receive a letter of official notification. Pending funding availability, all awards will be made no later than September 30, 2018. Applicants should plan their projects based on a start date of September 30, 2018 and must be completed within 24 months.

For More Information: Questions about this announcement can be directed to Christine Sorensen, Regional Coordinator, via 202–568–9832 or *Christine.Sorensen@wdc.usda.gov.*

A. Program Description

USDA Rural Development (RD) is authorized to administer cooperative agreement awards in accordance with 7 U.S.C. 2204b(b)(4). Rural Economic Development Innovation (REDI) aims to strengthen the capacity of rural communities (50,000 people or less in the United States plus Tribes and territories) in implementing strategic community and economic development plans as referenced in Section 379H of the Consolidated Farm and Rural Development Act (7 U.S.C. 2008v). The goal of this funding announcement is to solicit applications to provide cooperative agreement funding to eligible applicants to enable them to provide technical assistance and training and actionable planning of implementation of strategic community and economic development plans. Supporting regional economic development plans help rural communities overcome multi-jurisdictional challenges and better leverage Federal, state, local or private funding.

For purposes of this proposal, a quality regional economic plan will include but not be limited to the following:

- Evidence-based understanding of community assets, challenges and opportunities.
- Goals are focused, logical, targeted and timely with tasks identified and with a responsible party assigned.
- The plan was created through broad community participation, public input and buy-in.
- The format must be persuasive in a non-technical manner.
- The plan makes clear how each of its strategies is intended to help produce, either directly or indirectly, improvements in the local and regional economy.
- Regional economic development plans developed through REDI assistance should identify possible projects to be funded through RD programs and/or other Federal, state, local or private sector resources.

This funding opportunity expands rural communities' ability to access planning resources to convene, identify needs, create actionable economic development plans, and implement project priorities to improve quality of life in rural communities. Quality of life is a measure of human well-being that can be identified though economic and social indicators. Modern utilities, affordable housing, efficient transportation and reliable employment are economic indicators that must be integrated with social indicators like access to medical services, public safety, education and community resilience to empower rural communities to thrive. Economic development plans developed through this funding opportunity should focus on one or more of these economic and/or social indicators.

Applicants are encouraged to consider regional planning projects that provide measurable results in helping rural communities built robust and sustainable economies through strategic investments in infrastructure, partnerships, and innovation. Such projects should also support rural communities' ability to qualify for priority funding under Section 379H of the Consolidated Farm and Rural Development Act [7 U.S.C. 2008v].

This approach to comprehensive rural community development is unique in its attempt to improve rural communities in a way that is (1) rooted in emphasizing partnerships and collaboration among multiple public agencies and community partners and (2) focused on combining state resources to make wide-ranging quality-of-life impacts as opposed to separate, piecemeal, incremental improvements.

B. Federal Award Information

1. *Estimated Funding:* Interested applicants shall only propose applications with scope of work/budget that does not exceed $750,000 in Federal funding.

2. *Start Date and Performance Period:* Projects may be up to 2 years in duration. Applicants should plan their projects based on a project start date of September 30, 2018 and a project end date of no later than September 30, 2020.

3. *Type of Federal Award:* Cooperative Agreement. Rural Development will be substantially involved in the work performed under each approved cooperative agreement. Substantial involvement may include but is not limited to collaboration, participation, oversight, and control of the following:

i. Authority to suspend work if specification or work statements are not met;

ii. Review and approval of one stage of work before another may begin;

iii. Review and approval of substantive provisions of proposed sub-grants or contracts;

iv. Prior review and approval of key personnel; and

v. Agency collaboration and coordination with respect to deliverables and execution of the work plan. At a minimum, applicants should anticipate Agency participation in the selection of communities to receive regional planning assistance; the convening of community members, partners, and stakeholders; the delivery of training on RD programs and/or economic development principles; and the review/approval of regional economic development plans for purposes of priority funding under Section 379H of the Consolidated Farm and Rural Development Act (7 U.S.C. 2008v).

4. *Number of Awards:* The Agency anticipates that it may select one, multiple, or no award recipients from this notice of funding availability. The Agency reserves the right to withhold the awarding of any funds if no application receives a minimum score of at least 60 points.

5. *Eligibility of renewal or Supplemental Project Applications:* Applications for renewal or supplementation of any existing Federal awards are not eligible for this new Federal award. An application for renewal means a proposal submitted to continue an existing agreement by adding components to an existing agreement in order to meet the objectives of this solicitation.

C. Eligibility Information

Applicants must meet all of the following eligibility requirements by the application deadline. Applications which fail to meet any of these requirements by the application deadline will be deemed ineligible and will not be evaluated further and will not receive a Federal award.

1. *Applicant Eligibility:* Federally-recognized Tribes, institutions of higher education, nonprofit organizations, or private organizations with a demonstrated *national structure and/or capacity* to deliver and support multiple rural planning activities across the nation are eligible applicants. Entities are not eligible if they have been debarred or suspended or otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order 12549, ''Debarment and Suspension.'' In addition, an applicant will be considered ineligible for a cooperative agreement due to an outstanding judgment obtained by the U.S. in a Federal Court (other than U.S. Tax Court), is delinquent on the payment of Federal income taxes, or is delinquent on Federal debt.

2. *Eligible Project Purposes:* The Project purpose must be to strengthen the capacity of rural communities (50,000 people or less in the United States plus Tribes and territories) in developing and implementing regional plans for economic development as referenced in Section 379H of the Consolidated Farm and Rural Development Act. Eligible project purposes must include the two facets of technical assistance:

i. *Planning Technical Assistance:* The proposed project should provide planning technical assistance to rural communities by assisting in the development of regional economic development plans. Proposals should include descriptions on how technical assistance will result in actionable steps to support implementation of these plans. The proposed project should also provide technical assistance to expand rural communities' ability to access funding and planning resources to convene community members.

ii. *Implementation Technical Assistance:* The proposed project should provide technical assistance toward implementation of the project priorities emerging from the regional economic development plans. The technical assistance should include strategies for enhancing communities' efforts at leveraging Federal, state, local, and/or private funding to build resilient communities and improve quality of life. The applicant will demonstrate how their proposal will utilize partnerships outside of RD. The applicant will identify such partnerships and will demonstrate how they will provide access to such partnerships to support implementation of projects identified through development of regional economic development plans. The proposed project should also describe how it will support implementation of multi-jurisdictional and/or multi-sector regional economic development plans, as described in Section 379H of the Consolidated Farm and Rural Development Act.

3. *Cost Sharing or Matching Requirements:* There is a dollar or in-kind matching requirement that is at least equal to the amount of the cooperative agreement award. If this matching fund requirement is not met, the application will be deemed ineligible. Matching requirements are cash, confirmed funding commitments and/or third party in-kind contributions as defined in 2 CFR 200.96. that are at least equal to the cooperative agreement amount and committed for a period of not less than the cooperative agreement performance period. Applicants must recruit one or more private and/or public partner(s) to match one-for-one (in cash and/or in-kind contributions) the applicant's proposed funding request. Cost sharing/matching must be committed at the time of application submission. Applications must include written verification of commitments of cost sharing or matching support (including both cash and in-kind contributions) from third parties. Cost sharing or matching funds must meet the criteria stated at 2 CFR 200.306 and be valued in accordance with 2 CFR 200.306(d).

Additional details about cost sharing or matching funds/contributions is located at 2 CFR 200.306. Applicant matching funds must be included in the budget narrative. For matching funds offered by project partners, a separate commitment letter is required for each cash and/or in-kind match contribution. Commitment letters must be signed by the authorized organizational representative of the contributing organization and the applicant organization, which must include: (i) The name, address, and telephone number of the contributor; (ii) the name of the applicant organization; (iii) the title of the project for which the contribution is made, (iv) the dollar amount of the contribution; and (v) a statement that the contributor commits to furnish the contribution during the cooperative agreement period.

Applications without signed written commitments are deemed incomplete and will be ineligible. The value of applicant contributions to the project is established according to Federal cost principles. Applicants should refer to 2 CFR 200.306 for additional guidance on matching funds, in-kind contributions, and allowable costs.

4. Substantial Involvement: Proposed project must include a component that allows for active participation by the Agency in the majority of tasks. Examples of substantial involvement include but are not limited to the following: Joint-selection of communities to receive regional planning assistance; joint-convening of community members, partners, and stakeholders; joint-delivery of training on RD programs and/or economic development principles; and joint-review/approval of regional economic development plans for purposes of priority funding under Section 6025 Strategic Economic and Community Development. It is the intent of this project to engage Agency and state RD staff in the development of regional economic development plans and it is the responsibility of the applicant to identify tasks where RD staff can provide substantial involvement in the project. If you do not identify those tasks, your application is not eligible for funding.

5. *Use of Funds:* Use of project funds (including Federal and matching) must be consistent with the project purpose to strengthen the capacity of rural communities in developing and implementing regional plans for economic development. A non-exclusive list of eligible fund uses include: Costs incurred for the services of personnel actually engaged in the project, including share of employee benefits, travel and per diem expenses, costs of expendable supplies, and travel and per diem expenses associated with travel to USDA Headquarters in Washington, DC to coordinate and collaborate on project tasks. Use of funds must be allowable in adherence with 2 CFR part 200.

If you include funds in your budget that are unallowable, RD will consider the application for funding only if the unallowable costs total 10 percent or less of the total project budget, including Federal and matching funds. However, if the application is successful, those unallowable costs must be removed from the budget before RD will make an award. If RD cannot determine the percentage of unallowable costs or the amount of those costs exceeds 10 percent of the total project budget, the application will not be considered for funding.

6. *Rural Area:* The project must directly benefit a rural area. All ultimate beneficiaries and/or subrecipients must be located in rural areas, and any activities or tasks must occur in rural areas. The term 'rural area' means the Rural Business Service's Rural Area definition as out lined in Section 343(a)(13)(A)(i) of the Consolidated Farm and Rural Development Act which states: Any area other than: (1) A city or town that has a population of greater than 50,000 inhabitants; and (2) any urbanized area contiguous and adjacent to such a city or town.

7. *Number of Applications:* You cannot submit more than one application for this Notice.

D. Application and Submission Information

1. *Address to Request Application Page.* All necessary forms can be found within the *Grants.gov* ''Application Package.''

2. *Content and Form of Application Submission.* There is no pre-application process for this announcement. All checklist, application, and standard forms necessary for submission are included in the *Grants.gov* application package. Applications that are incomplete or fail to comply with the required content and formatting requirements will not be considered for funding.

i. *Content and Format:* Each page must be on numbered, letter-sized (8½ x 11) paper utilizing a white background that has 1″ margins; and the text of the application must be typed, single spaced, black, and in a font no smaller than 12 point.

ii. *Executive Summary (1-page maximum):* On a single page, provide the applicant entity name, duration of project in months, amount of Federal funding requested, amount of non-Federal cost-share/match funding committed, and project title. Identify geographic locations, and describe in non-technical language the issue or problem rural communities have in accessing economic development planning resources, the objectives to address this issue, the innovative approach to be employed (including the role of participating partners), how impact will be quantified, and the predicted benefits or deliverables of the project.

iii. *Standard Application Form:* Standard Form 424, ''Application for Federal Assistance'' is included as part of the application package posted on *Grants.gov*. Instructions for completing the form are also included.

iv. *Applicant Qualifications (1–2 pages):* Summary of the qualifications of the applicant organization is required. Interested applicant must have the organizational capacity, experience, and knowledge of rural planning needs and must meet the following minimum requirements:

a. Demonstrate *national structure and/or capacity* to support multiple rural planning activities across the nation;

b. Demonstrate *knowledge and prior experience* in regional planning, particularly related to rural issues;

c. Demonstrate *capacity* to assist rural communities to develop regional plans such as access to data for needs assessment and planners and other technical capacity on staff; and

d. Demonstrate *knowledge and prior experience* of leveraging other community-driven plans or projects such as Comprehensive Economic Development Strategies (CEDS) or other Federally-recognized regional economic development plans.

v. *Key Personnel Qualifications (1–2 pages):* Summary of the qualifications of each key person, including the project director, is required. Resumes or CVs will not be accepted. The summary should include relevant education, years of relevant experience, a description of skills relevant to the person's work on the proposed project, and the person's key accomplishments. If you expect to contract out a portion of the proposed work, but have not hired the contractor, you must include a summary of the qualifications you will require from the contractor.

vi. *Project Proposal (15-page maximum):* The project proposal must include a proposed Work Plan, along with the following information in order:

a. Project Background.

b. Project Objectives.

c. Project Approach/Methods.

d. Theory of Change.

e. Geographic Locations or Project Areas.

f. Project Management (Applicants are required to include a Work Plan Chart that lists each major Task by Key Personnel involved, Time Period of the task, Substantial Involvement of Rural Development staff, Deliverables, and Budget associated with each task).

g. Performance Metrics.

h. Graphics, References, Citations (Do not count against the 15-page maximum).

A Work Plan Chart template is available for applicants as part of this funding opportunity on *grants.gov*.

vii. *Budget Information (10-page maximum):* The budget portion of the application consists of two parts as described below:

a. *Standard Form (SF) 424A, ''Budget Information'':* Non-Construction Programs. The SF–424A is included as part of the application package posted on *Grants.gov*.

b. *Detailed Budget Narrative:* Provide a detailed narrative in support of the budget for the project, broken down by task. Discuss how the budget specifically supports the proposed activities. Justify the project cost effectiveness and include justification for personnel and consultant salaries with a description of duties. Statement(s) of work for any subcontractors and consultants must be included as part of the application. The budget narrative should include both the Federal funds requested and the applicant's matching funds. The format of the budget narrative can be in a chart, spreadsheet, table, etc. It should be readable on letter-size, printable pages. The information needs to be presented in such a way that the reviewers can readily understand what expenses are incurred to support the project.

viii. *Certifications:* All proposals must include the following signed certification forms, which are available at *Grants.gov*:

a. AD–3030, ''Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants.'' The AD–3030 must be submitted if entity is a corporate non-profit or for-profit corporation as indicated in the applicants SAM registration.

b. AD–3030, ''Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants.'' The AD–3030 must be submitted if entity is a corporate non-profit or for-profit corporation as indicated in the applicants SAM registration.

c. SF–424B, ''Assurances for Non-Construction Programs.'' The SF–242B must be completed by all applicants.

d. SF–424B, ''Assurances for Non-Construction Programs.'' The SF–242B must be completed by all applicants.

ix. *Verification of Matching Funds.* You must provide verification of all matching funds that will be contributed to the project. You must include a letter signed by the donating organization's authorized representative on the organization's letterhead that identifies the amount of matching funds, the time period during which matching funds will be available, and the source of the funds (*e.g.,* cash on hand, etc.). See Section Eligibility Information (C 3) for more information.

x. *Risk Review:* The Agency may request additional documentation from selected applicants in order to evaluate the financial, management, and performance risk posed by awardees as required by 2 CFR 200.205. Based on this risk review, the Agency may apply special conditions that correspond to the degree of risk assessed.

xi. *National Environmental Policy Act:* This Notice has been reviewed in accordance with 7 CFR part 1970, ''Environmental Policies and Procedures.'' We have determined that an Environmental Impact Statement is not required because the issuance of regulations and instructions, as well as amendments to them, describing administrative and financial procedures for processing, approving, and implementing the Agency's financial programs is categorically excluded in the National Environmental Policy Act (NEPA) regulation found at 7 CFR 1970.53(f). We have determined that this Notice does not constitute a major Federal action significantly affecting the quality of the human environment.

xii. *Civil Rights Compliance Requirements:* All awards made under this Notice are subject to Title VI of the Civil Rights Act of 1964 as required by 7 CFR part 15, subpart A and Section 504 of the Rehabilitation Act of 1973.

3. *Unique entity identifier and System for Award Management (SAM).* DUNS and SAM Numbers: Each applicant (unless the applicant is an individual excepted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to: (i) Be registered in SAM before submitting its application; (ii) provide a valid unique entity identifier (Data Universal Numbering System (DUNS) number) in its application; and (iii) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. The Agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time Agency is ready to make a Federal award, Agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Applicants must obtain a DUNS and register in SAM prior to registering with *Grants.gov*. Applicants are strongly encouraged to apply early for their DUNS number and SAM registration.

i. *Data Universal Numbering System (DUNS) Number:* A DUNS number is a unique, nine-digit sequence recognized as the universal standard for identifying and keeping track of over 70 million businesses worldwide. Applicants must obtain a DUNS number. Information on how to obtain a DUNS number can be found at *http://fedgov.dnb.com/webform* or by calling 1–866–705–5711. Please note that the registration may take up to 14 business days to complete.

ii. *System for Award Management (SAM) Registration:* SAM is the official Federal system that consolidated the capabilities of Central Contractor Registry, Federal Agency Registration, Online Representations and Certifications Application, and Excluded Parties List System. To register, go to: *https://www.sam.gov/portal/public/SAM/.* Please allow a minimum of 5 days to complete the SAM registration.

4. *Submission Dates and Times.* Midnight Eastern Standard Time on September 5, 2018. You must submit your application using *Grants.gov* by the deadline date and time. Note that there are registration requirements for submitting applications using the *Grants.gov* system. We recommend that you review the instructions for registering as soon as possible, but at least two weeks before you plan to submit your application. The requirements can be viewed at: *http://grants.gov/applicants/organization_registration.jsp*. Your application will be rejected by *Grants.gov* if you miss the deadline. We will not accept it in a different format, and we will not consider it for funding.

i. *Acknowledgement of receipt: Grants.gov* provides receipt of application submissions. The Agency acknowledges receipt of proposals received by the submission deadline via email. An applicant who does not receive such an email acknowledgement within 5 business days of the submission deadline, but believes the proposal was submitted within the submission deadline, must contact the Agency at 202–568–9832 or *Christine.Sorensen@wdc.usda.gov* within 10 business days of the submission deadline. Failure to do so may result in the proposal not being considered.

ii. *Withdrawal:* Proposals may be withdrawn by written notice at any time before award execution. Written notice of withdrawal must be signed by the applicant or an authorized representative.

All required application documents must be submitted by midnight Eastern Standard Time on Wednesday,

September 5 via *www.grants.gov* AND by emailing *RD.Innovation@osec.usda.gov.*

Submitting an application through *www.grants.gov* requires completing a variety of tasks and steps. There are also several preliminary registration steps before the applicant can submit the application. To register in the *Grants.gov* system, go to *www.grants.gov,* click on ''Applicants'', then click on ''Get Registered.'' If you have completed a prior *Grants.gov* application, you may already have completed the registration process.

Please allow sufficient time to register in *Grants.gov*, and for possible system delays. Below are instructions for accessing the forms necessary to complete an application in *Grants.gov:*

i. Go to *www.grants.gov.* Information about submitting an application using *Grants.gov* is located on the *Grants.gov* website, along with supplementary materials.

ii. Select the ''Applicant'' tab.

iii. Select the ''Apply for Grants'' heading.

iv. Click on ''Get Application Package.'' Follow all steps.

v. Provide the ''Funding Opportunity Number'' or return to the ''Search Grants'' section.

vi. All necessary forms are included within the *Grants.gov* ''Application Package.''

Applications not received through *Grants.gov* by the submission due date and time are not accepted for consideration. The emailed application must be assembled into one pdf file document in the order specified in section IV, part A. All applications must contain all of the elements of a complete package and meet the requirements described in this announcement. *Grants.gov* provides instructions for submitting the required application items through the portal. Application receipt date and time will be determined by the respective system-generated documentation of receipt date and time (*Grants.gov* provides date and time stamps for all proposals submitted through the portal).

The Agency is not responsible for any technical malfunctions or website problems related to *Grants.gov* or emailed submissions. If you encounter issues with *Grants.gov*, please contact the *Grants.gov* help desk at (800) 518–4726 or *support@grants.gov.* The applicant assumes the risk of any delays in application submission through *Grants.gov*.

5. *Intergovernmental Review.* Intergovernmental Review: Executive Order (E.O.) 12372, Intergovernmental Review of Federal Programs, applies to this program. This E.O. requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many States have established a Single Point of Contact (SPOC) to facilitate this consultation. A list of States that maintain an SPOC may be obtained at: *http://www.whitehouse.gov/omb/grants_spoc.* If your State has an SPOC, you must submit your application directly for review. Any comments obtained through the SPOC must be provided to us for consideration as part of your application. If your State has not established an SPOC, we will submit your application to the appropriate agency or agencies at our discretion. Applications from Federally-recognized Indian Tribes are not subject to Intergovernmental Review.

6. *Funding Restrictions.*

i. Pre-award Costs. Pre-award costs are not authorized.

ii. Use of Funds. Award funds may be used to pay up to 50 percent of the project costs.

iii. Period of Performance. The maximum Period of Performance is 2 years. Applicants should anticipate a Period of Performance beginning September 30, 2018 and ending no later September 30, 2020.

iv. Indirect Cost Rate. The indirect cost rate is limited to 10 percent of direct charges for all nonprofit institutions, including institutions of higher education. All other organizations must use the rate identified in their Negotiated Indirect Cost Rate Approval (NICRA). If you do not have a NICRA, you may elect to charge only direct costs to the award. If you have never had a NICRA, you may also choose to use a de minimis rate of 10 percent of modified total direct costs in accordance with 2 CFR 200.414(f). Your indirect cost rate must be included on Form SF–424A.

v. Program Income. If you expect to earn Program Income during the Period of Performance, you must identify the amount and how you expect to use it (*e.g.* Matching Funds) in your application. If your application is funded, unexpected Program Income or Program Income earned in excess of the amount you identify in your application will be deducted from the Federal share of the project in accordance with 2 CFR 200.307(e)(1).

vi. Prohibited Costs. In addition to costs identified as unallowable by 2 CFR part 200, the following costs are prohibited for this program. Neither award funds nor matching funds can be used to pay for the following types of expenses.

a. Duplicating services currently provided;

b. Funding a revolving loan fund;

c. Construction (in any form);

d. Salaries for positions involved in construction, renovations, rehabilitation, and any oversight of these types of activities;

e. Intermediary preparation of strategic plans for recipients;

f. Funding prostitution, gambling, or any illegal activities;

g. Grants to individuals;

h. Funding a grant where there may be a conflict of interest, or an appearance of a conflict of interest, involving any action by the Agency;

i. Providing assistance to only one individual, organization, or business;

j. Paying obligations incurred before the beginning date without prior Agency approval or after the ending date of the cooperative agreement;

k. Purchasing real estate;

l. Improvement or renovation of the recipient's office space or for the repair or maintenance of privately owned vehicles;

m. Any purpose prohibited in 2 CFR part 200 or 400;

n. Using cooperative agreement assistance or matching funds for Individual Development Accounts;

o. Purchasing vehicles.

V. Application Review Information

Applications will first be reviewed to determine if they meet the eligibility requirements and comply with the funding restrictions in this Notice. If we determine that your application is ineligible, we will discontinue processing it, which means that we will not evaluate it further or provide any scoring information. We will notify you in writing regarding the reason(s) for ineligibility, and we will provide a description of your options if you believe that our determination is incorrect. Note that in the event that our determination is reversed, either due to the discovery of an Agency error or through a formal appeal, funding is restricted to available fiscal year 2018 funds.

If your application is determined to be eligible, we will further evaluate it based on the following criteria. All applications will be competitively ranked and the minimum score requirements for a cooperative agreement award under this Notice is 60 points.

1. *Evaluation Criteria:* We will only use the information that you provide in your application to evaluate your proposed project. We will not review references to websites or publications, so we encourage you to fully address each criterion.

i. Soundness of Approach (0–20 points). The applicant can receive up to 20 points for soundness of approach. The maximum 20 points for this criterion will be based on the following:

a. The objectives must be clearly stated in the proposal and the applicant must define how this proposal will be implemented. The applicant must demonstrate how the proposal will strengthen the capacity of rural communities in developing and implementing regional plans for economic development. The applicant must demonstrate how the proposed technical assistance includes both the planning and implementation components referenced in Section C. The applicant must also demonstrate how the proposed technical assistance will expand rural communities' ability to access funding and planning resources to convene community members. The applicant must also demonstrate how the proposal will support implementation of regional economic development plans and should include descriptions on how proposed technical assistance will result in actionable steps to support implementation of these plans. (10 points)

b. The applicant clearly outlines their ability to provide the proposed technical assistance based on clearly stated and well-documented prior accomplishments. (5 points)

c. The proposal clearly outlines how it will implement activities to support alignment with one or more of the five key strategies (achieving e-connectivity, developing the rural economy, harnessing technological innovation, supporting a rural workforce, and improving quality of life in Rural America) the Agriculture and Rural Prosperity Task Force Report. (5 points)

ii. Partnerships (0–25 points). The applicant can receive up to 25 points for quality of the applicant's existing partnerships and proposed new partnerships for this effort. The applicant must recruit one or more private and/or public partners to meet match requirements and maximize leveraging of regional economic development plans developed through this project. The maximum 25 points for this criterion will be based on the following:

a. The applicant demonstrates how their proposal will focus on the quantity and quality of partnerships, including the ability to leverage new partners that have previously had limited engagement with RD projects or priorities to leverage resources, enhance technical assistance, and/or increase reach to underserved areas. The proposal must demonstrate that partners with shared missions and goals will be engaged to amplify reach in rural areas. (10 points)

b. The applicant demonstrates how their proposal will support the quantity and quality of match commitments to support this project, and percentage of match in cash form versus in-kind contributions. (5 points)

c. The applicant will demonstrate how their proposal will support the ability of applicant to leverage other community-driven plans or projects such as Comprehensive Economic Development Strategies (CEDS) or other Federally-recognized regional economic development plans. (5 points)

d. The applicant will demonstrate how their proposal will utilize partnerships outside of RD. The applicant will identify such partnerships and will demonstrate how they will provide access to such partnerships to support implementation of projects identified through development of regional economic development plans. (10 points)

iii. Innovation (0–10 points). The applicant can receive up to 10 points for innovative methods and practices to support development of regional economic development plans. The maximum 10 points for this criterion will be based on the following:

a. The applicant's proposal should demonstrate the ability of the applicant to propose methods and practices to utilize unique and innovative planning methods that are currently not being implemented at scale. (5 points)

b. The applicant's proposal should demonstrate the ability of the applicant to demonstrate that the proposed innovative methods and practices have been field-tested and ready to scale. (5 points) We are looking for unique and innovative ideas that are not currently being implemented at scale, so projects that propose innovative solutions that haven't been readily deployed before will receive higher points.

iv. Organizational Capacity & Qualifications (0–15 points). The applicant can receive up to 15 points based on organizational capacity and qualifications. The maximum 15 points for this criterion will be based on the following:

a. The applicant's proposal should demonstrate that the applicant has knowledge and prior experience in regional planning, particularly related to rural issues. The applicant should specify years of experience, types of communities served, and outcomes achieved. (10 points)

b. The applicant's proposal should demonstrate that the applicant has identified appropriate key personnel, both in terms of number of personnel and qualifications of personnel, to carry out the approach identified. Capacity of personnel to access data for needs assessments and access to planners and other technical experts will be evaluated. (5 points)

v. Work Plan (0–15 points). The applicant can receive up to 15 points based on the quality of the proposed work plan and approach. The maximum 15 points for this criterion will be based on the following:

a. Applicants should use the approved work plan template to include the following information: Description of objective, background approach, timeframe for key tasks along with substantial involvement, budget and deliverables that are necessary to implement project to support regional economic development planning in rural communities. Reasonableness and appropriateness of key tasks will be evaluated based on proposed project approach. (5 points)

b. The applicant's proposal should include a description of the types and general locations of rural communities to be served through this project, including the ability to support multiple rural planning activities across the nation and the reasonableness of effectively serving these communities based on key personnel, established timeframes, and budget. (5 points)

c. The applicant's proposal should include a description and appropriateness of the tasks to incorporate active participation from RD staff. (5 points)

vi. Performance Outcomes (0–15 points). The applicant can receive up to 15 points based on the quality of the proposed performance measures to evaluate progress and impacts of proposed project. The maximum 15 points for this criterion will be based on the following:

a. The applicant's proposal should include a description for how the results of the technical assistance will be measured, including the benchmarks to be used to measure effectiveness. Benchmarks should be specific and quantifiable. (10 points)

b. The applicant's proposal should include a description of benchmarks and outcomes achieved during previously deployed planning efforts. (5 points)

2. *Review and Selection Process:* All eligible applications will be evaluated based on the process described below.

i. Review Process. All eligible applications will be evaluated by an Application Review Panel using the criteria described in Section E.1 of this Notice. Panel members will be

appointed by the Agency and they will be qualified to evaluate the applications, based on the type of work proposed by the applicant.

ii. Selection Process. Applications will be ranked in descending order, according to the scores awarded by the Panel. Applications will be funded in rank order, until all available funds have been expended. Applications at or near the funding line may be funded in part, if the Agency believes an appropriate benefit can result from partial funding and if the applicant agrees to the amount of partial funding. In the event the Agency considers partial funding to be appropriate, we will contact the applicant and negotiate the final work plan and budget prior to approving an award.

iii. Anticipated Announcement and Award Dates. All awards must be obligated by September 30, 2018.

VI. Award Administration Information

1. Federal Award Notices:

i. Successful applicants. Successful applicants will be notified in writing by *the Agency* with a Letter of Conditions (LOC). The LOC is a notice of selection and does not indicate that an award has been approved, nor is it an authorization to begin performance on the award. While there may be special conditions that apply on a case-by-case basis, the following conditions are standard for all successful applicants.

a. Complete Form RD 1942–46, ''Letter of Intent to Meet Conditions.''

b. Complete Form RD 1940–1, ''Request for Obligation of Funds.''

c. Complete FMMI Vendor Code Request Form.

d. Provide a copy of your organization's Negotiated Indirect Cost Rate Agreement.

e. Certify that all work completed for the award will benefit a rural area.

f. Certify that you will comply with the Federal Funding Accountability and Transparency Act of 2006 and report information about subawards and executive compensation.

g. Certify that the U.S. has not obtained an outstanding judgement against your organization in a Federal Court (other than in the United States Tax Court).

h. Execute Form SF–424B, ''Assurances—Non-Construction Programs.''

i. Execute Form SF–LLL, ''Disclosure Form to Report Lobbying,'' if applicable or certify that your organization does not lobby.

j. Execute Form AD–1047, ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters-Primary Covered Transactions.''

k. Obtain a certification on Form AD–1048, ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions,'' from anyone you do business with as a result of this award.

l. Execute Form AD–1049, ''Certification Regarding a Drug-Free Workplace Requirements (Grants).''

m. Execute Form AD–3031, ''Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.''

n. Execute Form RD 400–4, ''Assurance Agreement.''

Once the conditions described in the LOC have been met, the award will be approved through the execution of Form RD 4280–2 in conjunction with the RDCA Program Attachment. If an applicant is unable to meet the conditions of the award within 90 calendar days, the award will be withdrawn.

ii. Unsuccessful applicants. Unsuccessful applicants will be notified in writing no later than October 31, 2018.

2. Administrative and National Policy Requirements. The terms of the award are available at: *http://forms.sc.egov.usda.gov/efcommon/eFileServices/eForms/RD4280-2.PDF.*

3. Reporting Requirements. The following reporting requirements apply to awards made through this program.

i. *Performance Reports:* Form SF–PPR, ''Performance Progress Report,'' must be submitted quarterly based on the following time periods: January 1–March 31, April 1–June 30, July 1–September 30, and October 1–December 31. Quarterly reports are due within 30 calendar days of the end of the reporting period. A final report is due within 90 calendar days of the completion of the project or the end of the period of performance, whichever comes first. Both quarterly and final performance reports must be submitted electronically to 202–568–9832 or *Christine.Sorensen@wdc.usda.gov.*

ii. *Financial Report:* Form SF–425, ''Federal Financial Report'' must be submitted quarterly based on the following time periods: January 1–March 31, April 1–June 30, July 1–September 30, October 1–December 31. Quarterly reports are due within 30 calendar days of the end of the reporting period. A final report is due within 90 calendar days of the completion of the project or the end of the period of performance, whichever is comes first. Both quarterly and final reports must be submitted electronically to *Christine.Sorensen@wdc.usda.gov.*

iii. *Report Suitable for Public Distribution:* A report suitable for public distribution that describes the accomplishments of the project is due within 90 calendar days of the completion of the project. There is no format prescribed for this report, but it is expected that it will be 1–2 pages in length and describe the project in such a way that a member of the public not familiar with the project would gain an understanding of the impact of the project.

VII. Federal Awarding Agency Contact

If you have questions, you may contact Christine Sorensen at 202–568–9832 or *Christine.Sorensen@wdc.usda.gov.*

VIII. Notice to Applicants

The Federal Government is not obligated to make any Federal award as a result of this announcement. Only authorized Federal officials can bind the Federal Government to the expenditure of funds.

IX. Nondiscrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program. Political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARTET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at: *http://www.ascr.usda.gov/complaint_filing_cust.html,* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the

information requested in the form. To request a copy of a complaint form, call, (866) 632–9992. Submit your completed form or letter to USDA by:

1. *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

2. *Fax:* (202) 690–7442; or

3. *Email at: program.intake@usda.gov.*

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Dated: August 10, 2018.

Anne Hazlett,

Assistant to the Secretary, USDA Rural Development.

BILLING CODE 3410–15–P

RURAL ECONOMIC DEVELOPMENT INNOVATION (REDI)

FY18 COOPERATIVE AGREEMENT

APPLICATION PACKAGE CHECKLIST

- ☐ Application Forms (in Grants.gov application package).
- ☐ Executive Summary (1-page maximum).
- ☐ Applicant Qualifications (1-2 pages).
- ☐ Key Personnel Qualifications (1-2 pages).
- ☐ Project Proposal (15-page maximum).
  - ☐ Project Background.
  - ☐ Project Objectives.
  - ☐ Project Methods.
  - ☐ Geographic Location or Project Areas.
  - ☐ Project Management (Applicants are required to include a Work Plan Chart that lists each major Task by Key Personnel involved, Time Period of the task, Substantial Involvement of Rural Development staff, Deliverables, and Budget associated with each task).
  - ☐ Performance Measures.
  - ☐ Graphics, References, Citations (Do not count against the 15-page maximum)
- ☐ Letters of Support (i.e. match requirement, additional resource commitment from partners, etc.).
- ☐ Budget Information (10-page maximum).

- SF-424 Budget Form.
- Detailed Budget Narrative (including indirect cost rate or indirect cost rate proposal).
- Certifications.
- Verification of Matching Funds.
- DUNS and SAM Registration.

[FR Doc. 2018–17765 Filed 8–16–18; 8:45 am]
BILLING CODE 3410–15–C

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Establishment of Maximum Interest Rate

AGENCY: Rural Housing Service, USDA.

ACTION: Request for information.

SUMMARY: The Rural Housing Service (RHS or Agency) seeks public comments on updating the provisions of the Single Family Housing Guaranteed Loan Program (SFHGLP), specifically regarding the maximum interest rate, its impact on loan making to potential SFHGLP borrowers, and possible changes to the interest rate cap. RHS is soliciting input regarding the maximum interest rate to help the Agency determine whether the interest rate cap should be modified in order to support the agency's mission to offer applicants, who are unable to secure the credit necessary for such housing from other sources under conventional credit terms, an opportunity to acquire new or existing housing for use as a primary residence; finance the repair and rehabilitation costs associated with the purchase of the home; and refinance an existing Section 502 loan to lower the interest rate.

These opportunities are provided to applicants under terms and conditions which the applicant can reasonably be expected to fulfill.

DATES: Written Comments: Interested parties must submit written comments on or before October 16, 2018.

ADDRESSES: Submit comments in either paper or electronic format by the following methods:

- Federal eRulemaking Portal at *http://www.regulations.gov.* Follow instructions for submitting comments.
- *Postal Mail/Commercial Delivery:* Please send your comments addressed to Kate Jensen, Finance and Loan Analyst, Single Family Housing Guaranteed Loan Program, USDA Rural Development, 1400 Independence Avenue, STOP 0784, Room 2250, Washington, DC 20250–1522.

FOR FURTHER INFORMATION CONTACT: Kate Jensen, Finance and Loan Analyst, at *kate.jensen@wdc.usda.gov* or (503) 894–2382.

SUPPLEMENTARY INFORMATION:

Background

RHS delivers programs authorized by the Housing Act of 1949, as amended (42 U.S.C. 1472 *et seq.*) (Housing Act). The preamble to the Housing Act declares that every American deserves a ''decent home and a suitable living environment.'' RHS guarantees a variety of housing loans for home purchases, repair, and rental housing development in rural areas. The SFHGLP provides low- and moderate-income borrowers access to mortgage credit by guaranteeing loans issued by agency-approved private sector lenders. Loans may finance the full construction and acquisition cost of a property up to 100 percent of the appraised value. Mortgages have 30-year terms and fixed rates negotiated with the lender that cannot exceed an interest rate cap that is determined by the Agency. Financing may also be used to refinance existing USDA guaranteed or direct loans. The program maintains its neutral or slightly negative subsidy status through guarantee and annual loan fees.

Request for Comment

Stakeholder input is vital to ensure that the maximum interest rate continues to support the agency's mission and not overly burden SFHGLP lenders and their customers. Currently, the maximum allowable interest rate is defined in Section 7.3.B of the program handbook (available at *https://www.rd.usda.gov/files/3555-1chapter07.pdf*) as the current Fannie Mae posted yield for 90-day delivery (Actual/Actual), plus one percent for 30-year fixed rate conventional loans, rounded up to the nearest one quarter of one percent. The Agency is considering whether to modify the maximum interest rate and would like stakeholder feedback on the issue.

The following questions and discussion items are posed to guide stakeholder comments. Where possible, RHS requests that comments include specific suggestions regarding ways to improve existing programs and delivery mechanisms and eliminate or minimize the duplication of RHS's regulation and policies with work performed by other entities, including federal, state, and local agencies. RHS welcomes pertinent comments that are beyond the scope of these questions.

1. Should the Agency continue with the requirement that the maximum allowable interest rate shall not exceed the current Federal National Mortgage Association posted yield for 90-day delivery (Actual/Actual) plus one percent for 30-year fixed rate conventional loans, rounded up to the nearest one quarter of one percent?

2. Should the Agency consider indexing the maximum allowable interest rate to a source other than the Federal National Mortgage Association?

3. Should a higher maximum allowable interest rate cap be established? If so, what maximum rate is recommended, and why?

4. Does the current maximum interest rate create any barriers to loan making in eligible rural areas? If so, how and under what circumstances?

5. What effect would increasing or eliminating the maximum interest rate have for loan originators and borrowers in underserved populations and rural communities?

6. If the maximum allowable interest rate cap were to be increased or

eliminated, what protections exist to prevent consumers from being overcharged?

7. If the maximum allowable interest rate is raised or removed, what steps should the Agency take to monitor lenders to ensure that borrowers are not overcharged?

Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *Fax:* (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

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Dated: August 13, 2018.

Joel C. Baxley,

Administrator, Rural Housing Service.

[FR Doc. 2018–17764 Filed 8–16–18; 8:45 am]

BILLING CODE 3410–XV–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Delaware Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of monthly planning meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Delaware State Advisory Committee to the Commission will convene by conference call, on Monday, September 17, 2018 at 10:00 a.m. (EDT). The purpose of the meeting is to discuss preparation of the Committee's report on implicit bias and policing in communities of color in Delaware.

DATES: Monday, September 17, 2018, at 10:00 a.m. (EDT).

ADDRESSES: *Public Call-In Information:* Conference call number: 1–800–210–9006 and conference call ID: 4124362.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–800–210–9006 and conference call ID: 4124362. Please be advised that before placing them into the conference call, the conference call operator may ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number herein.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call number: 1–800–210–9006 and conference call ID: 4124362.

Members of the public are invited to submit written comments; the comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *http://facadatabase.gov/committee/meetings.aspx?cid=240;* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Monday, September 17, 2018 at 10:00 a.m.

I. Welcome and Introductions
Rollcall
II. Planning Meeting
Discuss Project Report
III. Other Business
IV. Adjournment

Dated: August 13, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–17734 Filed 8–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Virginia Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the Virginia Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EST) on Wednesday, September 19, 2018. The purpose of the meeting is for Committee members to continue discussing plans for the in-person briefing on hate crimes in VA—incidences and responses.

DATES: Wednesday, September 19, 2018, at 12:00 p.m. EST.

ADDRESSES: *Public call-in information:* Conference call-in number: 1–800–474–8920 and conference call 8310490.

FOR FURTHER INFORMATION CONTACT: Ivy Davis at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–800–474–8920 and conference call 8310490. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call-in number: 1–800–474–8920 and conference call 8310490.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Corrine Sanders at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=279,* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Wednesday, September 19, 2018

I. Rollcall
II. Welcome
III. Planning Discussion
IV. Other Business
V. Adjourn

Dated: August 13, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–17735 Filed 8–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the District of Columbia Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of monthly planning meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the District of Columbia Advisory Committee to the Commission will convene at 12:00 p.m. (EDT) Thursday, September 6, 2018, at the offices of the U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue NW, Suite 1150, Washington, DC 20425. The purpose of the planning meeting is to continue project planning a briefing meeting on its civil rights project to examine the treatment of homeless persons that get swept up in the DC criminal justice system, including a review of the DC Mental Health Court.

DATES: Thursday, September 6, 2018 at 12:00 p.m. (EDT).

ADDRESSES: 1331 Pennsylvania Avenue NW, Suite 1150, Washington, DC 20425.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Persons with accessibility needs should contact the Eastern Regional Office no later than 10 working days before the scheduled meeting by sending an email to the following email address at *ero@usccr.gov.*

Members of the public are entitled to submit written comments. The comments must be received in the regional office by Tuesday, October 9, 2018. Comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425 or emailed to Evelyn Bohor at *ero@usccr.gov*. Persons who desire additional information may contact the Eastern Regional Office at 202–376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *http://facadatabase.gov/committee/meetings.aspx?cid=241*; click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone numbers, email or street address.

Agenda

Thursday, September 6, 2018, at 12:00 p.m.

I. Rollcall
II. Welcome and Introductions
III. Discuss Plans for the Briefing Meeting
IV. Other Business
V. Adjourn

Dated: August 13, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–17733 Filed 8–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the West Virginia Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the West Virginia Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EST) on Friday, September 7, 2018. The purpose of the meeting is to discuss plans for preparing the Committee report on the collateral consequences of a felony record on West Virginians' access to employment, housing, professional licenses and public benefits.

DATES: Friday, September 7, at 12:00 p.m. EST

ADDRESSES: *Public Call-In Information:* Conference call-in number: 1–800–474–8920 and conference call 5788080.

FOR FURTHER INFORMATION CONTACT: Ivy Davis at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–800–474–8920 and conference call 5788080. Please be advised that before placing

them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–888–364–3109 and providing the operator with the toll-free conference call-in number: 1–800–474–8920 and conference call 5788080.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Corrine Sanders at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=279,* click the ''Meeting Details'' and ''Documents'' links.Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Friday, September 7, 2018

I. Rollcall
II. Welcome
III. Planning Discussion
IV. Other Business
V. Adjourn

Dated: August 13, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–17739 Filed 8–16–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Idaho Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Idaho Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Mountain Time) Tuesday, September 18, 2018, for the purpose of reviewing the project proposal on Native American voting rights.

DATES: The meeting will be held on Tuesday, September 18, 2018, at 12:00 p.m. MT.

Public Call Information: Dial: 888–602–6363, Conference ID: 2385391.

FOR FURTHER INFORMATION CONTACT: Angelica Trevino at *atrevino@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the number listed above. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Angelica Trevino at *atrevino@usccr.gov*. Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *http://facadatabase.gov/committee/meetings.aspx?cid=245*. Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome and Roll Call
II. Discuss Project Proposal
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: August 14, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–17795 Filed 8–16–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–839]

Carbazole Violet Pigment 23 From India: Rescission of Countervailing Duty Administrative Review; 2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on carbazole violet pigment 23 (CVP–23) from India for the period January 1, 2016, through December 31, 2016.

DATES: Applicable August 17, 2018.

FOR FURTHER INFORMATION CONTACT: Gene H. Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

On December 4, 2017, Commerce published a notice of opportunity to request an administrative review of the CVD order on CVP–23 from India for the period of review (POR) January 1, 2016, through December 31, 2016.[1] On

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity*

Continued

December 5, 2017, Commerce received a timely-filed request to conduct an administrative review of the CVD order from Pidilite Industries Limited (Pidilite).[2] Based on this request, and in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an administrative review of the CVD order on CVP–23 from India.[3] On March 16, 2018, Pidilite timely withdrew its request for an administrative review.[4] No other party requested an administrative review.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review. In this case, Pidilite timely withdrew its request for review within the 90-day deadline, and no other party requested an administrative review of the CVD order. Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this administrative review in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries. Because Commerce is rescinding this administrative review in its entirety, entries of CVP–23 from India during the period January 1, 2016, through December 31, 2016, shall be assessed countervailing duties at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Order

This notice serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: August 13, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–17781 Filed 8–16–18; 8:45 am]

BILLING CODE 3510–DS–P

To Request Administrative Review, 82 FR 57219 (December 4, 2017).

[2] *See* Letter from Pidilite, ''Carbazole Violet Pigment 23 from India: Requests for Administrative Review,'' dated December 4, 2017.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 8058 (February 23, 2018).

[4] *See* Letter from Pidilite, ''Carbazole Violet Pigment 23 from India: Withdrawal of Review Request,'' dated March 16, 2018.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG414

Mid-Atlantic Fishery Management Council (MAFMC); Public Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council), jointly with the Atlantic States Marine Fisheries Commission (Commission's) Summer Flounder, Scup, and Black Sea Bass Board (Board), will hold 10 public hearings, including one webinar hearing, to solicit public comments on the Draft Summer Flounder Commercial Issues and Goals and Objectives Amendment to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP).

DATES: Written public comments must be received on or before 11:59 p.m. EST, October 12, 2018. The meetings will be held between September 10, 2018 and September 27, 2018. For specific dates and times, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The hearing documents are accessible electronically via the internet at: *http://www.mafmc.org/actions/summer-flounder-amendment* or by request to Dr. Chris Moore, Executive Director, Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

Meeting addresses: The public hearings will be held in Bourne, MA; Narragansett, RI; Old Lyme, CT; Stony Brook, NY; Toms River, NJ; Dover, DE; Berlin, MD; Newport News, VA; and Washington, NC. One additional hearing will be held by internet webinar. For specific locations, see **SUPPLEMENTARY INFORMATION.**

Public comments: Written comments may be sent by any of the following methods:

- *Email to: nmfs.flukeamendment@noaa.gov;* Include ''Summer Flounder Commercial Issues Amendment Comments'' in the subject line.
- *Submit via webform at: www.mafmc.org/comments/summer-flounder-amendment.*
- *Mail to:* Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901. Mark the outside of the envelope ''Summer Flounder Commercial Issues Amendment Comments.''
- *Fax to:* (302) 674–5399.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission have been preparing an amendment to the Summer Flounder, Scup, and Black Sea Bass FMP, known as the ''Summer Flounder Commercial Issues and Goals and Objectives Amendment.'' This amendment considers modifications to the qualification criteria for Federal commercial moratorium summer flounder permits, the current allocation of summer flounder commercial quota, and the current list of frameworkable items in the FMP (specifically, it considers adding a framework provision for commercial landings flexibility). An additional purpose of the action is to revise the FMP goals and objectives for summer flounder only. Additional information and amendment documents are available at: *http://www.mafmc.org/actions/summer-flounder-amendment.*

The Council and Board will hold 10 public hearings on this amendment, during which Council or Commission staff will brief the public on the contents of the amendment documents and alternatives under consideration, prior to opening the hearing for public comments. The hearings schedule is as follows:

1. *Monday, September 10, 2018 at 7 p.m.:* Connecticut Department of Energy and Environmental Protection Marine

Headquarters Boating Education Center (Rear Building), 333 Ferry Road, Old Lyme, CT 06371.

2. *Wednesday, September 12, 2018 at 6 p.m.:* North Carolina Division of Marine Fisheries Washington Regional Office, 943 Washington Square Mall, US Highway 17, Washington, NC 27889.

3. *Thursday, September 13, 2018 at 6 p.m.:* Delaware Dept. of Natural Resources & Environmental Control Auditorium, Richardson & Robbins Building, 89 Kings Highway, Dover, DE 19901.

4. *Thursday, September 13, 2018 at 6 p.m.:* Virginia Marine Resources Commission, 2600 Washington Avenue, 4th Floor, Newport News, VA 23607.

5. *Wednesday, September 19, 2018 at 5:30 p.m.:* Bourne Community Center, Room #2, 239 Main Street, Buzzards Bay, MA 02532.

6. *Wednesday, September 19, 2018 at 6 p.m.:* University of Rhode Island Bay Campus, Corless Auditorium, South Ferry Road, Narragansett, RI 02882.

7. *Monday, September 24, 2018 at 6 p.m.:* Ocean County Administrative Building, 101 Hooper Ave., Toms River, NJ 08753.

8. *Tuesday, September 25, 2018 at 6 p.m.:* Ocean Pines Library, 11107 Cathell Rd., Berlin, MD 21811.

9. *Thursday, September 27, 2018 at 6:30 p.m.:* New York State Department of Environmental Conservation, School of Marine and Atmospheric Sciences (SOMAS), Room 120 Endeavor; Stony Brook University, Stony Brook, NY 11794.

10. *Thursday, September 27, 2018 at 6:30 p.m.:* Internet webinar. Connection information to be posted at *www.mafmc.org* prior to the meeting.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at the Mid-Atlantic Council Office, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: August 14, 2018.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–17776 Filed 8–16–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG422

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) and its advisory entities will hold public meetings.

DATES: The Pacific Council and its advisory entities will meet September 5–12, 2018. The Pacific Council meeting will begin on Friday, September 7, 2018 at 10 a.m. Pacific Daylight Time (PDT), reconvening at 8 a.m. each day through Wednesday, September 12, 2018. All meetings are open to the public, except a closed session will be held from 8 a.m. to 10 a.m., Friday, September 7 to address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: Meetings of the Pacific Council and its advisory entities will be held at the Doubletree by Hilton Hotel Seattle Airport, 18740 International Blvd., Seattle, WA; telephone: (206) 246–8600.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220. Instructions for attending the meeting via live stream broadcast are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Mr. Chuck Tracy, Executive Director; telephone: (503) 820–2280 or (866) 806–7204 toll-free; or access the Pacific Council website, *http://www.pcouncil.org* for the current meeting location, proposed agenda, and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The September 7–12, 2018 meeting of the Pacific Council will be streamed live on the internet. The broadcasts begin initially at 10 a.m. PDT Friday, September 7, 2018 and continue at 8 a.m. daily through Wednesday, September 12, 2018. Broadcasts end daily at 5 p.m. PDT or when business for the day is complete. Only the audio portion and presentations displayed on the screen at the Pacific Council meeting will be broadcast. The audio portion is listen-only; you will be unable to speak to the Pacific Council via the broadcast. To access the meeting online, please use the following link: *http://www.gotomeeting.com/online/webinar/join-webinar* and enter the September Webinar ID, 530–089–227, and your email address. You can attend the webinar online using a computer, tablet, or smart phone, using the GoToMeeting application. It is recommended that you use a computer headset to listen to the meeting, but you may use your telephone for the audio-only portion of the meeting. The audio portion may be attended using a telephone by dialing the toll number 1–562–247–8321 (not a toll-free number), audio access code 240–052–611, and entering the audio pin shown after joining the webinar.

The following items are on the Pacific Council agenda, but not necessarily in this order. Agenda items noted as ''Final Action'' refer to actions requiring the Council to transmit a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the Magnuson-Stevens Fishery Conservation and Management Act. Additional detail on agenda items, Council action, advisory entity meeting times, and meeting rooms are described in Agenda Item A.5, Proposed Council Meeting Agenda, and will be in the advance September 2018 briefing materials and posted on the Pacific Council website at *www.pcouncil.org* no later than Monday, August 20, 2018.

A. Call to Order
1. Opening Remarks
2. Council Member Appointments
3. Roll Call
4. Executive Director's Report
5. Approve Agenda

B. Open Comment Period
1. Comments on Non-Agenda Items

C. Coastal Pelagic Species
1. Amendment 17: Live Bait Fishery Allowance

D. Habitat
1. Current Habitat Issues

E. Salmon
1. Salmon Methodology Review—Final Topic Selection
2. Update on Salmon Rebuilding Plans

F. Administrative
1. Research and Data Needs Document—Final Adoption
2. Legislative Matters
3. Electronic Monitoring Program Review and Cost Allocation Procedural Directive
4. Fiscal Matters
5. Approval of Council Meeting Record

6. Membership Appointments and Council Operating Procedures
7. Future Council Meeting Agenda and Workload Planning

G. Ecosystem Management
1. West Coast Ecosystem-Based Fishery Management Roadmap Implementation
2. Fishery Ecosystem Plan Five-Year Review—Scoping
3. Climate and Communities Initiative Update

H. Highly Migratory Species
1. National Marine Fisheries Service Report
2. Final Recommendations on Non-Deep-Set Buoy Gear Exempted Fishing Permits (EFPs)
3. Recommend International Management Activities
4. Biennial Harvest Specifications and Management Measures
5. Drift Gillnet Performance Metrics Methodology
6. Swordfish Monitoring and Management Plan

I. Groundfish Management
1. National Marine Fisheries Service Report
2. Amendment 28—Essential Fish Habitat and Rockfish Conservation Area—Implementation Update
3. Endangered Species Act Consultation on Eulachon
4. Stock Assessment Terms of Reference—Final Action
5. Methodology Review—Preliminary Topic Selection
6. Science Improvement Report
7. Five-Year Catch Share Follow On Action—Preliminary Action
8. Continuing Midwater Trawl and Gear EFP and Salmon Bycatch Provisions in New EFPs
9. Omnibus Workload Planning Process
10. Inseason Adjustments—Final Action

J. Pacific Halibut Management
1. 2019 Catch Sharing Plan and Annual Regulations

Advisory Body Agendas

Advisory body agendas will include discussions of relevant issues that are on the Pacific Council agenda for this meeting, and may also include issues that may be relevant to future Council meetings. Proposed advisory body agendas for this meeting will be available on the Pacific Council website *http://www.pcouncil.org/council-operations/council-meetings/current-briefing-book/* no later than Monday, August 20, 2018.

Schedule of Ancillary Meetings

Day 1—Wednesday, September 5, 2018

Scientific and Statistical Committee Ecosystem Subcommittee: 8 a.m.

Day 2—Thursday, September 6, 2018

Coastal Pelagic Species Advisory Subpanel: 8 a.m.
Coastal Pelagic Species Management Team: 8 a.m.
Ecosystem Advisory Subpanel: 8 a.m.
Ecosystem Workgroup: 8 a.m.
Habitat Committee: 8 a.m.
Scientific and Statistical Committee: 8 a.m.
Legislative Committee: 10 a.m.
Budget Committee: 1 p.m.

Day 3—Friday, September 7, 2018

California State Delegation: 7 a.m.
Oregon State Delegation: 7 a.m.
Washington State Delegation: 7 a.m.
Ecosystem Advisory Subpanel: 8 a.m.
Ecosystem Plan Development Team: 8 a.m.
Highly Migratory Species Advisory Subpanel: 8 a.m.
Highly Migratory Species Management Team: 8 a.m.
Enforcement Consultants: 8 a.m.
Scientific and Statistical Committee: 8 a.m.

Day 4—Saturday, September 8, 2018

California State Delegation: 7 a.m.
Oregon State Delegation: 7 a.m.
Washington State Delegation: 7 a.m.
Groundfish Advisory Subpanel: 8 a.m.
Groundfish Management Team: 8 a.m.
Highly Migratory Species Advisory Subpanel: 8 a.m.
Highly Migratory Species Management Team: 8 a.m.
Enforcement Consultants: Ad Hoc

Day 5—Sunday, September 9, 2018

California State Delegation: 7 a.m.
Oregon State Delegation: 7 a.m.
Washington State Delegation: 7 a.m.
Groundfish Advisory Subpanel: 8 a.m.
Groundfish Management Team: 8 a.m.
Enforcement Consultants: Ad Hoc

Day 6—Monday, September 10, 2018

California State Delegation: 7 a.m.
Oregon State Delegation: 7 a.m.
Washington State Delegation: 7 a.m.
Groundfish Advisory Subpanel: 8 a.m.
Groundfish Management Team: 8 a.m.
Enforcement Consultants: Ad Hoc

Day 7—Tuesday, September 11, 2018

California State Delegation: 7 a.m.
Oregon State Delegation: 7 a.m.
Washington State Delegation: 7 a.m.
Groundfish Advisory Subpanel: 8 a.m.
Groundfish Management Team: 8 a.m.
Enforcement Consultants: Ad Hoc

Day 8—Wednesday, September 12, 2018

California State Delegation: 7 a.m.
Oregon State Delegation: 7 a.m.
Washington State Delegation: 7 a.m.

Although non-emergency issues not contained in this agenda may come before the Pacific Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Pacific Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280, ext. 411 at least ten business days prior to the meeting date.

Dated: August 14, 2018.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–17775 Filed 8–16–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG415–X

Marine Mammals; File No. 22222

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Tamara McGuire, 310 W 123rd Ave., Anchorage, AK 99515, has applied in due form for a permit to conduct research on endangered Cook Inlet beluga whales.

DATES: Written, telefaxed, or email comments must be received on or before September 17, 2018.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22222 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources,

NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov*. Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Sara Young, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Ms. McGuire requests a 5-year permit to conduct research on endangered Cook Inlet beluga whales (*Delphinapterus leucas*), in Cook Inlet, AK. The purpose of the research is to (1) continue to build and maintain the species' photo-identification catalog, (2) describe the population's characteristics, and (3) determine life history characteristics of the species. Research may result in up to 6,800 annual takes of whales by Level B harassment during vessel surveys for observation, photography, and photo-identification. Up to 100 harbor seals (*Phoca vitulina*) annually could be incidentally disturbed during surveys.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: August 14, 2018.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–17772 Filed 8–16–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG403

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Science and Statistical Committee Subgroup (SSC Subgroup) will hold a public meeting.

DATES: The meeting will be held on Monday, September 10, 2018 from 9 a.m. to 4 p.m.

ADDRESSES: The meeting will be held in Room 2079, at the Alaska Fisheries Science Center (AFSC), 7700 Sand Point Way NE, Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Stephani Zador, AFSC staff; telephone: (206) 526–4693.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, September 10, 2018

The agenda will include: (a) AFSC review of Alaska surveys and budget considerations; (b) discussion of alternatives for survey planning based on different budget scenarios; (c) develop recommendations for the SSC and Council; (d) other business. The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org/upcoming-meetings/.*

Public Comment

Public comment letters will be accepted until the start of the meeting, and should be submitted either electronically to Diana Evans, Council staff: *diana.evans@noaa.gov* or through the mail: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252. In-person oral public testimony will be accepted at the discretion of the chair.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: August 14, 2018.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–17774 Filed 8–16–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG346

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 61 in-person Data/Assessment Workshop for Gulf of Mexico Red Grouper.

SUMMARY: The SEDAR 61 assessment of the Gulf of Mexico Red Grouper will consist of one in-person Data/Assessment Workshop and a series of webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 61 Data/Assessment Workshop will be held from 9 a.m. until 5 p.m. on September 11, 2018, from 8:30 a.m. until 5 p.m. on September 12, 2018, and from 8:30 a.m. until 1 p.m. on September 13, 2018.

ADDRESSES:

Meeting address: The SEDAR 61 Data/Assessment Workshop will be held at the Hilton St. Petersburg Bayfront, 333 1st Street S, St. Petersburg, FL 33701; telephone: 1–800–445–8667.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366. Email: *Julie.neer@safmc.net*.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data/Assessment Workshop, and (2) a series of webinars. The product of the Data/Assessment Workshop is a report which compiles and evaluates potential

datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Data/Assessment Workshop are as follows:

1. An assessment data set and associated documentation will be developed during the workshop.

2. Participants will evaluate proposed data and select appropriate sources for providing information on life history characteristics, catch statistics, discard estimates, length and age composition, and fishery dependent and fishery independent measures of stock abundance.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 14, 2018.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–17773 Filed 8–16–18; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Addition and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed addition to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add a product to the Procurement List that will be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities, and deletes products and services previously furnished by such agencies.

DATES: Comments must be received on or before: September 16, 2018.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Addition

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice will be required to procure the product listed below from nonprofit agency employing persons who are blind or have other severe disabilities.

The following product is proposed for addition to the Procurement List for production by the nonprofit agency listed:

Product

NSN(s)—Product Name(s): 7360–00–139–0480—Disposable Dinnerware Kit
Mandatory Source of Supply: Expanco, Inc., Fort Worth, TX
Contracting Activity: Defense Logistics Agency Troop Support

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s):
COE001—Blazer
COE002—Blazer
COE004—Shirt
COE005—Shirt
COE006—Shirt
COE007—Shirt
COE008—Tab Bow
COE009—Tie
COE010—Tie Tac
COE011—pants
COE012—Pants
COE013—Skirt
COE014A—Shirt
COE014B—Shirt
COE015B—Shirt
COE015A—Shirt
COE016A—Trousers
COE016B—Trousers
COE018—Cap
COE027—Shirt COE032—pants
COE033—Pants
COE034A—Gloves
COE034B—Gloves
Mandatory Source of Supply: Human Technologies Corporation, Utica, NY
Contracting Activity: W072 Endist Pittsburgh, Pittsburgh, PA
NSN(s)—Product Name(s): 7510–00–NSH–0114—Black
Mandatory Source of Supply: TRI Industries NFP, Vernon Hills, IL
Contracting Activity: Kansas City Acquisition Branch, Kansas City, MO

Services

Service Type:
Mandatory for: VA Outpatient Clinic, Mobile, AL
Mandatory Source of Supply: Lakeview Center, Inc., Pensacola, FL
Contracting Activity: Veterans Affairs, Department of, NAC

Service Type: Janitorial Service
Mandatory for: Naval Operations Support Center (NOSC) Bldgs. 245 and 247, Cheyenne, WY
Mandatory Source of Supply: Skils'kin, Spokane, WA
Contracting Activity: Dept of the Navy, NAVFAC Northwest

Service Type: Janitorial/Custodial Service
Mandatory for: Orlando VA Medical Center: 2500 Leahy Avenue, Orlando, FL
Mandatory Source of Supply: Lakeview Center, Inc., Pensacola, FL
Contracting Activity: Veterans Affairs, Department of, 675–Orlando

Service Type: Food Service Attendant
Mandatory for: USDA, Animal and Plant Health Inspection Service: Otis Methods Dev. Center, Building 1398, Otis ANG Base, MA
Mandatory Source of Supply: Unknown,
Contracting Activity: Dept of the Air Force, FA7014 AFDW PK

Service Type: Laundry Service
Mandatory for:

Aiken CBOC, 951 Milbrook Avenue, Aiken, SC
Athens VA CBOC, 9249 Highway 29 South, Athens, GA
Carl Vinson VA Medical Center, 1826 Veterans Boulevard, Dublin, GA
Charlie Norwood VA Medical Center Uptown Division, 1 Freedom Way, Augusta, GA
Charlie Norwood VA Medical Center Downtown Division, 800 Balie Street, Augusta, GA
Ralph H. Johnson VA Medical Center, 109 Bee Street, Charleston, SC
W.J.B. Dorn VA Medical Center, 6439 Garners Ferry Road, Columbia, SC
Mandatory Source of Supply: GINFL Services, Inc., Jacksonville, FL
Contracting Activity: Veterans Affairs, Department of, 247–Network Contract Office 7

Michael R. Jurkowski,

Business Management Specialist, Business Operations.

[FR Doc. 2018–17806 Filed 8–16–18; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes products and services from the Procurement List previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date deleted from the Procurement List:* September 16, 2018.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 7/6/2018 (83 FR 130) and 7/13/2018 (83 FR 135), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products

NSN(s)—Product Name(s):
7930–01–648–5018—Floor Finish/Sealer, Black, Water-Based, Slip-Resistant, Asphalt Floors, 5 Gal. Can
7930–01–648–6105—Floor Finish/Sealer, Black, Water-Based, Slip-Resistant, Asphalt Floors, 4/1 Gal. Bottles
Mandatory Source(s) of Supply: Lighthouse for the Blind of Houston, Houston, TX
Contracting Activity: General Services Administration, Fort Worth, TX

NSN(s)—Product Name(s): 530–01–611–6426—Steno Book, 60 Pages, 6″x9″, Green
Mandatory Source(s) of Supply: Alabama Industries for the Blind, Talladega, AL
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 7510–00–307–7885—Refill, Eraser, Mechanical Pencil, Grey
Mandatory Source(s) of Supply: San Antonio Lighthouse for the Blind, San Antonio, TX
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s):
8415–01–581–6578—Liner, Parka, US Navy, Coyote Brown, Medium/XX-Long
8415–01–588–8415—Liner, Parka, US Navy, Coyote Brown, Medium/XX-Long
Mandatory Source(s) of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Bestwork Industries for the Blind, Inc., Cherry Hill, NJ
Contracting Activity: W6QK ACC–APG NATICK, NATICK, MA

NSN(s)—Product Name(s): 8415–01–588–8415—Liner, Parka, US Navy, Coyote Brown, Medium/XX-Long
Mandatory Source(s) of Supply: Bestwork Industries for the Blind, Inc., Cherry Hill, NJ
Contracting Activity: Defense Logistics Agency Troop Support

Services

Service Type: Operation of Postal Service Center Service
Mandatory for: Eglin Air Force Base: East of Memorial Trail (excluding the airfield) Eglin, FL
Mandatory Source(s) of Supply: Lakeview Center, Inc., Pensacola, FL
Contracting Activity: DEPT OF THE AIR FORCE, FA2823 AFTC PZIO

Service Type: Furniture Service
Mandatory for: MCALF Bogue Field, HWY 70, Bogue, NC, MCAS Cherry Point, Hwy. 101, Cherry Point, NC, MCOLF Atlantic Field, Air Base Road, Atlantic, NC
Mandatory Source(s) of Supply: Coastal Enterprises of Jacksonville, Inc., Jacksonville, NC
Contracting Activity: DOD/DEPARTMENT OF THE NAVY

Service Type: Custodial Service
Mandatory for: U.S. Geological Survey, Willamette Research Station, 1350 SE Goodnight Avenue, Corvallis, OR
Mandatory Source(s) of Supply: Willamette Valley Rehabilitation Center, Inc., Lebanon, OR
Contracting Activity: GEOLOGICAL SURVEY, OFFICE OF ACQUISITION AND GRANTS—SACRAMENTO

Service Type: Administrative Service
Mandatory for: National Advocacy Center, 1620 Pendleton Street, Columbia, SC
Mandatory Source(s) of Supply: UNKNOWN
Contracting Activity: Dept of Justice, Offices, Boards and Divisions,

Service Type: Janitorial/Custodial Service
Mandatory for: Department of the Air Force: 440th Airlift Wing, 300 East College Avenue, Milwaukee, WI
Mandatory Source(s) of Supply: Milwaukee Center for Independence, Inc., Milwaukee, WI
Contracting Activity: DEPT OF THE AIR FORCE, FA6605 440 AW LGC GEN MITCHEL ARS

Service Type: Custodial Service
Mandatory for: Air National Guard, 1401 Robert B. Miller, Jr., Drive, Garden City, GA
Mandatory Source(s) of Supply: Trace, Inc., Boise, ID
Contracting Activity: DEPT OF THE ARMY, W7M3 USPFO ACTIVITY GA ARNG

Service Type: Parts Sorting—Hardware/Small Handtool & Denumbering Service
Mandatory for: Robins Air Force Base, Robins AFB, GA
Mandatory Source(s) of Supply: Houston County Association for Exceptional Citizens, Inc., Warner Robins, GA
Contracting Activity: DEPT OF THE AIR FORCE, FA7014 AFDW PK

Michael R. Jurkowski,

Business Management Specialist, Business Operations.

[FR Doc. 2018–17807 Filed 8–16–18; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0030]

Proposed Extension of Approval of Information Collection; Comment Request—Testing and Recordkeeping Requirements for Carpets and Rugs

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: Pursuant to the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC) requests comments on a proposed extension of approval of information collection requirements for manufacturers and importers of carpets and rugs under the Standard for the Surface Flammability of Carpets and Rugs and the Standard for the Surface Flammability of Small Carpets and Rugs. The CPSC will consider all comments received in response to this notice before requesting an extension of this collection of information from the Office of Management and Budget (OMB).

DATES: Submit written or electronic comments on the collection of information by October 16, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2012–0030, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number CPSC–2012–0030, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Bretford Griffin, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7037, or by email to: *bgriffin@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Safety Standard for the Flammability of Carpets and Rugs and Standard for the Flammability of Small Carpets and Rugs.

OMB Number: 3041–0017.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of carpets and rugs.

Estimated Number of Respondents: Out of 215 domestic manufacturers, approximately half, or 108 manufacturers, elect to issue a guaranty of compliance with the FFA. Additionally, of the approximately 6,000 firms that import carpets and rugs, approximately 1,500 elect to issue guaranties of compliance. Staff estimates that the average firm issuing a continuing guarantee under the FFA is required to conduct, at most, 200 tests per year, although the actual number of tests required by a given firm may vary from one to 200, depending upon the number of carpet styles and the annual production volume. To estimate burden, we selected the midpoint, 100 tests per year.

Estimated Time per Response: 2.5 hours to conduct each test, and to establish and maintain test records.

Total Estimated Annual Burden: The time required to conduct each test is estimated to be 2.5 hours, including the time required to establish and maintain the test records. We estimate the total annualized cost/burden to respondents could be as many as 160,800 tests per year (1,608 firms × 100 tests), at 2.5 hours per test, or 402,000 hours.

Total Estimated Annual Cost to Respondents: The total annualized costs to all respondents for the hour burden for collection of information is estimated to be as high as $27,830,460, using a mean hourly employer cost-per-hour-worked of $69.23 (Bureau of Labor Statistics: Total compensation rates for management, professional, and related occupations in private goods-producing industries, March 2018) (402,000 hours × $69.23).

General Description of Collection: The Standard for the Surface Flammability of Carpets and Rugs (16 CFR part 1630) and the Standard for the Surface Flammability of Small Carpets and Rugs (16 CFR part 1631) establish requirements to reduce the flammability of carpets and rugs. The standards' provisions include requirements for testing and recordkeeping for manufacturers and importers who furnish guaranties subject to the carpet and rug flammability standards. Separate from the guaranties, the Consumer Product Safety Improvement Act of 2008 (CPSIA) established product certification requirements for applicable consumer product safety standards and rules. 15 U.S.C. 2063(g).

Request for Comments

The CPSC solicits written comments from all interested persons about the proposed collection of information. The CPSC specifically solicits information relevant to the following topics:

—Whether the collection of information described is necessary for the proper performance of the CPSC's functions, including whether the information would have practical utility;
—Whether the estimated burden of the proposed collection of information is accurate;
—Whether the quality, utility, and clarity of the information to be collected could be enhanced; and
—Whether the burden imposed by the collection of information could be minimized by use of automated, electronic, or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2018–17720 Filed 8–16–18; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0024]

Proposed Extension of Approval of Information Collection; Comment Request; Notification Requirements for Coal and Wood Burning Appliances

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: Pursuant to the Paperwork Reduction Act (PRA) of 1995, the

Consumer Product Safety Commission (CPSC) requests comments on a proposed extension of approval of information collection regarding notification requirements for coal and wood burning appliances. The CPSC will consider all comments received in response to this notice, before requesting an extension of this collection of information from the Office of Management and Budget (OMB).

DATES: Submit written or electronic comments on the collection of information by October 16, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2012–0024, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number CPSC–2012–0024, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Bretford Griffin, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7037, or by email to: *bgriffin@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Notification Requirements for Coal and Wood Burning Appliances.

OMB Number: 3041–0040.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of coal and wood burning appliances.

Estimated Number of Respondents: An estimated five submissions annually.

Estimated Time per Response: Three hours per submission and 30 minutes for collecting and mailing the information to the CPSC.

Total Estimated Annual Burden: 17.5 hours (5 submissions × 3.5 hours).

Total Estimated Annual Cost to Respondents: $1,212, based on an average total hourly employee compensation rate of $69.23 for management, professional, and related occupations (Bureau of Labor Statistics: Total compensation rates for management, professional, and related occupations in private goods-producing industries, March 2018) (17.5 hours × $69.23).

General Description of Collection: 16 CFR part 1406, Coal and Wood Burning Appliances—Notification of Performance and Technical Data requires that manufacturers and importers provide consumers with written notification regarding certain technical and performance information related to safety on each coal and wood burning appliance. Manufacturers are also required to provide to the CPSC a copy of the notification to consumers and an explanation of all clearance distances contained in the notification. For existing models, all known manufacturers have complied with the requirements. Accordingly, there is no new burden associated with the requirements of 16 CFR part 1406, except in cases where existing models are changed, or new models are introduced. Less than five submissions are estimated annually from new stove models coming into the market, or new firms entering the market.

Request for Comments

The CPSC solicits written comments from all interested persons about the proposed collection of information. The CPSC specifically solicits information relevant to the following topics:

—Whether the collection of information described is necessary for the proper performance of the CPSC's functions, including whether the information would have practical utility;

—Whether the estimated burden of the proposed collection of information is accurate;

—Whether the quality, utility, and clarity of the information to be collected could be enhanced; and

—Whether the burden imposed by the collection of information could be minimized by use of automated, electronic, or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2018–17721 Filed 8–16–18; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2018–HQ–0002]

Submission for OMB Review; Comment Request

AGENCY: Department of the Air Force, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 17, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov*. Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil*.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: National Defense Science and Engineering Graduate (NDSEG) Fellowships Program; OMB Number 0701–0154.

Type of Request: Extension.

Number of Respondents: 3,577.

Responses per Respondent: 1.

Annual Responses: 3,577.

Average Burden per Response: 12 Hours.

Annual Burden Hours: 42,924.

Needs and Uses: The information collection requirement is necessary to obtain Support of Science, Mathematics, and Engineering Education to 10 U.S.C.

2191 which states that ''the Secretary of Defense shall prescribe regulations providing for the award of fellowships to citizens and nationals of the United States who agree to pursue graduate degrees in science, engineering or other fields of study designated by the Secretary (of Defense) to be of priority interest to the DoD. The DoD is committed to increasing the number and quality of the nation's scientists and engineers. The NDSEG fellowships allow recipients to pursue their graduate studies at whichever United States institution they choose to attend. The goal is to provide the United States with talented, doctorally trained, American men and women who will lead state of the art research projects in disciplines having the greatest payoff to national defense requirements. Recipients shall be selected on the basis of a nationwide competition. Application information will be used for evaluation and selection of students to be awarded fellowships.

Affected Public: Individuals or Households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: August 14, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–17778 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0030]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 17, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: National Security Education Program (NSEP) Service Agreement Report for Scholarship and Fellowship Awards; DD Form 2752 and DD Form 2753; OMB Control Number 0704–0368.

Type of Request: Reinstatement with change.

Number of Respondents: 1,650.

Responses per Respondent: 1.

Annual Responses: 1,650.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 275 hours.

Needs and Uses: The information collection requirement is necessary to record the original award amount and service requirement for each NSEP award recipient (DD Form 2752) and the progress of each NSEP award recipient in fulfilling his/her Congressionally-mandated service requirement signed at the time of award (DD Form 2753).

Affected Public: Individuals or Households; Not-for-Profit Institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: August 14, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–17771 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0054]

Proposed Collection; Comment Request

AGENCY: Under Secretary of Defense for Research and Engineering, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Technical Information Center (DTIC) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 16, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Technical Information Center, ATTN: Ms. Vakare Valaitis, 8725 John J. Kingman Road, Ft. Belvoir, VA 22060–6218, or call (703) 767–9159.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense User Registration System (DURS); OMB Control Number 0704–0546.

Needs and Uses: DTIC requires all eligible users to be registered for access to DTIC's repository of access-controlled scientific and technical information documents. This system is called the Defense User Registration System, or DURS. The registration of a user enforces validation of an individual's identity, as well as that individual's persona (*i.e.,* whether the individual is DoD, Federal government, or a contractor supporting the DoD or another federal agency) and that individual's authority to access limited and classified documents with distribution controls. A role-based environment based on a user's identification ensures security for DTIC's electronic information collection while the online systems increase availability of information to each user based on his or her mission needs.

Affected Public: Federal Government; Individuals or Households; Business or Other For-Profit; Not-For-Profit Institutions.

Annual Burden Hours: 1,325 hours.

Number of Respondents: 6,625.

Responses per Respondent: 1.

Annual Responses: 6,625.

Average Burden per Response: 0.2 hours.

Frequency: On occasion.

Dated: August 14, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–17808 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0053]

Proposed Collection; Comment Request

AGENCY: Under Secretary of Defense for Acquisition and Sustainment, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Logistics Agency (DLA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 16, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to: The Defense Logistics Agency, Office of Small Business Programs, ATTN: Sherry Savage, 8725 John J. Kingman Road, Fort Belvoir, VA 22060 or write to *sherry.savage@dla.mil* or call (571) 767–1656.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Procurement Technical Assistance Center Cooperative Agreement Performance Report; DLA Form 1806; OMB Control Number 0704–0320.

Needs and Uses: This information collection by the Defense Logistics Agency (DLA) gathers data to be used in measuring, on a quarterly basis, cooperative agreement recipients' performance against goals and objectives established by awards. The Department of Defense (DoD) Procurement Technical Assistance (PTA) Cooperative Agreement Program was established by Congress in 1985 to assist state and local governments, tribal organizations, tribal economic enterprises, and other non-profit entities in establishing or maintaining PTA activities to help business firms market their goods and services to the DoD, other federal agencies, and state and local governments. Administrative requirements for the program are established by the DoD Grant and Agreement Regulations (DoDGARS).

Affected Public: State, Local, or Tribal Government; Not-for-Profit Institutions.

Annual Burden Hours: 1,900.

Number of Respondents: 95.

Responses per Respondent: 4.

Annual Responses: 380.

Average Burden per Response: 5 hours.

Frequency: Quarterly.

Dated: August 14, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–17804 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0031]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 17, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Report of Medical History; DD Forms 2807–1 and 2807–2; OMB Control Number 0704–0413.

Type of Request: Reinstatement without change.

Number of Respondents: 773,003.

Responses per Respondent: 1.

Annual Responses: 773,003.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 128,834.

Needs and Uses: The information collection requirement is necessary per Title 10 U.S.C. Chapter 31: Sections 504 and 505, and Chapter 33, Section 532, which requires applicants to meet accession medical standards prior to enlistment into the Armed Forces, including the Coast Guard. If applicants' medical history reveals a medical condition that does not meet the accession medical standards, they are medically disqualified for military entrance. These forms also will be used by all service members not only in their initial medical examination but also for periodic medical examinations.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: August 14, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–17802 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0052]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Undersecretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 16, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the Under Secretary of Defense (Personnel and Readiness) (FE&T), Office of Financial Readiness, ATTN: Mr. Andrew Cohen, 4000 Defense Pentagon, Washington, DC 20301–4000, or telephone Mr. Cohen at (703) 692–5286.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Mandatory Disclosures as Part of Limitations on Terms of Consumer Credit Extended to Service Members and Dependents; OMB Control Number 0704–0444.

Needs and Uses: With respect to any extension of consumer credit to a covered borrower, a creditor is required to provide to the borrower a statement of Military Annual Percentage Rate (MAPR). The required information would be included in standard account agreements. Additionally, a creditor may, at its discretion, identify the status of a consumer-applicant, as permitted under 32 CFR, 232.5(b) of the Final Rule and, in the event that the information indicates that consumer-applicant is not a covered borrower, take advantage of a safe harbor from liability under 10 U.S.C. 987 by retaining a record of the information so obtained. This includes Military Annual Percentage Rate (MAPR) applicable to the extension of consumer credit, and the total dollar amount of all charges included in the MAPR.

Affected Public: Business or other for-profit.

Annual Burden Hours: 2,000,000.

Number of Respondents: 37,500.

Responses per Respondent: Varies by type of respondent.

Annual Responses: 238,000,000.

Average Burden per Response: 30 seconds.

Frequency: As required.

Respondents are creditors extending consumer credit as defined in the Final

Rule (32 CFR, 232.3(f)) to covered borrowers (32 CFR, 232.3(g)) property. Each response is a statutory requirement that obligates creditors to provide a clear description of the payment obligation of the covered member or dependent, as applicable. A payment schedule may satisfy this requirement.

The creditor shall provide the disclosures in writing in a form the covered borrower can keep. The creditor also shall provide the required disclosures orally. In mail and internet transactions, the creditor satisfies this requirement by providing a toll-free telephone number on or with the written disclosures that consumers may use to obtain oral disclosures. One disclosure for each transaction involving consumer credit; one covered-borrower check for each transaction involving consumer credit.

Dated: August 14, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–17746 Filed 8–16–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0086]

Agency Information Collection Activities; Comment Request; Federal Family Educational Loan Program—Servicemembers Civil Relief Act (SCRA)

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 16, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0086. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9081, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Ian Foss, 202–377–3681.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Family Educational Loan Program—Servicemembers Civil Relief Act (SCRA).

OMB Control Number: 1845–0093.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 16,731.

Total Estimated Number of Annual Burden Hours: 50,115.

Abstract: The Department is requesting a revision of the current information collection. These Federal Family Education Loan (FFEL) Program regulations require a loan holder to match its database against the Defense Manpower Data Center (DMDC) and automatically apply the interest rate limitation, as appropriate, to borrowers under the Servicemembers Civil Relief Act (SCRA). There has been no change in the statute or in the regulations. The Department is revising downward the overall collection burden due to the decreasing number of FFEL loan holders and affected loans. Additionally, the Department is removing the minimal burden previously assessed individuals as a separate form was created subsequent to the initial information collection and the burden on individuals is more appropriate linked to that information collection.

Dated: August 14, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–17758 Filed 8–16–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0085]

Agency Information Collection Activities; Comment Request; Servicemembers Civil Relief Act (SCRA): Interest Rate Limitation Request

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 16, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0085. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection

activities, please contact Ian Foss, 202–377–3681.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Servicemembers Civil Relief Act (SCRA): Interest Rate Limitation Request.

OMB Control Number: 1845–0135.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 200.

Total Estimated Number of Annual Burden Hours: 67.

Abstract: The Servicemembers Civil Relief Act (SCRA) provides that those on active duty military service are entitled to have an interest rate in excess of 6% be capped at 6% for the duration of their qualifying military service. The Department is requesting am extension of the currently approved information collection. These Federal Family Education Loan (FFEL) Program and Direct Loan Program regulations have not changed. The regulations require a loan holder to match its database against the Department of Defense's Defense Manpower Data Center (DMDC) and automatically apply the interest rate limitation, as appropriate, to borrowers under the Servicemembers Civil Relief Act. The form in this collection would only be used in limited cases where the borrower is not found in the Defense Manpower Data Center, or does not have a copy of military orders, but still wishes to receive benefits under the SCRA.

Dated: August 14, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer Office of Management.

[FR Doc. 2018–17744 Filed 8–16–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL18–192–000]

North Carolina Electric Membership Corporation v. Duke Energy Progress, LLC; Notice of Complaint

Take notice that on August 10, 2018, pursuant to section 206 of the Federal Power Act, 16 U.S.C. 824e, Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2018), and section 16.1 of the Fifth Amended and Restated Power Supply and Coordination Agreement between Duke Energy Progress, LLC (DEP or Respondent) and the North Carolina Electric Membership Corporation (NCEMC or Complainant), FERC Rate Schedule No. 182, NCEMC filed a formal complaint against DEP alleging that the Respondent's Fixed Demand Rate, Variable Demand Rate, and the formula production rate that will go into effect January 1, 2020, are excessive, unjust and unreasonable, and not cost-based as required by the Respondent's Market-Based Rate Tariff, as more fully explained in the complaint.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent listed on the Commission's list of Corporate Officials and on the North Carolina Utilities Commission and the South Carolina Public Service Commission.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 30, 2018.

Dated: August 13, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–17761 Filed 8–16–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9040–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7156 or *https://www2.epa.gov/nepa/.*

Weekly receipt of Environmental Impact Statements
Filed 08/06/2018 Through 08/10/2018
Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20180181, Draft, DOC, NAT, Draft Environmental Impact Statement for the Summer Flounder

Commercial Issues Amendment, Comment Period Ends: 10/12/2018, Contact: Emily Gilbert 978–491–8024

EIS No. 20180182, Draft, USFS, NV, Lee Canyon EIS, Comment Period Ends: 10/01/2018, Contact: Jonathan Stein 702–515–5418

EIS No. 20180183, Draft, TVA, TN, Transmission System Vegetation Management Programmatic EIS, Comment Period Ends: 10/01/2018, Contact: Anita E. Masters 423–751–8697

EIS No. 20180184, Draft, BLM, UT, Draft Bears Ears National Monument Indian Creek and Shash Jaa Units Monument Management Plans and Associated Environmental Impact Statement, Comment Period Ends: 11/15/2018, Contact: Lance Porter 435–259–2100

EIS No. 20180185, Draft, BLM, UT, Grand Staircase-Escalante National Monument-Grand Staircase, Kaiparowits, and Escalante Canyon Units and Federal Lands Previously Included in the Monument That Are Excluded From the Boundaries Draft Resource Management Plans and Associated Environmental Impact Statement, Comment Period Ends: 11/15/2018, Contact: Matt Betenson 435–644–1200

EIS No. 20180186, Final, USFS, OR, East Hills Project, Review Period Ends: 09/17/2018, Contact: Jody Perozzi 541–353–2723

Amended Notice

Revision to the **Federal Register** Notice published 07/06/2018, extend comment period from 08/20/2018 to 09/04/2018.

EIS No. 20180149, Draft, FHWA, ND, Little Missouri Crossing, Contact: Gary Goff 701–221–9466

Dated: August 14, 2018.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2018–17747 Filed 8–16–18; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Meetings

TIME AND DATE: Friday, August 24, 2018, 9:00 a.m. Eastern Time.

PLACE: Jacqueline A. Berrien Training Center on the First Floor of the EEOC Office Building, 131 ''M'' Street NE, Washington, DC 20507.

STATUS: The meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Closed Session

The Associate Legal Counsel has certified that, in her opinion, exemption 10 of the Sunshine Act, 5 U.S.C. 552b(c)(10) and 29 CFR 1612.4(j), permits consideration of the scheduled matters at the closed meeting.

Agency Adjudication and Determination on Federal Agency Discrimination Complaint Appeals:

The Commission will be considering four (4) cases.

Note: Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission meetings in the **Federal Register**, the Commission also provides information about Commission meetings on its website, *www.eeoc.gov.,* and provides a recorded announcement a week in advance on future Commission sessions.)

Please telephone (202) 663–7100 (voice) and (202) 663–4074 (TTY) at any time for information on these meetings. The EEOC provides sign language interpretation and Communication Access Realtime Translation (CART) services at Commission meetings for the hearing impaired. Requests for other reasonable accommodations may be made by using the voice and TTY numbers listed above.

CONTACT PERSON FOR FURTHER INFORMATION: Bernadette B. Wilson, Executive Officer on (202) 663–4077.

Dated: August 15, 2018.

Bernadette B. Wilson,

Executive Officer, Executive Secretariat.

[FR Doc. 2018–17922 Filed 8–15–18; 4:15 pm]

BILLING CODE 6570–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3357–FN]

Medicare and Medicaid Program; Application From DNV GL—Healthcare (DNV GL) for Continued Approval of Its Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the DNV GL—Healthcare for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: This decision is effective August 17, 2018 through September 26, 2022.

FOR FURTHER INFORMATION CONTACT: Karena Meushaw (410) 786–6609, or Monda Shaver (410) 786–3410.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital, provided that certain requirements are met. Section 1861(e) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide the Centers for Medicare and Medicaid Services (CMS) with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require accrediting organizations to reapply for continued approval of its accreditation program

every 6 years or sooner as determined by CMS. DNV GL's current term of approval for their hospital accreditation program expires September 26, 2018.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

In the April 17, 2018 **Federal Register** (83 FR 16862), we published a proposed notice announcing DNV GL's request for continued approval of its Medicare hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of DNV GL's Medicare hospital accreditation renewal application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of DNV GL's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospitals; and, (5) survey review and decision-making process for accreditation.
- The comparison of DNV GL's Medicare hospital accreditation program standards to our current Medicare hospitals Conditions of Participation (CoPs).
- A documentation review of hospital's survey process to:

++ Determine the composition of the survey team, surveyor qualifications, and DNV GL's ability to provide continuing surveyor training.

++ Compare DNV GL's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospitals.

++ Evaluate DNV GL's procedures for monitoring hospitals it has found to be out of compliance with DNV GL's program requirements. (This pertains only to monitoring procedures when DNV GL identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)).

++ Assess DNV GL's ability to report deficiencies to the surveyed hospital and respond to the hospital's plan of correction in a timely manner.

++ Establish DNV GL's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of DNV GL's staff and other resources.

++ Confirm DNV GL's ability to provide adequate funding for performing required surveys.

++ Confirm DNV GL's policies with respect to surveys being unannounced.

++ Obtain DNV GL's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the April 17, 2018 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare CoPs for hospitals. We received two comments in response to our proposed notice. All of the comments received expressed unanimous support for DNV GL's hospital accreditation program.

IV. Provisions of the Final Notice

A. Differences Between DNV GL's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared DNV GL's hospital accreditation program requirements and survey process with the Medicare CoPs at 42 CFR part 482, and the survey and certification process requirements of Parts 488 and 489. Our review and evaluation of DNV GL's hospital application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, DNV GL has revised its standards and certification processes in order to meet the requirements at:

- Section 482.11 through 482.58, to ensure its standards replace the use of the word ''shall'' to ''must'' in all situations where CMS regulations use the word ''must'' or, clarify in DNV's glossary the intended definition of the word ''shall'' means ''must.''
- State Operations Manual, Section 3012, to ensure that DNV GL's policies related to the timeframe(s) for follow-up activities, including follow-up surveys, for facilities that have previously demonstrated non-compliance at the condition level.
- Section 488.5(a)(4)(iv), to ensure that the hospital and provider-based locations (or a sample when allowed) are included in the hospital survey and deficiencies cited under the appropriate CoPs.
- Section 488.5(a)(11)(ii), to ensure that the data submitted in to CMS is timely, complete and accurate.
- Section 488.5(a)(12), to ensure a clearly defined complaint investigation process is in place that meets the requirements in the State Operations Manual Chapter 5 Section 5010 and Chapter 5 Section 5075.2 that includes the following:

++ Complete and accurate tracking of complaints as well as a process for maintaining a documented record of contacts made (for example, phone, email and United States mail) with the complainant, and others, if applicable;

++ Define the number of contact attempts required before closing out a complaint, if the complainant does not respond;

++ Educate DNV GL complaint intake staff that when complaint allegations could potentially result in condition-level non-compliance affecting the health and safety of patients, a survey is to be considered regardless if the allegation also involves payment related allegations; and,

++ The complaint must be investigated onsite within an appropriate timeframe.

- Section 488.26(b), to ensure that DNV GL survey documentation includes a detailed deficiency statement that clearly supports the manner and degree of non-compliance and that all observed non-compliance is cited at the appropriate level (condition verses standard level).
- Section 488.26(c)(4), to ensure that DNV GL surveyors review a sufficient number of inpatient and outpatient medical records during the survey process; the appropriate number of documents, logs, personnel and credentialing files are reviewed during the survey process; the document sources are clearly identified in the survey file; and that DNV GL surveyors have been appropriately trained and determined by DNV GL to be competent in identifying Immediate Jeopardy (IJ)

situations and appropriateness of facility actions to mitigate IJ risk factors prior to the exit of the survey team.

- Section 488.28(a), to ensure that the corrective action plan submitted by hospitals fully addresses the deficiencies cited and that the hospital's corrective actions are hospital wide and not focused solely on the area in which the deficiency was identified.
- Section 488.28(d), to ensure that all corrective action plans contain an expected correction completion date, consistent with CMS requirements.
- Section 488.18(a), to ensure all observations of non-compliance are adequately documented in the survey report and ensure corrective action is required by the hospital.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve DNV GL as a national accreditation organization for hospitals that request participation in the Medicare program, effective August 17, 2018 through September 26, 2022.

To verify DNV GL's continued compliance with the provisions of this final notice, CMS will conduct a follow-up corporate on-site visit and survey observation within 18 months of the publication date of this notice.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 6, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–17815 Filed 8–16–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: LIHEAP Household Report FRN1 Clearance.

Title: Annual Report on Households Assisted by the Low Income Home Energy Assistance (LIHEAP).

OMB No.: 0970–0060.

Description: This report is an annual activity required by statute (42 U.S.C. 8629) and Federal regulations (45 CFR 96.92) for the Low Income Home Energy Assistance Program (LIHEAP). Submission of the completed report is one requirement for LIHEAP grantees applying for Federal LIHEAP block grant funds.

States, the District of Columbia, and the Commonwealth of Puerto Rico are required to report statistics for the previous Federal fiscal year on:

- Assisted and applicant households, by type of LIHEAP assistance;
- Assisted and applicant households, by type of LIHEAP assistance and poverty level;
- Assisted households receiving nominal payments of $50 or less;
- Assisted households receiving only utility payment assistance; this information will automatically be transferred to the grantee's Performance Data Form.
- Assisted households, regardless of the type(s) of LIHEAP assistance, excluding households that only receive nominal payments of $50 or less;
- Assisted households, by type of LIHEAP assistance, having at least one vulnerable member who is at least 60 years or older, disabled, or five years old or younger;
- Assisted households, by type of LIHEAP assistance, with at least one member age 2 years or under;
- Assisted households, by type of LIHEAP assistance, with at least one member ages 3 years through 5 years; and
- Assisted households, regardless of the type(s) of LIHEAP assistance, having at least one member 60 years or older, disabled, or five years old or younger. Insular areas (other than the Commonwealth of Puerto Rico) and Indian Tribal Grantees are required to submit data only on the number of households receiving heating, cooling, energy crisis, and/or weatherization benefits.

The information is being collected for the Department's annual LIHEAP Report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The data elements will allow the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

Respondents: State Governments, Tribal Governments, Insular Areas, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Assisted Household Report-Long Form	56	1	39	2,184
Assisted Household Report-Short Form	160	1	1	160
Estimated Total Annual Burden Hours	.....	.....	.....	2,344

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap. 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert A. Sargis,

Report Clearance Officer.

[FR Doc. 2018–17768 Filed 8–16–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: LIHEAP Carryover and Reallotment Report FRN1 Clearance.

Title: Low Income Home Energy Assistance Program (LIHEAP) Carryover and Reallotment Report.

OMB No.: 0970–0106.

Description: The LIHEAP statute and regulations require LIHEAP grantees to report certain information to HHS concerning funds forwarded and funds subject to reallotment. The 1994 reauthorization of the LIHEAP statute, the Human Service Amendments of 1994 (Pub. L. 103–252), requires that the carryover and reallotment report for one fiscal year be submitted to HHS by the grantee before the Allotment for the next fiscal year may be awarded.

We are requesting no changes in the collection of data with the Carryover and Reallotment Report for FY 2018, a form for the collection of data, and the Simplified Instructions for Timely Obligations of FY 2019 LIHEAP Funds and Reporting Funds for Carryover and Reallotment. The form clarifies the information being requested and ensures the submission of all the required information. The form facilitates our response to numerous queries each year concerning the amounts of obligated funds. Use of the form is voluntary. Grantees have the option to use another format.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Carryover & Reallotment	177	1	3	531
Estimated Total Annual Burden Hours				531

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert A. Sargis,

Reports Clearance Officer.

[FR Doc. 2018–17777 Filed 8–16–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Science and Regulation of Live Microbiome-Based Products Used To Prevent, Treat, or Cure Diseases in Humans; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) are announcing a public workshop entitled ''Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans.'' The purpose of the public workshop is to exchange information with the scientific community about the clinical, manufacturing, and regulatory considerations associated with live microbiome-based products, when administered to prevent, treat, or cure a disease or condition in humans. The public workshop will bring together government Agencies, academia, industry, and other stakeholders involved in research, development, and regulation of live microbiome-based products for such uses.

DATES: The public workshop will be held on September 17, 2018, from 9 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the NIAID Conference Center, 5601 Fishers Lane, Rm. 1D13, Rockville, MD 20852. Entrance for public workshop participants is through the lobby, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.niaid.nih.gov/about/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240–402–8010, email: *CBERPublicEvents@fda.hhs.gov* (subject

line: Live Microbiome-Based Products Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

Live microbiome-based products used to prevent, treat, or cure a disease or condition in humans are biological products. There is increasing interest in the use of such products for the treatment and/or prevention of conditions such as necrotizing enterocolitis and diarrhea. Historically, these products have presented with unique scientific and regulatory challenges.

II. Topics for Discussion at the Public Workshop

The topics for discussion at the public workshop include the clinical, manufacturing, and regulatory considerations for live microbiome-based products to prevent, treat, or cure a disease or condition in humans, and the objective is to provide a forum for the exchange of information and perspectives on these topics.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.eventbrite.com/e/science-and-regulation-of-live-microbiome-based-products-used-to-prevent-treat-or-cure-diseases-in-tickets-44649072578.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 28, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Loni Warren Henderson or Sherri Revell no later than September 10, 2018 (See **FOR FURTHER INFORMATION CONTACT**).

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17732 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1592]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 17, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0797. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10a.m.–12 midnight, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

OMB Control Number 0910–0797—Extension

This information collection supports the above captioned Agency guidance. FDA has agreed to specific program enhancements and performance goals specified in the Generic Drug User Fee Reauthorization (GDUFA II) Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The GDUFA II Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain timeframes. To support these program goals, we have developed the guidance entitled ''Controlled Correspondence Related to Generic Drug Development.'' The guidance document is intended to facilitate FDA's prompt consideration of controlled correspondence and to assist in meeting the prescribed timeframes by providing procedural recommendations to include the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any; (4) the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s); (5) a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs and the ANDA number, if applicable; (6) a concise statement of the inquiry; (7) a recommendation of the appropriate FDA review discipline; and (8) relevant prior research and supporting materials.

The GDUFA II Commitment Letter also includes details on FDA's commitment to respond to requests to clarify ambiguities in FDA's controlled correspondence response within certain timeframes. To facilitate FDA's prompt consideration of the request and to assist in meeting the prescribed timeframes, the guidance document recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number, submission date of the controlled correspondence on which the requestor is seeking clarification, a copy of that previous controlled correspondence, and FDA's response to the controlled correspondence; and (4) the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification.

In the **Federal Register** of May 22, 2018, (83 FR 23692), we published a 60-day notice requesting public comment on the proposed collection of

information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of controlled correspondence	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic drug manufacturers, related industry, and representatives	390	3.8	1,496	5	7,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This is the first extension of the information collection. We base our estimate on a review of Agency data of Fiscal Year submissions for 2014, 2015, and 2016, which reflects an increase in submissions that we attribute to an increase in generic drug development. Accordingly, we estimate 390 generic drug manufacturers and related industry (*e.g.,* contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives will each submit an average of 3.8 inquiries annually for a total of 1,496 inquiries [1,496 ÷ 390 = 3.8]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence may range from a simple inquiry on generic drug labeling to a more complex inquiry for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 1 and 10 burden hours.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate that it will take an average of 5 hours per inquiry for industry to gather necessary information, prepare the request, and submit the request to FDA. As a result, we estimate that it will take an average of 7,480 hours annually for industry to prepare and submit inquiries considered controlled correspondence.

Dated: August 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17787 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2310]

Process To Request a Review of Food and Drug Administration's Decision Not To Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' FDA is issuing this draft guidance to comply with changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the FDA Reauthorization Act of 2017 (FDARA), to specify the process afforded to persons denied a Certificate to Foreign Government (CFG) for a device. This draft guidance describes the information that the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) will provide to a person whose request for a CFG for a device is denied, and the process for seeking review of such a denial. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by October 16, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2310 for ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance entitled ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff '' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joann Belt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3658, Silver Spring, MD 20993–0002, *exportcert@cdrh.fda.gov*, 301–796–7400, option 3; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance to comply with section 704 of FDARA (Pub. L. 115–52), which amended section 801 of the FD&C Act, to specify the process afforded to persons denied a CFG for a device. This draft guidance describes the information that CDRH and CBER will provide to a person whose request for a CFG for a device is denied, and the process for seeking review of such a denial. This draft guidance applies to the process for persons denied CFGs requested pursuant to section 801(e)(4)(A) of the FD&C Act (21 U.S.C. 381(e)(4)(A) for devices manufactured in an establishment registered under section 510 of the FD&C Act (21 U.S.C. 360) (*i.e.,* FDA-approved, cleared, or exempted devices) that are exported from the United States. This draft guidance supplements the FDA's guidance ''FDA Export Certificates,'' which is available at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm*. This draft guidance is not final nor is it in effect at this time.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the process for persons denied a certificate to foreign government for a device. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. This guidance document is also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov*. Persons unable to download an electronic copy of ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17044 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 801(e) and 802 (21 U.S.C. 382) of the FD&C Act have been approved under OMB control number 0910–0498; the collections of information in 21 CFR part 807, subparts A through E, have been approved under OMB control number 0910–0625; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in the guidance ''Center for Devices and Radiological Health Appeals Processes'' have been approved under OMB control number 0910–0738.

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17796 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1896]

Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff; Information Available to Industry; Extension of the Proposal Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the proposal period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is extending the proposal period for the ''Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff,'' published in the **Federal Register** of June 29, 2018. FDA is extending the proposal period to allow interested persons additional time to submit an electronic or written proposal.

DATES: FDA is extending the proposal period on the notice published June 29, 2018 (83 FR 30751). Submit either an electronic or written proposal by December 17, 2018 directly to Tara Gooen Bizjak or Stephen Ripley (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993–0002, 301–796–3257, email: *Tara.Gooen@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2018 (83 FR 30751), FDA announced the availability of a notice for industry entitled ''Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff.'' Interested persons were originally given until August 28, 2018, to submit a proposal to the Quality Metrics Site Visit Program per the notice. The Agency believes that extending the proposal period for an additional 120 days from the date of publication of this notice will allow adequate time for interested persons to submit proposals for FDA's consideration. The Site Visit Program is to provide experiential and firsthand learning opportunities to FDA staff involved in the development of the FDA Quality Metrics Program and to provide stakeholders with an opportunity to explain the advantages and challenges associated with implementing and managing a robust Quality Metrics Program. The program and information to be included in the proposal are explained more fully in the original notice.

II. Electronic Access

Persons with access to the internet may obtain the information about the FDA Quality Metrics for Drug Manufacturing Program, including this Quality Metric Site Visit Program, at *https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm526869.htm.*

Dated: August 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17783 Filed 8–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0279]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 16, 2018.

ADDRESSES: Submit your comments to *Sherette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990–0279—Extension Institutional Review Board Registration Form

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, on the Protection of Human Subjects, on the Institutional Review Board (IRB) Form. The purpose of the IRB Registration Form is to provide a simplified procedure for institutions engaged in research conducted or supported by HHS to satisfy the (1) HHS regulations for the protection of human subjects at 45 CFR 46.103((b), 45 CFR 46.107, and 45 CFR 46, subpart E, Registration of Institutional Review Boards; and, the Food and Drug Administration (FDA) regulations for institutional review boards at 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration 0990–0279	5,650	2	1	11,300
	350	2	1.5	525
Total				11,825

Terry Clark,

Asst. Information Collection Clearance Officer.

[FR Doc. 2018–17748 Filed 8–16–18; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Neurological Sciences Training Initial Review Group; NST–1 Subcommittee.

Date: September 17–18, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 West Kinzie Street, Chicago, IL 60654.

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., SUITE 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–0660, *benzingw@mail.nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (T32) Program.

Date: November 14–15, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact Person: Elizabeth A. Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–1917, *webbere@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 13, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–17780 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information To Solicit Feedback on the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative

AGENCY: National Institutes for Health, HHS.

ACTION: Notice.

SUMMARY: The purpose of this Request for Information (RFI) is to solicit input on how best to accomplish the ambitious vision for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® set forth in BRAIN 2025: A Scientific Vision. NIH is soliciting input from all interested stakeholders, including members of the scientific community, trainees, academic institutions, the private sector, health professionals, professional societies, advocacy groups, and patient communities, as well as other interested members of the public.

DATES: The Request for Information is open for public comment. To assure consideration, your responded must be received by November 15, 2018, 11:59 p.m.

ADDRESSES: Responses to this RFI must be submitted electronically using the web-based form at *https://www.braininitiative.nih.gov/rfi.aspx.*

FOR FURTHER INFORMATION CONTACT: Please direct all inquiries to Samantha White, Ph.D., National Institute of Neurological Disorders and Stroke, 301–496–1675; *BRAINFeedback@nih.gov* with ''BRAIN RFI'' in the subject line.

SUPPLEMENTARY INFORMATION:

Background

The BRAIN Initiative aims to develop new tools and technologies to understand and manipulate networks of cells in the brain. BRAIN 2025: A Scientific Vision serves as the strategic plan for the BRAIN Initiative at NIH and outlines an overarching vision, seven high level scientific priorities, and many specific goals. Designed to be achieved over at least a decade, the first five years of BRAIN 2025 emphasizes development of tools and technology, and the next five years shifts emphasis to using these tools to make fundamental discoveries about how brain circuits work and what goes wrong in disease.

The BRAIN Initiative is well underway (see *http://www.braininitiative.nih.gov*), and we are now approaching the midpoint. At this time, NIH is seeking feedback on the BRAIN Initiative's progress and on opportunities moving forward given the current state of the science. NIH has established a new BRAIN Initiative Advisory Committee of the NIH Director (ACD) Working Group that will provide scientific guidance to the ACD on how best to continue to accelerate the ambitious vision for the BRAIN Initiative.

The ACD–WG will use the responses to this RFI, along with information gathered through a series of public workshops, to help inform their discussions of the BRAIN Initiative's progress and potential updates to the plan moving forward.

Information Requested

Anyone wishing to submit a response is asked to include:

- Ideas for new tools and technologies that have the potential to transform brain circuit research.
- Suggestions for fundamental questions about brain circuit function in

humans or animal models that could be addressed with new technologies.

- Considerations for data sharing infrastructure and policies.
- Areas and topics for research on the ethical implications of BRAIN Initiative-supported emerging neurotechnologies and advancements and their applications.
- Approaches for disseminating new tools and technologies as well as training the broader neuroscience research community.
- Any other topic relevant to the strategic plan of the BRAIN Initiative.

Responses to this RFI are voluntary. Any personal identifiers will be removed when responses are compiled. Individual feedback will not be provided to any responder. Proprietary, classified, confidential, or sensitive information should not be included in your response. This Request for Information (RFI) is for planning purposes only and is not a solicitation for applications or an obligation on the part of the United States (U.S.) Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any comment submitted or for its use of that comment.

Dated: August 10, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018–17759 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health (NIH) Office of Science Policy (OSP) Recombinant or Synthetic Nucleic Acid Research: Proposed Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) seeks public comment on its proposal to amend the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to streamline oversight for human gene transfer clinical research protocols and reduce duplicative reporting requirements already captured within the existing regulatory framework. Specifically, NIH proposes amendments to: Delete the NIH protocol registration submission and reporting requirements under Appendix M of the *NIH Guidelines,* and modify the roles and responsibilities of entities that involve human gene transfer or the Recombinant DNA Advisory Committee (RAC).

DATES: To ensure consideration, comments must be submitted in writing by October 16, 2018.

ADDRESSES: Comments may be submitted electronically by visiting: *https://osp.od.nih.gov/comment-form-nih-guidelines/.* Comments may also be sent via fax to 301–496–9839, or by mail to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892–7985. All written comments received in response to this notice will be available for public inspection at NIH Office of Science Policy (OSP), 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892–7985, weekdays between the hours of 8:30 a.m. and 5 p.m. and may be posted without change, including any personal information, to the NIH OSP website.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional background information about these proposed changes, please contact the NIH by email at *SciencePolicy@od.nih.gov*, or telephone at 301–496–9838. You may also contact Jessica Tucker, Ph.D., Director of the Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy, Office of Science Policy, NIH, at 301–451–4431 or *Jessica.Tucker@nih.gov.*

SUPPLEMENTARY INFORMATION: NIH is proposing a series of actions to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to streamline oversight of human gene transfer research (HGT), and to focus the *NIH Guidelines* more specifically on biosafety issues associated with research involving recombinant or synthetic nucleic acid molecules. The field of HGT has recently experienced a series of advances that have resulted in the translation of research into clinical practice, including U.S. Food and Drug Administration (FDA) approvals for licensed products. Additionally, oversight mechanisms for ensuring HGT proceeds safely have sufficiently evolved to keep pace with new discoveries in this field.

At this time, there is duplication in submitting protocols, annual reports, amendments, and serious adverse events for HGT clinical protocols to both NIH and FDA that does not exist for other areas of clinical research. Historically, this duplication was conceived as harmonized reporting, enabling FDA to provide regulatory oversight while NIH provided a forum for open dialogue and transparency. However, since these complementary functions were first envisioned, we have now seen several converging systems emerge that provide some of these functions. For instance, *ClinicalTrials.gov* has been instituted, which provides a transparent and searchable database for clinical trials. In addition, the protection of human research subjects was improved through changes that updated provisions of the Common Rule. In 2018, FDA released a suite of draft guidance documents pertaining to gene therapy that includes new guidance on manufacturing issues, long-term follow-up, and pathways for clinical development in certain areas, including hemophilia, ophthalmologic indications, and rare diseases.

While the science and oversight system have evolved, HGT protocols continue to receive special oversight that is not afforded to other areas of clinical research. This observation was also noted in a 2014 Institute of Medicine of the National Academies report, *Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee,* in which it was recommended that NIH begin to limit RAC review to only exceptional HGT protocols that meet certain criteria and that would significantly benefit from RAC review. As very few protocols have been assessed by NIH to merit review under this new system, NIH asserts it is an opportune time to make changes to the *NIH Guidelines* to make oversight of HGT commensurate with oversight afforded to other areas of clinical research given the robust infrastructure in place to oversee this type of research.

Briefly to summarize, NIH proposes amending the *NIH Guidelines* to:

1. Eliminate RAC review and reporting requirements to NIH for HGT protocols.

2. Modify roles and responsibilities of investigators, institutions, IBCs, the RAC, and NIH to be consistent with these goals including:

a. Modifying roles of IBCs in reviewing HGT to be consistent with review of other covered research, and

b. Eliminating references to the RAC, including its roles in HGT and biosafety.

NIH suggests that the series of changes proposed in this Notice is a rational next step in the process of considering appropriate oversight of HGT. Consistent with these proposed changes to the *NIH Guidelines,* Section I–A, the Purpose of the *NIH Guidelines,* is proposed to be amended to clarify that the focus of the policy is biosafety

oversight of research involving recombinant or synthetic nucleic acid molecules. NIH notes that some of the duties of Institutional Biosafety Committees (IBCs) as currently written in the *NIH Guidelines* (*e.g.,* review of informed consent documents) are duplicative with the oversight provided by FDA or Institutional Review Boards (IRBs). NIH proposes that IBCs retain responsibility to review and approve HGT protocols; however, NIH proposes that these responsibilities be modified to be similar to those responsibilities IBCs currently have for review and approval of other research subject to the *NIH Guidelines.*

With the proposed elimination of the requirements for safety reporting under Appendix M, IBC oversight should be completed immediately after the last participant is administered the final dose of product. Additionally, the role of IBC review is proposed to be amended to be consistent with FDA's current guidance regarding individual patient expanded access to investigational drugs. In this way, the role of the IBCs will be focused on providing local biosafety oversight of basic and clinical research involving recombinant or synthetic nucleic acids. In particular, NIH seeks comment on whether the expectations of IBCs, in light of these proposed changes, have been articulated clearly in the proposed revisions to the *NIH Guidelines.*

Notably, the roles and responsibilities of the RAC are proposed to be removed from the *NIH Guidelines.* NIH recognizes the value of the RAC in discussions of science, safety, and ethics. In an effort to use the RAC as a public forum to advise on issues associated with emerging biotechnologies, the RAC's charter will be modified to change the committee's focus from research solely involving recombinant or synthetic nucleic acids to emerging biotechnologies research. In light of this modification to the committee, NIH proposes eliminating references to the RAC in the *NIH Guidelines,* though NIH may continue to seek advice from the RAC on biosafety issues that fall under the purview of the *NIH Guidelines.* Similarly, NIH may choose to seek advice from internal working groups or Federal Advisory Committees on a variety of issues, when warranted.

The proposed changes outlined above will require amendment of multiple portions of the *NIH Guidelines.* Sections and appendices proposed to be deleted from the current *NIH Guidelines* may be accessed at *https://osp.od.nih.gov/biotechnology/nih-guidelines/.* Following deletions, sections and appendices will be relabeled to proceed consecutively throughout the *NIH Guidelines.*

Proposed Amendments to the *NIH Guidelines*

Section I–A currently states:

Section I–A. Purpose

The purpose of the *NIH Guidelines* is to specify the practices for constructing and handling: (i) Recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.

Section I–A is proposed to be amended as follows:

Section I–A. Purpose

The purpose of the *NIH Guidelines* is to specify the biosafety practices and containment principles for constructing and handling: (i) Recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.

Section I–A–1 currently states:

Section I–A–1. Any nucleic acid molecule experiment, which according to the *NIH Guidelines* requires approval by NIH, must be submitted to NIH or to another federal agency that has jurisdiction for review and approval. Once approvals, or other applicable clearances, have been obtained from a federal agency other than NIH (whether the experiment is referred to that agency by NIH or sent directly there by the submitter), the experiment may proceed without the necessity for NIH review or approval. (See exception in Section I–A–1-a regarding requirement for human gene transfer protocol registration.)

Section I–A–1 is proposed to be amended as follows:

Section I–A–1. Any nucleic acid molecule experiment, which according to the *NIH Guidelines* requires approval by NIH, must be submitted to NIH or to another federal agency that has jurisdiction for review and approval. Once approvals, or other applicable clearances, have been obtained from a federal agency other than NIH (whether the experiment is referred to that agency by NIH or sent directly there by the submitter), the experiment may proceed without the necessity for NIH review or approval.

Section I–A–1–a currently states:

Section I–A–1–a. For experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants (human gene transfer), no research participant shall be enrolled (see definition of enrollment in Section I–E–7) until the NIH protocol registration process has been completed (see Appendix M–I–B, *Selection of Individual Protocols for Public RAC Review and Discussion*); Institutional Biosafety Committee (IBC) approval (from the clinical trial site) has been obtained; Institutional Review Board (IRB) approval has been obtained; and all applicable regulatory authorization(s) have been obtained.

For a clinical trial site that is added after the completion of the NIH protocol registration process, no research participant shall be enrolled (see definition of enrollment in Section I–E–7) at the clinical trial site until IBC approval and IRB approval from that site have been obtained. Within 30 days of enrollment (see definition of enrollment in Section I–E–7) at a clinical trial site, the following documentation shall be submitted to NIH OSP: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document(s); and (4) NIH grant number(s) if applicable.

Section I–A–1–a is proposed to be amended as follows:

Section I–A–1–a. For experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants (human gene transfer), no human gene transfer experiment shall be initiated (see definition of initiation in Section I–E–7) until Institutional Biosafety Committee (IBC) approval (from the clinical trial site) has been obtained; and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

Section I–E. General Definitions is proposed to be amended to delete the current definitions I–E–4, I–E–7 through I–E–12 and to include a new definition for ''initiation.''

Section I–E–4 is proposed to be amended to define initiation as the following: ''Initiation'' of research is the introduction of recombinant or synthetic nucleic acid molecules into organisms, cells, or viruses.

Section III currently states:

Section III. Experiments Covered by the *NIH Guidelines*

This section describes six categories of experiments involving recombinant or synthetic nucleic acid molecules: (i) Those that require Institutional Biosafety Committee (IBC) approval, RAC review, and NIH Director approval before initiation (see Section III–A), (ii) those that require NIH OSP and Institutional Biosafety Committee approval before initiation (see Section III–B), (iii) those that require Institutional Biosafety Committee and Institutional Review Board approvals and RAC review before research participant enrollment (see Section III–C), (iv) those that require Institutional Biosafety Committee approval before initiation (see Section III–D), (v) those that require Institutional Biosafety Committee notification simultaneous with initiation (see Section III–E), and (vi) those that are exempt from the *NIH Guidelines* (see Section III–F).

Note: If an experiment falls into Sections III–A, III–B, or III–C and one of the other sections, the rules pertaining to Sections III–A, III–B, or III–C shall be followed. If an experiment falls into Section III–F and into either Sections III–D or III–E as well, the experiment is considered exempt from the *NIH Guidelines.*

Any change in containment level, which is different from those specified in the *NIH Guidelines,* may not be initiated without the express approval of NIH OSP (see Section IV–C–1–b–(2) and its subsections, Minor Actions).

Section III is proposed to be amended as follows:

Section III. Experiments Covered by the *NIH Guidelines*

This section describes six categories of experiments involving recombinant or synthetic nucleic acid molecules: (i) Those that require Institutional Biosafety Committee (IBC) approval and NIH Director approval before initiation (see Section III–A), (ii) those that require NIH OSP and Institutional Biosafety Committee approval before initiation (see Section III–B), (iii) those that require Institutional Biosafety Committee approval before initiation of human gene transfer (see Section III–C), (iv) those that require Institutional Biosafety Committee approval before initiation (see Section III–D), (v) those that require Institutional Biosafety Committee notification simultaneous with initiation (see Section III–E), and (vi) those that are exempt from the *NIH Guidelines* (see Section III–F).

Note: If an experiment falls into Sections III–A, III–B, or III–C and one of the other sections, the rules pertaining to Sections III–A, III–B, or III–C shall be followed. If an experiment falls into Section III–F and into either Sections III–D or III–E as well, the experiment is considered exempt from the *NIH Guidelines.*

Any change in containment level, which is different from those specified in the *NIH Guidelines,* may not be initiated without the express approval of NIH OSP (see Section IV–C–1–b–(2) and its subsections, Minor Actions).

Section III–A currently states:

Section III–A. Experiments That Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation (See Section IV–C–1–b–(1), Major Actions).

Experiments considered as *Major Actions* under the *NIH Guidelines* cannot be initiated without submission of relevant information on the proposed experiment to the Office of Science Policy, National Institutes of Health, preferably by email to: *NIHGuidelines@od.nih.gov*, the publication of the proposal in the **Federal Register** for 15 days of comment, review by RAC, and specific approval by NIH. The containment conditions or stipulation requirements for such experiments will be recommended by RAC and set by NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D, *Major Actions Taken under the NIH Guidelines,* which may be obtained from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: *NIHGuidelines@od.nih.gov*; additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*).

Section III–A–1–a. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V–B, *Footnotes and References of Sections I–IV*), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC.

Consideration should be given as to whether the drug resistance trait to be used in the experiment would render that microorganism resistant to the primary drug available to and/or indicated for certain populations, for example children or pregnant women.

At the request of an Institutional Biosafety Committee, NIH OSP will make a determination regarding whether a specific experiment involving the deliberate transfer of a drug resistance trait falls under Section III–A–1-a and therefore requires RAC review and NIH Director approval. An Institutional Biosafety Committee may also consult with NIH OSP regarding experiments that do not meet the requirements of Section III–A–1–a but nonetheless raise important public health issues. NIH OSP will consult, as needed, with one or more experts, which may include the RAC.

Section III–A is proposed to be amended as follows:

Section III–A. Experiments That Require Institutional Biosafety Committee Approval and NIH Director Approval Before Initiation (See Section IV–C–1–b–(1), Major Actions).

Section III–A–1. Major Actions Under the *NIH Guidelines*

Experiments considered as *Major Actions* as defined in Section III–A–1-a under the *NIH Guidelines* cannot be initiated without submission of relevant information on the proposed experiment to the Office of Science Policy, National Institutes of Health, preferably by email to: *NIHGuidelines@od.nih.gov*, the publication of the proposal in the **Federal Register** for 15 days of comment, and specific approval by NIH. The containment conditions or stipulation requirements for such experiments will be set by NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D, *Major Actions Taken under the NIH Guidelines,* which may be obtained from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: *NIHGuidelines@od.nih.gov*; additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*).

Section III–A–1-a. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V–B, *Footnotes and References of Sections I–IV*), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will require NIH Director approval.

Consideration should be given as to whether the drug resistance trait to be used in the experiment would render that microorganism resistant to the primary drug available to and/or indicated for certain populations, for example children or pregnant women.

At the request of an Institutional Biosafety Committee, NIH OSP will

make a determination regarding whether a specific experiment involving the deliberate transfer of a drug resistance trait falls under Section III–A–1-a and therefore requires NIH Director approval. An Institutional Biosafety Committee may also consult with NIH OSP regarding experiments that do not meet the requirements of Section III–A–1-a but nonetheless raise important public health issues.

Section III–C currently states:

Section III–C. Experiments that Require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review (if applicable) Before Research Participant Enrollment

Section III–C–1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants

Human gene transfer is the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable integration into the genome (*e.g., cis* elements involved in integration); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

No research participant shall be enrolled (see definition of enrollment in Section I–E–7) until the NIH protocol registration process has been completed (see Appendix M–I–B, *Selection of Individual Protocols for Public RAC Review and Discussion*).

In its evaluation of human gene transfer protocols, NIH will make a determination, following a request from one or more oversight bodies involved in the review at an initial site(s), whether a proposed human gene transfer experiment meets the requirements for selecting protocols for public RAC review and discussion (See Appendix M–I–B). The process of public RAC review and discussion is intended to foster the safe and ethical conduct of human gene transfer experiments. Public review and discussion of a human gene transfer experiment (and access to relevant information) also serves to inform the public about the technical aspects of the proposal, the meaning and significance of the research, and any significant safety, social, and ethical implications of the research.

Public RAC review and discussion of a human gene transfer experiment will be initiated in two exceptional circumstances: (1) Following a request for public RAC review from one or more oversight bodies involved in the review at an initial site(s), the NIH concurs that (a) the individual protocol would significantly benefit from RAC review and (b) that the submission meets one or more of the following NIH RAC review criteria: (i) The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; (ii) the protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or (iii) the proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight and federal regulatory bodies to evaluate the protocol rigorously. However, if one or more oversight bodies involved in the review at an initial site(s) requests public RAC review, but NIH does not concur that (a) the individual protocol would significantly benefit from RAC review and (b) that the submission meets one or more of the RAC review criteria (listed in i, ii, or iii), then the NIH OSP will inform, within 10 working days, the requesting and other oversight bodies involved in the review at an initial site(s) that public RAC review is not warranted. (2) The NIH Director, in consultation (if needed) with appropriate regulatory authorities, determines that the submission: (a) Meets one or more of the NIH RAC review criteria (listed in i, ii, or iii) and that public RAC review and discussion would provide a clear and obvious benefit to the scientific community or the public; or (b) raises significant scientific, societal, or ethical concerns.

For a clinical trial site that is added after the completion of the NIH protocol registration process, no research participant shall be enrolled (see definition of enrollment in Section I–E–7) at the clinical trial site until IBC approval and IRB approval from that site have been obtained. Within 30 days of enrollment (see definition of enrollment in Section I–E–7) at a clinical trial site, the following documentation shall be submitted to NIH OSP: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document(s); and (4) NIH grant number(s) if applicable.

In order to maintain public access to information regarding human gene transfer (including protocols that are not publicly reviewed by the RAC), the NIH OSP will maintain the documentation described in Appendices M–I through M–II. The information provided in response to Appendix M should not contain any confidential commercial or financial information or trade secrets, enabling all aspects of RAC review to be open to the public.

Note: For specific directives concerning the use of retroviral vectors for gene delivery, consult Appendix B–V–1, *Murine Retroviral Vectors.*

Section III–C is proposed to be amended as follows:

Section III–C. Experiments Involving Human Gene Transfer That Require Institutional Biosafety Committee Approval Prior to Initiation

Section III–C–1. Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived From Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants

Human gene transfer is the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable integration into the genome (*e.g., cis* elements involved in integration); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

Research cannot be initiated until Institutional Biosafety Committee and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

An individual patient expanded access IND is not research subject to the *NIH Guidelines* and thus does not need to be submitted to an IBC, if the following conditions are met: (i) A PI is submitting an individual patient expanded access IND using Form FDA 3926; (ii) the PI selects the appropriate box on that form to request a waiver under 21 CFR 56.105 of the requirements in 21 CFR 56.108(c); and (iii) the FDA concludes that such a waiver is appropriate.

Section III–D–7–b currently states:

Section III–D–7–b. Highly Pathogenic Avian Influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1). Experiments involving influenza viruses containing a majority of genes and/or segments from a HPAI H5N1 influenza virus shall be conducted at BL3 enhanced containment, (see Appendix G–II–C–5, Biosafety Level 3 Enhanced for Research Involving Risk Group 3 Influenza Viruses). Experiments involving influenza viruses containing a minority of genes and/or segments from a HPAI H5N1 influenza virus shall be conducted at BL3 enhanced unless a risk assessment performed by the IBC determines that they can be conducted safely at biosafety level 2 and after they have been excluded pursuant to 9 CFR 121.3(e). NIH OSP is available to IBCs to provide consultation with the RAC and influenza virus experts when risk assessments are being made to determine the appropriate biocontainment for experiments with influenza viruses containing a minority of gene/segments from HPAI H5N1. Such experiments may be performed at BL3 enhanced containment or containment may be lowered to biosafety level 2, the level of containment for most research with other influenza viruses. (USDA/APHIS regulations and decisions on lowering containment also apply). In deciding to lower containment, the IBC should consider whether, in at least two animal models (*e.g.,* ferret, mouse, Syrian golden hamster, cotton rat, non-human primates), there is evidence that the resulting influenza virus shows reduced replication and virulence compared to the parental RG3 virus at relevant doses. This should be determined by measuring biological indices appropriate for the specific animal model (*e.g.,* severe weight loss, elevated temperature, mortality or neurological symptoms).

Section III–D–7–b is proposed to be amended as follows:

Section III–D–7–b. Highly Pathogenic Avian Influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1). Experiments involving influenza viruses containing a majority of genes and/or segments from a HPAI H5N1 influenza virus shall be conducted at BL3 enhanced containment, (see Appendix G–II–C–5, Biosafety Level 3 Enhanced for Research Involving Risk Group 3 Influenza Viruses). Experiments involving influenza viruses containing a minority of genes and/or segments from a HPAI H5N1 influenza virus shall be conducted at BL3 enhanced unless a risk assessment performed by the IBC determines that they can be conducted safely at biosafety level 2 and after they have been excluded pursuant to 9 CFR 121.3(e). NIH OSP is available to IBCs to provide consultation with influenza virus experts when risk assessments are being made to determine the appropriate biocontainment for experiments with influenza viruses containing a minority of gene/segments from HPAI H5N1. Such experiments may be performed at BL3 enhanced containment or containment may be lowered to biosafety level 2, the level of containment for most research with other influenza viruses. (USDA/APHIS regulations and decisions on lowering containment also apply). In deciding to lower containment, the IBC should consider whether, in at least two animal models (*e.g.,* ferret, mouse, Syrian golden hamster, cotton rat, non-human primates), there is evidence that the resulting influenza virus shows reduced replication and virulence compared to the parental RG3 virus at relevant doses. This should be determined by measuring biological indices appropriate for the specific animal model (*e.g.,* severe weight loss, elevated temperature, mortality or neurological symptoms).

Section III–D–7–d currently states:

Section III–D–7–d. Antiviral Susceptibility and Containment. The availability of antiviral drugs as preventive and therapeutic measures is an important safeguard for experiments with 1918 H1N1, HPAI H5N1, and human H2N2 (1957–1968). If an influenza virus containing genes from one of these viruses is resistant to both classes of current antiviral agents, adamantanes and neuraminidase inhibitors, higher containment may be required based on the risk assessment considering transmissibility to humans, virulence, pandemic potential, alternative antiviral agents if available, etc.

Experiments with 1918 H1N1, human H2N2 (1957–1968) or HPAI H5N1 that are designed to create resistance to neuraminidase inhibitors or other effective antiviral agents (including investigational antiviral agents being developed for influenza) would be subject to Section III–A–1 (*Major Actions*) and require RAC review and NIH Director approval. As per Section I–A–1 of the *NIH Guidelines,* if the agent is a Select Agent, the NIH will defer to the appropriate federal agency (HHS or U.S. Department of Agriculture (USDA) Select Agent Divisions) on such experiments.

Section III–D–7–d is proposed to be amended as follows:

Section III–D–7–d. Antiviral Susceptibility and Containment. The availability of antiviral drugs as preventive and therapeutic measures is an important safeguard for experiments with 1918 H1N1, HPAI H5N1, and human H2N2 (1957–1968). If an influenza virus containing genes from one of these viruses is resistant to both classes of current antiviral agents, adamantanes and neuraminidase inhibitors, higher containment may be required based on the risk assessment considering transmissibility to humans, virulence, pandemic potential, alternative antiviral agents if available, etc.

Experiments with 1918 H1N1, human H2N2 (1957–1968) or HPAI H5N1 that are designed to create resistance to neuraminidase inhibitors or other effective antiviral agents (including investigational antiviral agents being developed for influenza) would be subject to Section III–A–1 (*Major Actions*) and NIH Director approval. As per Section I–A–1 of the *NIH Guidelines,* if the agent is a Select Agent, NIH will defer to the appropriate Federal agency (HHS or USDA Select Agent Divisions) on such experiments.

Section III–F–6 currently states:

Section III–F–6. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV–C–1–b–(1)–(c), *Major Actions*). See Appendices A–I through A–VI, *Exemptions under Section III–F–6—Sublists of Natural Exchangers,* for a list of natural exchangers that are exempt from the *NIH Guidelines.*

Section III–F–6 is proposed to be amended as follows:

Section III–F–6. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director after appropriate notice and opportunity for public comment (see Section IV–C–1–b–(1)–(c), *Major Actions*). See Appendices A–I through A–VI, *Exemptions under Section III–F–6—Sublists of Natural Exchangers,* for a list of natural exchangers that are exempt from the *NIH Guidelines.*

Section III–F–8 currently states:

Section III–F–8. Those that do not present a significant risk to health or the

environment (see Section IV–C–1–b–(1)–(c), *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III–F–8* for other classes of experiments which are exempt from the *NIH Guidelines.*

Section III–F–8 is proposed to be amended as follows:

Section III–F–8. Those that do not present a significant risk to health or the environment (see Section IV–C–1–b–(1)–(c), *Major Actions*), as determined by the NIH Director, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III–F–8* for other classes of experiments which are exempt from the *NIH Guidelines.*

Section IV–B–1–f currently states:

Section IV–B–1–f. Ensure that when the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects: (i) The Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary), (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; and (iii) no research participant shall be enrolled (see definition of enrollment in Section I–E–7) in a human gene transfer experiment until the NIH protocol registration process has been completed (see Appendix M–I–B, *Selection of Individual Protocols for Public RAC Review and Discussion*), Institutional Biosafety Committee approval has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained. Institutional Biosafety Committee approval must be obtained from the clinical trial site.

Section IV–B–1–f is proposed to be amended as follows:

Section IV–B–1–f. Ensure that when the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects: (i) The Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary), and (ii) no human gene transfer experiment shall be initiated until Institutional Biosafety Committee approval has been obtained, and all other applicable institutional and regulatory authorization(s) and approvals have been obtained. Institutional Biosafety Committee approval must be obtained from the clinical trial site.

None of the other sub-sections under Section IV–B–1. General Information are proposed to be amended.

Section IV–B–2–a–(1) currently states:

Section IV–B–2–a–(1). The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (*e.g.,* officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants,* require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals,* require Institutional Biosafety Committee prior approval. When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV–B–3, *Biological Safety Officer*). When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution must ensure that: (i) The Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary); (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iii) no research participant shall be enrolled (see definition of enrollment in Section I–E–7) in a human gene transfer experiment until the NIH protocol registration process has been completed (see Appendix M–I–B, *Selection of Individual Protocols for Public RAC Review and Discussion*); and (iv) final IBC approval is granted only after the NIH protocol registration process has been completed (see Appendix M–I–B, *Selection of Individual Protocols for Public RAC Review and Discussion*). Institutional Biosafety Committee approval must be obtained from the clinical trial site.

Section IV–B–2–a–(1) is proposed to be amended as follows:

Section IV–B–2–a–(1). The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (*e.g.,* officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants,* require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals,* require Institutional Biosafety Committee prior approval. When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV–B–3, *Biological Safety Officer*). When the institution participates in or sponsors

recombinant or synthetic nucleic acid molecule research involving human research participants, the institution must ensure that the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary). Institutional Biosafety Committee approval must be obtained from the clinical trial site.

Section IV–B–2–b–(1) currently states:

Section IV–B–2–b–(1). Reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, *Experiments Covered by the NIH Guidelines,* and approving those research projects that are found to conform with the *NIH Guidelines.* This review shall include: (i) Independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research; (iii) ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iv) ensuring that no research participant is enrolled (see definition of enrollment in Section I–E–7) in a human gene transfer experiment until the NIH protocol registration process has been completed (see Appendix M–I–B, *Selection of Individual Protocols for Public RAC Review and Discussion*), Institutional Biosafety Committee approval (from the clinical trial site) has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained; (v) for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the recommendations; (vi) ensuring that final IBC approval is granted only after the NIH protocol registration process has been completed (see Appendix M–I–B, *Selection of Individual Protocols for Public RAC Review and Discussion*); and (vii) ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines.*

Section IV–B–2–b–(1) is proposed to be amended as follows:

Section IV–B–2–b–(1). Reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, *Experiments Covered by the NIH Guidelines,* and approving those research projects that are found to conform with the *NIH Guidelines.* This review shall include: (i) Independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research; (iii) for recombinant or synthetic nucleic acid molecule research involving human research participants, assessment focused on biosafety issues (*e.g.,* administration, shedding).

Section IV–B–2–b–(8) currently states:

Section IV–B–2–b–(8). The Institutional Biosafety Committee may not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until NIH (with the advice of the RAC when required) establishes the containment requirement.

Section IV–B–2–b–(8) is proposed to be amended as follows:

Section IV–B–2–b–(8). The Institutional Biosafety Committee may not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until NIH establishes the containment requirement.

None of the other sub-sections under Section IV–B–2. Institutional Biosafety Committee (IBC) are proposed to be amended.

Section IV–B–6 currently states:

Section IV–B–6. Human Gene Therapy Expertise

When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects, the institution must ensure that: (i) The Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary) and (ii) all aspects of Appendix M, *Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Subjects (Points to Consider*), have been appropriately addressed by the Principal Investigator prior to its approval.

Section IV–B–6 is proposed to be amended as follows:

Section IV–B–6. Human Gene Transfer Expertise

When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects, the institution must ensure that the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary).

Section IV–B–7 currently states:

Section IV–B–7. Principal Investigator (PI)

On behalf of the institution, the Principal Investigator is responsible for full compliance with the *NIH Guidelines* in the conduct of recombinant or synthetic nucleic acid molecule research. A Principal Investigator engaged in human gene transfer research may delegate to another party, such as a corporate sponsor, the reporting functions set forth in Appendix M, with written notification to the NIH OSP of the delegation and of the name(s), address, telephone, and fax numbers of the contact. The Principal Investigator is responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.

Section IV–B–7 is proposed to be amended as follows:

Section IV–B–7. Principal Investigator (PI)

On behalf of the institution, the Principal Investigator is responsible for full compliance with the *NIH Guidelines* in the conduct of recombinant or synthetic nucleic acid molecule research.

Section IV–B–7–b–(6) is proposed to be deleted in its entirety

Section IV–B–7–e–(5) is proposed to be deleted in its entirety

None of the other sub-sections under Section IV–B–7. Principal Investigator are proposed to be amended.

Section IV–C currently states:

Section IV–C. Responsibilities of the National Institutes of Health (NIH)

Section IV–C–1. NIH Director

The NIH Director is responsible for: (i) Establishing the *NIH Guidelines,* (ii) overseeing their implementation, and (iii) their final interpretation. The NIH Director has responsibilities under the *NIH Guidelines* that involve OSP and RAC. OSP's responsibilities under the *NIH Guidelines* are administrative. Advice from RAC is primarily scientific, technical, and ethical. In certain circumstances, there is specific opportunity for public comment with published response prior to final action.

Section IV–C–1-a. General Responsibilities

The NIH Director is responsible for:

Section IV–C–1–a–(1). Promulgating requirements as necessary to implement the *NIH Guidelines;*

Section IV–C–1–a–(2). Establishing and maintaining RAC to carry out the responsibilities set forth in Section IV–C–2, *Recombinant DNA Advisory Committee* (RAC membership is specified in its charter and in Section IV–C–2);

Section IV–C–1–a–(3). Establishing and maintaining NIH OSP to carry out the responsibilities defined in Section IV–C–3, *Office of Science Policy;*

Section IV–C–1–a–(4). Conducting and supporting training programs in laboratory safety for Institutional Biosafety Committee members, Biological Safety Officers and other institutional experts (if applicable), Principal Investigators, and laboratory staff.

Section IV–C–1–a–(5). Establishing and convening Gene Therapy Policy Conferences as described in Appendix L, *Gene Therapy Policy Conferences.*

Section IV–C–1–b. Specific Responsibilities

In carrying out the responsibilities set forth in this section, the NIH Director, or a designee shall weigh each proposed action through appropriate analysis and consultation to determine whether it complies with the *NIH Guidelines* and presents no significant risk to health or the environment.

Section IV–C–1–b–(1). Major Actions

To execute *Major Actions,* the NIH Director shall seek the advice of RAC and provide an opportunity for public and federal agency comment. Specifically, the Notice of Meeting and *Proposed Actions* shall be published in the **Federal Register** at least 15 days before the RAC meeting. The NIH Director's decision/recommendation (at his/her discretion) may be published in the **Federal Register** for 15 days of comment before final action is taken. The NIH Director's final decision/recommendation, along with responses to public comments, shall be published in the **Federal Register**. The RAC and Institutional Biosafety Committee Chairs shall be notified of the following decisions:

Section IV–C–1–b–(1)–(a). Changing containment levels for types of experiments that are specified in the *NIH Guidelines* when a *Major Action* is involved;

Section IV–C–1–b–(1)–(b). Assigning containment levels for types of experiments that are not explicitly considered in the *NIH Guidelines* when a *Major Action* is involved;

Section IV–C–1–b–(1)–(c). Promulgating and amending a list of classes of recombinant or synthetic nucleic acid molecules to be exempt from the *NIH Guidelines* because they consist entirely of DNA segments from species that exchange DNA by known physiological processes or otherwise do not present a significant risk to health or the environment;

Section IV–C–1–b–(1)–(d). Permitting experiments specified by Section III–A, *Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before Initiation;*

Section IV–C–1–b–(1)–(e). Certifying new host-vector systems with the exception of minor modifications of already certified systems (the standards and procedures for certification are described in Appendix I–II, *Certification of Host-Vector Systems*). Minor modifications constitute (*e.g.,* those of minimal or no consequence to the properties relevant to containment); and

Section IV–C–1–b–(1)–(f). Adopting other changes in the *NIH Guidelines.*

Section IV–C–1–b–(2). Minor Actions

NIH OSP shall carry out certain functions as delegated to it by the NIH Director (see Section IV–C–3, *Office of Science Policy*). *Minor Actions* (as determined by NIH OSP in consultation with the RAC Chair and one or more RAC members, as necessary) will be transmitted to RAC and Institutional Biosafety Committee Chairs:

Section IV–C–1–b–(2)–(a). Changing containment levels for experiments that are specified in Section III, *Experiments Covered by the NIH Guidelines* (except when a *Major Action* is involved);

Section IV–C–1–b–(2)–(b). Assigning containment levels for experiments not explicitly considered in the *NIH Guidelines;*

Section IV–C–1–b–(2)–(c). Revising the *Classification of Etiologic Agents* for the purpose of these *NIH Guidelines* (see Section V–A, *Footnotes and References of Sections I–IV*).

Section IV–C–1–b–(2)–(d). Interpreting the *NIH Guidelines* for experiments to which the *NIH Guidelines* do not specifically assign containment levels;

Section IV–C–1–b–(2)–(e). Setting containment under Sections III–D–1–d, *Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems,* and III–D–2–b, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems;*

Section IV–C–1–b–(2)–(f). Approving minor modifications of already certified host-vector systems (the standards and procedures for such modifications are described in Appendix I–II, *Certification of Host-Vector Systems*);

Section IV–C–1–b–(2)–(g). Decertifying already certified host-vector systems;

Section IV–C–1–b–(2)–(h). Adding new entries to the list of molecules toxic for vertebrates (see Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*); and

Section IV–C–1–b–(2)–(i). Determining appropriate containment conditions for experiments according to case precedents developed under Section IV–C–1–b–(2)–(c).

Section IV–C is proposed to be amended as follows:

Section IV–C. Responsibilities of the National Institutes of Health (NIH)

Section IV–C–1. NIH Director

The NIH Director is responsible for: (i) Establishing the *NIH Guidelines,* (ii) overseeing their implementation, and (iii) their final interpretation. The NIH Director has responsibilities under the *NIH Guidelines* that involve OSP. OSP's responsibilities under the *NIH Guidelines* are administrative. In certain circumstances, there is specific opportunity for public comment with published response prior to final action.

Section IV–C–1–a. General Responsibilities

The NIH Director is responsible for:

Section IV–C–1–a–(1). Promulgating requirements as necessary to implement the *NIH Guidelines;*

Section IV–C–1–a–(2). Establishing and maintaining NIH OSP to carry out the responsibilities defined in Section IV–C–3, *Office of Science Policy;*

Section IV–C–1–a–(3). Conducting and supporting training programs in laboratory safety for Institutional Biosafety Committee members, Biological Safety Officers and other institutional experts (if applicable), Principal Investigators, and laboratory staff.

Section IV–C–1–b. Specific Responsibilities

In carrying out the responsibilities set forth in this section, the NIH Director or a designee shall weigh each proposed action through appropriate analysis and consultation to determine whether it complies with the *NIH Guidelines* and presents no significant risk to health or the environment.

Section IV–C–1–b–(1). Major Actions

To execute *Major Actions,* the NIH Director shall provide an opportunity for public and Federal agency comment. The NIH Director's decision/recommendation (at his/her discretion) may be published in the **Federal Register** for 15 days of comment before final action is taken. The NIH Director's final decision/recommendation, along with responses to public comments, shall be published in the **Federal Register**. Institutional Biosafety Committee Chairs shall be notified of the following decisions:

Section IV–C–1–b–(1)–(a). Changing containment levels for types of experiments that are specified in the *NIH Guidelines* when a *Major Action* is involved;

Section IV–C–1–b–(1)–(b). Assigning containment levels for types of experiments that are not explicitly considered in the *NIH Guidelines* when a *Major Action* is involved;

Section IV–C–1–b–(1)–(c). Promulgating and amending a list of classes of recombinant or synthetic nucleic acid molecules to be exempt from the *NIH Guidelines* because they consist entirely of DNA segments from species that exchange DNA by known physiological processes or otherwise do not present a significant risk to health or the environment;

Section IV–C–1–b–(1)–(d). Permitting experiments specified by Section III–A, *Experiments that Require Institutional Biosafety Committee Approval, and NIH Director Approval Before Initiation;*

Section IV–C–1–b–(1)–(e). Certifying new host-vector systems with the exception of minor modifications (*e.g.,* those of minimal or no consequence to the properties relevant to containment) of already certified systems (the standards and procedures for certification are described in Appendix I–II, *Certification of Host-Vector Systems;* and

Section IV–C–1–b–(1)–(f). Adopting other changes in the *NIH Guidelines.*

Section IV–C–1–b–(2). Minor Actions

NIH OSP shall carry out certain functions as delegated to it by the NIH Director (see Section IV–C–3, *Office of Science Policy*). *Minor Actions* will be transmitted to Institutional Biosafety Committee Chairs:

Section IV–C–1–b–(2)–(a). Changing containment levels for experiments that are specified in Section III, *Experiments Covered by the NIH Guidelines* (except when a *Major Action* is involved);

Section IV–C–1–b–(2)–(b). Assigning containment levels for experiments not explicitly considered in the *NIH Guidelines;*

Section IV–C–1–b–(2)–(c). Revising the *Classification of Etiologic Agents* for the purpose of these *NIH Guidelines* (see Section V–A, *Footnotes and References of Sections I–IV*).

Section IV–C–1–b–(2)–(d). Interpreting the *NIH Guidelines* for experiments to which the *NIH Guidelines* do not specifically assign containment levels;

Section IV–C–1–b–(2)–(e). Setting containment under Sections III–D–1–d, *Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems,* and III–D–2–b, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems;*

Section IV–C–1–b–(2)–(f). Approving minor modifications of already certified host-vector systems (the standards and procedures for such modifications are described in Appendix I–II, *Certification of Host-Vector Systems*);

Section IV–C–1–b–(2)–(g). Decertifying already certified host-vector systems;

Section IV–C–1–b–(2)–(h). Adding new entries to the list of molecules toxic for vertebrates (see Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*); and

Section IV–C–1–b–(2)–(i). Determining appropriate containment conditions for experiments according to case precedents developed under Section IV–C–1–b–(2)–(c).

Section IV–C–2. Recombinant DNA Advisory Committee (RAC) is proposed to be deleted in its entirety.

Section IV–C–3. Office of Science Policy (OSP) is proposed to be amended as follows:

Sections IV–C–3–a through IV–C–3–f are proposed to be deleted in their entirety. Section IV–C–3–h is proposed to be deleted in its entirety. Section IV–C–3–g will be renumbered to Section IV–C–3–a. Section IV–C–i will be renumbered to Section IV–C–3–b; Section IV–C–3–i–(1), Section IV–C–3–i–(2) and Section IV–C–3–i–(3) are proposed to be deleted in their entirety. Section IV–C–3–j will be renumbered to Section IV–C–3–c.

Section IV–C–3 is proposed to be amended as follows:

Section IV–C–3. Office of Science Policy (OSP)

OSP shall serve as a focal point for information on recombinant or synthetic nucleic acid molecule activities and provide advice to all within and outside NIH including institutions, Biological Safety Officers, Principal Investigators, Federal agencies, state and local governments, and institutions in the private sector. OSP shall carry out such other functions as may be delegated to it by the NIH Director. OSP's responsibilities include (but are not limited to) the following:

Section IV–C–3–a. Reviewing and approving experiments involving the cloning of genes encoding for toxin molecules that are lethal for vertebrates at an LD_{50} of less than or equal to 100 nanograms per kilogram body weight in organisms other than *Escherichia coli* K–12 (see Section III–B–1, *Experiments Involving the Cloning of Toxin Molecules with LD_{50} of Less than 100 Nanograms Per Kilogram Body Weight,* Appendix F, *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates*);

Section IV–C–3–b. Publishing in the **Federal Register**, as needed.

Section IV–C–3–c. Reviewing and approving the membership of an institution's Institutional Biosafety Committee, and where it finds the Institutional Biosafety Committee meets the requirements set forth in Section IV–B–2, *Institutional Biosafety Committee (IBC),* giving its approval to the Institutional Biosafety Committee membership.

Section IV–D–5 currently states:

Section IV–D–5. Protection of Proprietary Data—Voluntary Compliance

Section IV–D–5–a. General

In general, the Freedom of Information Act requires federal agencies to make their records available to the public upon request. However, this requirement does not apply to, among other things, ''trade secrets and commercial or financial information that is obtained from a person and that is privileged or confidential.'' Under 18 U.S.C. 1905, it is a criminal offense for an officer or employee of the U.S. or any federal department or agency to publish, divulge, disclose, or make known ''in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, (or) processes . . . of any person, firm, partnership, corporation, or association.'' This provision applies to all employees of the federal government, including special Government

employees. Members of RAC are ''special Government employees.''

Section IV–D–5 is proposed to be amended as follows:

Section IV–D–5–a. General

In general, the Freedom of Information Act requires federal agencies to make their records available to the public upon request. However, this requirement does not apply to, among other things, ''trade secrets and commercial or financial information that is obtained from a person and that is privileged or confidential.'' Under 18 U.S.C. 1905, it is a criminal offense for an officer or employee of the United States or any federal department or agency to publish, divulge, disclose, or make known ''in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, (or) processes . . . of any person, firm, partnership, corporation, or association.'' This provision applies to all employees of the federal government, including special Government employees.

None of the other sub-sections under Section IV are proposed to be amended.

Section V currently states:

Section V. Footnotes and References of Sections I through IV

Section V–A. The NIH Director, with advice of the RAC, may revise the classification for the purposes of the *NIH Guidelines* (see Section IV–C–1–b–(2)–(e), *Minor Actions*). The revised list of organisms in each Risk Group is reprinted in Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard.*

Section V–B. Section III, *Experiments Covered by the NIH Guidelines,* describes a number of places where judgments are to be made. In all these cases, the Principal Investigator shall make the judgment on these matters as part of his/her responsibility to ''make the initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*'' (see Section IV–B–7–c–(1)). For cases falling under Sections III–A through III–E, *Experiments Covered by the NIH Guidelines,* this judgment is to be reviewed and approved by the Institutional Biosafety Committee as part of its responsibility to make an ''independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research'' (see Section IV–B–2–b–(1), *Institutional Biosafety Committee*). The Institutional Biosafety Committee may refer specific cases to NIH OSP as part of NIH OSP's functions to ''provide advice to all within and outside NIH'' (see Section IV–C–3). NIH OSP may request advice from the RAC as part of the RAC's responsibility for ''interpreting the *NIH Guidelines* for experiments to which the *NIH Guidelines* do not specifically assign containment levels'' (see Section IV–C–1–b–(2)–(f), *Minor Actions*).

Section V is proposed to be amended as follows:

Section V–A. The NIH Director may revise the classification for the purposes of the *NIH Guidelines* (see Section IV–C–1–b–(2)–(e), *Minor Actions*). The revised list of organisms in each Risk Group is reprinted in Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard.*

Section V–B. Section III, *Experiments Covered by the NIH Guidelines,* describes a number of places where judgments are to be made. In all these cases, the Principal Investigator shall make the judgment on these matters as part of his/her responsibility to ''make the initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*'' (see Section IV–B–7–c–(1)). For cases falling under Sections III–A through III–E, *Experiments Covered by the NIH Guidelines,* this judgment is to be reviewed and approved by the Institutional Biosafety Committee as part of its responsibility to make an ''independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research'' (see Section IV–B–2–b–(1), *Institutional Biosafety Committee*). The Institutional Biosafety Committee may refer specific cases to NIH OSP as part of NIH OSP's functions to ''provide advice to all within and outside NIH'' (see Section IV–C–3).

Appendix A currently states:

Appendix A. Exemptions Under Section III–F–6—Sublists of Natural Exchangers

Certain specified recombinant or synthetic nucleic acid molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent are exempt from these *NIH Guidelines* (see Section III–F–6, *Exempt Experiments*). Institutional Biosafety Committee registration is not required for these exempt experiments. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice from the RAC after appropriate notice and opportunity for public comment (see Section IV–C–1-b-(1)-(c), *NIH Director—Specific Responsibilities*). For a list of natural exchangers that are exempt from the *NIH Guidelines,* see Appendices A–I through A–VI, *Exemptions under Section III–F–6 Sublists of Natural Exchangers.* Section III–F–6, *Exempt Experiments,* describes recombinant or synthetic nucleic acid molecules that are: (1) Composed entirely of DNA segments from one or more of the organisms within a sublist, and (2) to be propagated in any of the organisms within a sublist (see *Classification of Bergey's Manual of Determinative Bacteriology;* 8th edition, R.E. Buchanan and N.E. Gibbons, editors, Williams and Wilkins Company; Baltimore, Maryland 1984). Although these experiments are exempt, it is recommended that they be performed at the appropriate biosafety level for the host or recombinant/synthetic organism (see Biosafety in Microbiological and Biomedical Laboratories, 5th edition, 2007, U.S. DHHS, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia, and NIH Office of Biosafety, Bethesda, Maryland).

Appendix A is proposed to be amended as follows:

Appendix A. Exemptions Under Section III–F–6—Sublists of Natural Exchangers

Certain specified recombinant or synthetic nucleic acid molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent are exempt from these *NIH Guidelines* (see Section III–F–6, *Exempt Experiments*). Institutional Biosafety Committee registration is not required for these exempt experiments. A list of such exchangers will be prepared and periodically revised by the NIH Director after appropriate notice and opportunity for public comment (see Section IV–C–1-b-(1)-(c), *NIH Director—Specific Responsibilities.* For a list of natural exchangers that are exempt from the *NIH Guidelines,* see Appendices A–I through A–VI, *Exemptions under Section III–F–6 Sublists of Natural Exchangers.* Section III–F–6, *Exempt Experiments,* describes recombinant or synthetic nucleic acid molecules that are: (1) Composed entirely of DNA segments from one or more of the organisms within a sublist, and (2) to be propagated in any of the organisms within a sublist (see *Bergey's Manual of Systematic Bacteriology;* 2nd edition, Springer-Verlag; New York, NY). Although these experiments are exempt, it is recommended that they be performed at the appropriate biosafety level for the host or recombinant/synthetic organism (see Biosafety in Microbiological and Biomedical Laboratories, 5th edition, 2007, U.S. DHHS, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia, and NIH Office of Biosafety, Bethesda, Maryland).

Appendix C–IX–A currently states:

Appendix C–IX–A

The NIH Director, with advice of the RAC, may revise the classification for the purposes of these *NIH Guidelines* (see Section IV–C–

1–b–(2)–(b), *Minor Actions*). The revised list of organisms in each Risk Group is located in Appendix B.

Appendix C–IX–A is proposed to be amended as follows:

Appendix C–IX–A

The NIH Director may revise the classification for the purposes of these *NIH Guidelines* (see Section IV–C–1–b–(2)–(b), *Minor Actions*). The revised list of organisms in each Risk Group is located in Appendix B.

None of the other sub-sections under Appendix C–IX. Footnotes and References of Appendix C are proposed to be amended.

Appendix D currently states in part:

Appendix D. Major Actions Taken Under the NIH Guidelines

As noted in the subsections of Section IV–C–1–b–(1), the Director, NIH, may take certain actions with regard to the *NIH Guidelines* after the issues have been considered by the RAC. Some of the actions taken to date include the following:

Appendix D is proposed to be amended as follows:

Appendix D. Major Actions Taken Under the NIH Guidelines

As noted in the subsections of Section IV–C–1–b–(1), the Director, NIH, may take certain actions with regard to the *NIH Guidelines.* (Entries up to and including D–118 were approved using a process that involved the RAC.) Some of the actions taken to date include the following:

Appendix I–II currently states:

Appendix I–II. Certification of Host-Vector Systems

Appendix I–II–A. Responsibility

Host-Vector 1 systems (other than *Escherichia coli* K–12) and Host-Vector 2 systems may not be designated as such until they have been certified by the NIH Director. Requests for certification of host-vector systems may be submitted to the Office of Science Policy, National Institutes of Health, preferably by email to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). Proposed host-vector systems will be reviewed by the RAC (see Section IV–C–1–b–(1)–(f), *Major Actions*). Initial review will based on the construction, properties, and testing of the proposed host-vector system by a subcommittee composed of one or more RAC members and/or *ad hoc* experts. The RAC will evaluate the subcommittee's report and any other available information at the next scheduled RAC meeting. The NIH Director is responsible for certification of host-vector systems, following advice of the RAC. Minor modifications to existing host-vector systems (*i.e.,* those that are of minimal or no consequence to the properties relevant to containment) may be certified by the NIH Director without prior RAC review (see Section IV–C–1–b–(2)–(f), *Minor Actions*). Once a host-vector system has been certified by the NIH Director, a notice of certification will be sent by NIH OSP to the applicant and to the Institutional Biosafety Committee Chairs. A list of all currently certified host-vector systems is available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). The NIH Director may rescind the certification of a host-vector system (see Section IV–C–1–b–(2)–(g), *Minor Actions*). If certification is rescinded, NIH will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher level of physical containment level, unless NIH determines that the already constructed clones incorporate adequate biological containment. Certification of a host-vector system does not extend to modifications of either the host or vector component of that system. Such modified systems shall be independently certified by the NIH Director. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications to a certified host-vector system requires submission of complete testing data.

Appendix I–II–B. Data To Be Submitted for Certification

Appendix I–II–B–1. Host-Vector 1 Systems Other than *Escherichia coli* K–12

The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction, survival, and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and the type of information is exchanged; and any relevant information about its pathogenicity or toxicity; (ii) a description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such an Host-Vector 1 system.

Appendix I–II–B–2. Host-Vector 2 Systems

Investigators planning to request Host-Vector 2 systems certification may obtain instructions from NIH OSP concerning data to be submitted (see Appendices I–III–N and O, *Footnotes and References of Appendix I*). In general, the following types of data are required: (i) Description of construction steps with indication of source, properties, and manner of introduction of genetic traits; (ii) quantitative data on the stability of genetic traits that contribute to the containment of the system; (iii) data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment; (iv) data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions; (v) data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation; and (vi) in some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals or one or more human subjects. Such *in vivo* data may be required to confirm the validity of predicting *in vivo* survival on the basis of *in vitro* experiments. Data shall be submitted 12 weeks prior to the RAC meeting at which such data will be considered by the Office of Science Policy, National Institutes of Health, preferably by email to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). Investigators are encouraged to publish their data on the construction, properties, and testing of proposed Host Vector 2 systems prior to consideration of the system by the RAC and its subcommittee. Specific instructions concerning the submission of data for proposed *Escherichia coli* K–12 Host-Vector 2 system (EK2) involving either plasmids or bacteriophage in *Escherichia coli* K–12, are available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: *NIHGuidelines@od.nih.gov;*additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*).

Appendix I–II is proposed to be amended as follows:

Appendix I–II. Certification of Host-Vector Systems

Appendix I–II–A. Responsibility

Host-Vector 1 systems (other than *Escherichia coli* K–12) and Host-Vector 2 systems may not be designated as such until they have been certified by the NIH Director. Requests for certification of host-vector systems may be submitted to the Office of Science Policy, National Institutes of Health, preferably by email to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). Proposed host-vector systems will be reviewed based on the construction, properties, and testing of the proposed host-vector system by *ad hoc* experts. The NIH Director is responsible for certification of host-vector systems. Once a host-vector system has been certified by the NIH Director, a notice of certification will be sent by NIH OSP to the applicant and to the Institutional Biosafety Committee Chairs. A list of all currently certified host-vector systems is available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: *NIHGuidelines@od.nih.gov;*

additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). The NIH Director may rescind the certification of a host-vector system (see Section IV–C–1–b–(2)–(g), *Minor Actions*). If certification is rescinded, NIH will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher level of physical containment level, unless NIH determines that the already constructed clones incorporate adequate biological containment. Certification of a host-vector system does not extend to modifications of either the host or vector component of that system. Such modified systems shall be independently certified by the NIH Director. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications to a certified host-vector system requires submission of complete testing data.

Appendix I–II–B. Data To Be Submitted for Certification

Appendix I–II–B–1. Host-Vector 1 Systems Other than *Escherichia coli* K–12

The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction, survival, and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and the type of information is exchanged; and any relevant information about its pathogenicity or toxicity; (ii) a description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such an Host-Vector 1 system.

Appendix I–II–B–2. Host-Vector 2 Systems

Investigators planning to request Host-Vector 2 systems certification may obtain instructions from NIH OSP concerning data to be submitted (see Appendices I–III–N and O, *Footnotes and References of Appendix I*). In general, the following types of data are required: (i) Description of construction steps with indication of source, properties, and manner of introduction of genetic traits; (ii) quantitative data on the stability of genetic traits that contribute to the containment of the system; (iii) data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment; (iv) data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions; (v) data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation; and (vi) in some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals or one or more human subjects. Such *in vivo* data may be required to confirm the validity of predicting *in vivo* survival on the basis of *in vitro* experiments. Data shall be submitted to the Office of Science Policy, National Institutes of Health, preferably by email to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). Investigators are encouraged to publish their data on the construction, properties, and testing of proposed Host Vector 2 systems prior to consideration of the system by NIH. Specific instructions concerning the submission of data for proposed *Escherichia coli* K–12 Host-Vector 2 system (EK2) involving either plasmids or bacteriophage in *Escherichia coli* K–12, are available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*).

Appendix L, GENE THERAPY POLICY CONFERENCES (GTPCS), is proposed to be deleted in its entirety.

Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Research Participants (Points to Consider), is proposed to be deleted in its entirety.

Dated: August 7, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018–17760 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–17–144: Limited Competition: National Primate Research Centers (P51).

Date: September 11–14, 2018.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Vintage Portland, 422 SW Broadway, Portland, OR 97205.

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: September 13–14, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Orlando at SeaWorld, 6677 Sea Harbor Drive, Orlando, FL 32821.

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 13, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–17785 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night; Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces a meeting to peer review the Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night. NTP has conducted a literature-based assessment to determine whether night shift work (*e.g.,* working at least three hours between 12 a.m. and 6 a.m.) and light at night are cancer hazards and should

be listed the Report on Carcinogens. The peer-review meeting will be held at the National Institute of Environmental Health Sciences (NIEHS) in Research Triangle Park, NC and is open to the public. Registration is requested for attendance at the meeting either in-person or by webcast and to present oral comments. Information about the meeting and registration is available at *https://ntp.niehs.nih.gov/go/36051.*

DATES:

Meeting: Scheduled for October 5, 2018, 8:30 a.m. to adjournment at approximately 5:00 p.m. Eastern Daylight Time (EDT). The preliminary agenda is available at *https://ntp.niehs.nih.gov/go/36051* and will be updated one week before the meeting.

Document Availability: The draft RoC monograph should be available by August 24, 2018, at *https://ntp.niehs.nih.gov/go/36051.*

Written Public Comment Submissions: Deadline is September 21, 2018.

Registration for Oral Comments: Deadline is September 21, 2018.

Registration To Attend Meeting In-Person or To View Webcast: Deadline is October 5, 2018.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Web Page: The draft RoC monograph, preliminary agenda, registration, and other meeting materials will be available at *https://ntp.niehs.nih.gov/go/36051.*

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Kate Helmick, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293–1673, Fax: (919) 293–1645, Email: *NTP-Meetings@icf.com.*

SUPPLEMENTARY INFORMATION:

Background: The invention of electric light transformed society, from one in which people's activities and sleep patterns were limited by the natural light: Dark cycle to a culture in which people now work, sleep, eat, and receive goods or services throughout the 24-hour day. Through lifestyle choices, home location, and work schedule, people are exposed to different patterns and types of light, including electric light at night (LAN), which may lead to cancer and other adverse health effects. These health effects may arise from misalignment of daily physiological and behavioral cycles (*i.e.,* circadian rhythms) with external stimuli or with each other (*i.e.,* circadian disruption). Circadian rhythms can include processes and behaviors like sleep-wake cycles, eating, and body temperature, among others.

NTP has conducted a literature-based assessment and applied the *Report on Carcinogens (RoC) listing criteria* to this assessment to determine whether night shift work (*e.g.,* working at least three hours between midnight and 6 a.m.) and light at night are cancer hazards. As circadian disruption is thought to be a key intermediate step, NTP has also reviewed the literature on this topic.

The monograph assesses the evidence from cancer studies in humans and experimental animals and mechanistic data and provides NTP's preliminary recommendation regarding whether night shift work and or light at night should be listed in the Report on Carcinogens, and if so, how the two exposure scenarios should be defined. The listing categories include *known or reasonably anticipated to be a human carcinogen.*

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment; in-person attendance at the NIEHS is limited by the space available (~100 attendees). Registration for in-person attendance is on a first-come, first-served basis. After the first 100 registrants, persons will be placed on a wait list and notified should an opening become available. Registration to attend the meeting in-person or view the webcast is by October 5, 2018, at *https://ntp.niehs.nih.gov/go/36051.* The URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in person is available at *https://www.niehs.nih.gov/about/visiting/index.cfm.* Individuals with disabilities who need accommodation to view the webcast should contact Kate Helmick by phone: (919) 293–1673 or email: *NTP-Meetings@icf.com.* TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.

Public Comment Registration: NTP invites written and oral public comments on the draft RoC monograph that address scientific/technical issues. Guidelines for public comments are available at *https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

The deadline for submission of written comments is September 21, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific/technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

The agenda allows for one oral public comment period (up to 12 commenters, up to 5 min per speaker). Registration to provide oral comments is September 21, 2018, at *https://ntp.niehs.nih.gov/go/36051.* Registration is on a first-come, first-served basis. Each organization is allowed one time slot. Oral comments may be presented in person at NIEHS or by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified after September 21, 2018, the deadline to register for oral public comments, about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Kate Helmick by email: *NTP-Meetings@icf.com* by September 21, 2018.

Meeting Materials: The draft RoC monograph and preliminary agenda will be available on the NTP website at *https://ntp.niehs.nih.gov/go/36051.* The draft RoC monograph should be available by August 24, 2018. Additional information will be posted when available or may be requested in hardcopy, contact Kate Helmick by phone: (919) 293–1673 or email: *NTP-Meetings@icf.com.* The preliminary meeting agenda will be available on the meeting web page and will be updated one week before the meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on the RoC: Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. For each listed substance, the RoC contains a substance profile, which provides information on cancer studies that support the listing—including those in humans and animals and studies on possible mechanisms of action, information about potential sources of exposure to humans, and current Federal regulations to limit exposures. The 14th RoC, the latest edition, was published on November 3, 2016

(available at *https://ntp.niehs.nih.gov/go/roc14*).

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Kate Helmick by email: *NTP-Meetings@icf.com.* The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: August 8, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018–17782 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0565]

Lifejacket Approval Harmonization

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Coast Guard announces that it is harmonizing personal flotation device (PFD) standards between the United States and Canada by accepting a new standard for approval of PFDs. Specific elements of the new standard are contained in a policy letter and deregulatory savings analysis, on which we are requesting public comment, and are intended to promote the Coast Guard's maritime safety and stewardship missions.

DATES: Comments must be submitted to the online docket via *http://www.regulations.gov,* or reach the Docket Management Facility, on or before October 16, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0565 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the ''Public Participation and Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Jacqueline Yurkovich, Coast Guard; telephone 202–372–1389, email *Jacqueline.M.Yurkovich@uscg.mil*.

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments on the lifejacket approval harmonization policy letter entitled, ADOPTION OF ANSI/CAN/UL 12402–5 AND –9, and the deregulatory savings analysis entitled, ''Approval for Personal Floatation Devices/Adoption of ANSI/CAN/UL 12402–5 and 9,'' which are available in the docket. The policy letter is also available on the USCG website, *https://www.dco.uscg.mil/CG-ENG,* listed as CG–ENG Policy 02–18. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of the document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments or other documents are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Discussion

The United States Coast Guard (USCG) has statutory authority under Title 46, U.S. Code, Sections 3306(a) and (b), 4102(a) and (b), 4302(a), and 4502(a) and (c)(2)(B) to prescribe regulations for the design, construction, performance, testing, carriage, use, and inspection of lifesaving equipment on commercial and recreational vessels. Since 2008, the USCG has been working closely with Transport Canada (TC) and a diverse group of U.S. and Canadian stakeholders to harmonize PFD standards with the current international standard (ISO 12402) to create a single North American standard for PFD approval. A single North American standard will allow manufacturers the opportunity to produce more innovative equipment that meets the approval requirements of both the United States and Canada.

In 2015, Underwriters Laboratories Inc. published bi-national standards [1] to set forth performance requirements and manufacturing standards for PFDs that are being used when vessels are close to shore, or where a rescue may be imminent. UL 12402–5 sets forth the performance requirements for PFDs and, within UL 12402–5, there are two levels of performance: Level 50 and Level 70. A Level 70 PFD provides an equivalent level of safety to a Type III PFD currently approved under 46 CFR 160.064, 160.076, or 160.077–15, and certified to UL 1123 (Marine Buoyant Devices). A Level 50 PFD provides a reduced level of performance, and is not included in this policy. UL 12402–9 sets forth the test methods for determining compliance with UL 12402–5.

In April 2017, the USCG and TC signed a Memorandum of Understanding (MOU) outlining intended cooperation for approval of personal lifesaving appliances that comply with mutually acceptable standards, are tested by mutually accepted conformity assessment bodies or independent test laboratories, and are covered by a mutually acceptable follow-up program. In January 2018, TC published a policy stating it will accept UL 12402–5 as a substitute for its PFD standards in support of the MOU. The policy letter on which we are requesting comment builds on the efforts described above by establishing that the USCG will accept Level 70 PFDs complying

[1] ANSI/CAN/UL 12402–5, Standard for Personal Flotation Devices—Part 5: Buoyancy Aids (Level 50)—Safety Requirements (UL 12402–5), and ANSI/CAN/UL 12402–9, Standard for Personal Flotation Devices—Part 9: Test Methods (UL12402–9).

with UL 12402–5 as equivalent to PFDs meeting the requirements in 46 CFR 160.064 and 160.076, with certain exceptions.

The adoption of this policy marks the culmination of over a decade of dedicated work across the lifejacket and recreational boating safety community and supports National Boating Safety Advisory Council Resolution 2009–83–01, which is available in the docket.[2] This policy also responds to a comment submitted by the Lifejacket Association in response to the Coast Guard's request for public input on ''Evaluation of Existing Coast Guard Regulations, Guidance Documents, Interpretive Documents, and Collections of Information,'' [3] recommending the Coast Guard consider full adoption of UL 12402–5 and UL 12402–9. In order to provide the maximum benefit to the public with minimum delay, the Coast Guard evaluated which elements of the new standards could be implemented without a change to the regulations. Those elements are being adopted by this policy. The remaining elements of the standards that cannot be adopted without a change to the regulations are being considered for possible future regulatory action.

This policy letter allows manufacturers to have their products certified to the new bi-national standard, in lieu of the legacy standards codified in title 46 CFR. This allowance is intended to reduce the burden of maintaining approvals in U.S. and Canadian markets and to make additional types of PFDs available to U.S. and Canadian boaters.

This policy does not impact existing PFD approvals, and does not require any action on the part of boaters or mariners who have approved PFDs onboard. An existing approved PFD will continue to meet the same carriage requirements, as long as it remains in good and serviceable condition.

The Coast Guard has prepared a Deregulatory Savings Analysis for the policy letter that identifies and examines the potential costs and savings associated with implementing the new standards plan and is available in the docket. We request your comments on any concerns that you may have related to the policy changes.

This notice is issued under authority of 5 U.S.C. 552(a).

[2] The Resolution requested the U.S. Coast Guard work cooperatively with stakeholders to devise and implement within 3 years an improved regulatory approach to the testing and approval of personal flotation devices, including life jackets.

[3] 82 FR 26632 (June 8, 2017).

Dated: August 9, 2018.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2018–17799 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

[Docket ID FEMA–2014–0022]

Technical Mapping Advisory Council

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) Technical Mapping Advisory Council (TMAC) will meet in person on Tuesday, September 25, 2018, and Wednesday, September 26, 2018, in Reston, Virginia. The meeting will be open to the public.

DATES: The TMAC will meet on Tuesday, September 25, 2018, from 8:00 a.m.–5:30 p.m. Eastern Daylight Time (EDT), and Wednesday, September 26, 2018, from 8:00 a.m.–5:30 p.m. EDT. Please note that the meeting will close early if the TMAC has completed its business.

ADDRESSES: The meeting will be held at the United States Geological Survey (USGS) Headquarters at 12201 Sunrise Valley Drive, Reston, VA 20192. Members of the public who wish to attend the meeting must register in advance by sending an email to *FEMA-TMAC@fema.dhs.gov* (Attention: Michael Nakagaki) by 11:00 p.m. EDT on Wednesday, September 19, 2018. Members of the public must follow signs for the Visitor's Entrance on the U.S. Geological Survey Drive entrance of the USGS; once you pull into the Visitor's Entrance, facility security will direct you to parking and where to check in at the front desk of the visitor's entrance at the USGS. Photo identification is required.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed below in the **FOR FURTHER INFORMATION CONTACT** as soon as possible.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the TMAC, as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated meeting materials will be available at *www.fema.gov/TMAC* for review by Wednesday, September 19, 2018. Written comments to be considered by the committee at the time of the meeting must be submitted and received by Friday, September 21, 2018, identified by Docket ID FEMA–2014–0022, and submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address the email TO: *FEMA-RULES@fema.dhs.gov* and CC: *FEMA-TMAC@fema.dhs.gov.* Include Docket ID FEMA–2014–0022 in the subject line of the message. Include name and contact information in the body of the email.
- *Mail:* Regulatory Affairs Division, Office of Chief Counsel, FEMA, 500 C Street SW, Room 8NE, Washington, DC 20472–3100.

Instructions: All submissions received must include the words ''Federal Emergency Management Agency'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For docket access to read background documents or comments received by the TMAC, go to *http://www.regulations.gov* and search for the Docket ID FEMA–2014–0022.

A public comment period will be held on Tuesday, September 25, 2018, from 4:00 p.m. to 4:30 p.m. EDT and again on Wednesday, September 26, 2018, from 11:30 a.m. to 12:00 p.m. EDT. Speakers are requested to limit their comments to no more than three minutes. The public comment period will not exceed 30 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker by close of business on Friday, September 21, 2018.

FOR FURTHER INFORMATION CONTACT: Michael Nakagaki, Designated Federal Officer for the TMAC, FEMA, 400 C Street SW, Washington, DC 20024, telephone (202) 212–2148, and email *michael.nakagaki@fema.dhs.gov.* The TMAC website is: *http://www.fema.gov/TMAC.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. Appendix.

In accordance with the *Biggert-Waters Flood Insurance Reform Act of 2012,* the TMAC makes recommendations to the FEMA Administrator on: (1) How to improve, in a cost-effective manner, the (a) accuracy, general quality, ease of use, and distribution and dissemination of

flood insurance rate maps and risk data; and (b) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States; (2) mapping standards and guidelines for (a) flood insurance rate maps, and (b) data accuracy, data quality, data currency, and data eligibility; (3) how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification; (4) procedures for delegating mapping activities to State and local mapping partners; and (5)(a) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination, and (b) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies. Furthermore, the TMAC is required to submit an annual report to the FEMA Administrator that contains: (1) A description of the activities of the Council; (2) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update Flood Insurance Rate Maps; and (3) a summary of recommendations made by the Council to the FEMA Administrator.

Agenda: During the two-day meeting, TMAC members will discuss and conduct a review of the final draft TMAC 2018 Annual Report. The TMAC will also receive public input on the report recommendations and content; the recommendations and summary of content will be posted to the FEMA TMAC website at *http://www.fema.gov/TMAC* prior to the meeting to provide the public an opportunity to review the materials. A public comment period will be held on Tuesday, September 25, 2018, from 4:00 p.m. to 4:30 p.m. EDT and again on Wednesday, September 26, 2018, from 11:30 a.m. to 12:00 p.m. EDT and will occur prior to any vote. The full agenda and related meeting materials will be posted by Friday, September 21, 2018, at *http://www.fema.gov/TMAC.*

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Federal Emergency Management Agency.

[FR Doc. 2018–17813 Filed 8–16–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7005–N–15]

60-Day Notice of Proposed Information Collection: Home Equity Conversion Mortgage (HECM) Counseling Standardization and Roster

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 16, 2018.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: John Olmstead, Housing Program Specialist, Office of Housing Counseling, Office of Policy and Grant Administration, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *john.olmstead@hud.gov* or telephone (802) 951–6290. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Application for Home Equity Conversion Mortgage (HECM) Counselor Roster and Certificate of HECM Counseling.

OMB Approval Number: 2502–0586.

Type of Request: Reinstatement, with change, of previously approved collection for which approval will expire. (OMB Expiration Date: August 31, 2018).

Form Numbers: HUD–92902 and HUD–92904.

Description of the need for the information and proposed use: The HECM Counselor examination and Roster application assists HUD in evaluating the knowledge and capacity of individuals interested in providing HECM counseling to potential HECM borrowers thereby reducing the risk to the insurance fund. The collection of information assists HUD in providing and maintaining a current roster of HUD-approved HECM counselors to the general public and interested customers. The transfer of the Certificate of HECM Counseling, form HUD 92900, from OMB Collection 2502–0524 to this collection is needed since the Office of Housing Counseling is responsible for all services offered by HUD-approved housing counselors which includes HECM Roster Counselors. OMB Collection 2502–0524 was recently approved by OMB and has an expiration date of March 31, 2021.

Respondents (*i.e.* affected public): State, Local or Tribal Government.

Estimated Number of Respondents: 1,055.

Estimated Number of Responses: 80,058.50.

Frequency of Response: HUD–92902—Certificate of HECM Counseling: Once HUD 92904—HECM Counseling Roster: 94.11.

Average Hours per Response: 2 hours.

Total Estimated Burden: 120,841.25.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the

collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: July 31, 2018.

Vance T. Morris,

Special Assistant to Assistant Secretary for Housing, Federal Housing Commissioner.

[FR Doc. 2018–17790 Filed 8–16–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7001–N–42]

30-Day Notice of Proposed Information Collection: Indian Community Development Block Grant

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* September 17, 2018.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Colette.Pollard@hud.gov,* or telephone 202–402–3400. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on April 27, 2018 at 83 FR 18585.

A. Overview of Information Collection

Title of Information Collection: Indian Community Development Block Grant.

OMB Approved Number: 2577–0191.

Type of Request: Extension of currently approved collection.

Form Number: HUD–4123, HUD–4125.

Description of the need for the information and proposed use: Title I of the Housing and Community Development Act of 1974 authorizes Indian Community Development Block Grants (ICDBG) and requires that grants be awarded annually on a competitive basis. The purpose of the ICDBG program is to develop viable Indian and Alaska Native communities by creating decent housing, suitable living environments, and economic opportunities primarily for low- and moderate-income persons. Consistent with this objective, not less than 70 percent of the expenditures are to benefit low and moderate-income persons. Eligible applicants include Federally-recognized tribes, which includes Alaska Native communities, and tribally authorized tribal organizations. Eligible categories of funding include housing rehabilitation, land acquisition to support new housing, homeownership assistance, public facilities and improvements, economic development, and microenterprise programs. For a complete description of eligible activities, please refer to 24 CFR part 1003, subpart C.

The ICDBG program regulations are at 24 CFR part 1003. The ICDBG program requires eligible applicants to submit information to enable HUD to select the best projects for funding during annual competitions. Additionally, the information submitted is essential for HUD in monitoring grants to ensure that grantees are complying with applicable statutes and regulations and implementing activities as approved.

ICDBG applicants must submit a complete application package which includes an Application for Federal Assistance (SF–424), Applicant/Recipient Disclosure/Update Report (HUD–2880), Cost Summary (HUD–4123), and Implementation Schedule (HUD–4125). If the applicant has a waiver of the electronic submission requirement and is submitting a paper application, an Acknowledgement of Application Receipt (HUD–2993) must also be submitted. If the applicant is a tribal organization, a resolution from the tribe stating that the tribal organization is submitting an application on behalf of the tribe must also be included in the application package.

ICDBG recipients are required to submit a quarterly Federal Financial Report (SF–425) that describes the use of grant funds drawn from the recipient's line of credit. The reports are used to monitor cash transfers to the recipients and obtain expenditure data from the recipients. (2 CFR 200.327)

The regulations at 24 CFR part 200 require that grantees and sub-grantees take all necessary affirmative steps to assure that minority firms, women's business enterprises, and labor surplus area firms are used when possible. Consistent with these regulations, 24 CFR 1003.506(b) requires that ICDBG grantees report on these activities on an annual basis, with Contract and Subcontract Activity Report being due to HUD on October 10 of each year (HUD–2516).

The regulations at 24 CFR 1003.506 instruct recipients to submit to HUD an Annual Status and Evaluation Report (ASER) that describes the progress made in completing approved activities with a listing of work to be completed; a breakdown of funds expended; and when the project is completed, a program evaluation expressing the effectiveness of the project in meeting community development needs. The ASER is due by November 15 each year and at grant closeout.

The information collected will allow HUD to accurately audit the program.

Respondents: Federally recognized Native American Tribes, Alaska Native communities and corporations, and tribal organizations.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Grant Application (Includes SF–424, HUD–2880, HUD–2993, HUD–4123, HUD–4125)	240.00	1.00	240.00	30.00	7,200.00	$19.23	$138,456.00
Federal Financial Report (SF–425)	100.00	4.00	400.00	0.50	200.00	19.23	3,846.00
Contract and Subcontract Activity Report (HUD–2516)	100.00	1.00	100.00	1.00	100.00	19.23	1,923.00
Annual Status and Evaluation Report (ASER)	100.00	1.00	100.00	4.00	400.00	19.23	7,692.00
Total			840.00		7,900.00		151,917.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond: Including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 3, 2018.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2018–17788 Filed 8–16–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7001–N–41]

30-Day Notice of Proposed Information Collection: Single Family Mortgage Insurance on Hawaiian Homelands

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* September 17, 2018.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Colette.Pollard@hud.gov,* or telephone 202–402–3400. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on February 28, 2018 at 83 FR 8694.

A. Overview of Information Collection

Title of Information Collection: Single Family Mortgage Insurance for Hawaiian Homelands.

OMB Approved Number: 2502–0358.

Type of Request: Extension of currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: FHA insures mortgages on single-family dwellings under provisions of the National Housing Act (12 U.S.C. 1709). The Housing and Urban Rural Recovery Act (HURRA), Public Law 98–181, amended the National Housing Act to add Section 247 (12 U.S.C. 1715z–12) to permit FHA to insure mortgages for properties located on Hawaiian Homelands. Under this program, the mortgagor must be a native Hawaiian. In accordance with 24 CFR 203.43i, the collection of information is verification that a loan applicant is a native Hawaiian and that the applicant holds a lease on land in a Hawaiian Homelands area. A borrower must obtain verification of eligibility from Department of Hawaiian Homelands (DHHL) and submit it to the lender. A borrower cannot obtain a loan under these provisions without proof of status as a native Hawaiian. United States citizens living in Hawaii are not eligible for this leasehold program unless they are native Hawaiians. The eligibility document is required to obtain benefits.

In accordance with 24 CFR 203.439(c), lenders must report monthly to HUD and the DHHL on delinquent borrowers and provide documentation to HUD to support that the loss mitigation requirements of 24 CFR 203.602 have been met. To assist the DHHL in identifying delinquent loans, lenders report monthly. A delinquent mortgage that is reported timely would allow DHHL to intervene and prevent foreclosure.

	Number of respond-ents	Frequency of response	Responses per year	Average burden hours per response	Annual burden hours	Hourly cost per response	Total annual cost
Certification that borrower is a native Hawaiian [1]	200.00	1.00	200.00	.08 (5 minutes per loan)	16.00	[3] $23.06	$368.96

	Number of respondents	Frequency of response	Responses per year	Average burden hours per response	Annual burden hours	Hourly cost per response	Total annual cost
Copy of lease on land in Hawaiian Homelands area [1]	200.00	1.00	200.00	.08 (5 minutes per loan)	16.00	23.06	368.96
Notice of Delinquency [2]	46.00	1.00	46.00	.42 (25 minutes per loan)	19.32	23.06	445.51
Totals	446.00	.....	446.00	.....	51.32	.....	1183.43

Notes:
1. Respondents are lenders (The total number of approved lenders equal 15,871).
2. Lenders reporting delinquent loans to DHHL monthly.
3. The $23.06/hour cost is based on a lender's clerical staff average annual salary of $47,960.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond: Including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 3, 2018.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2018–17789 Filed 8–16–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2018–N054; FXES11130400000C2–156–FF04E00000]

Endangered and Threatened Wildlife and Plants; Draft Recovery Plan for Neosho Mucket

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and request for public comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of the draft recovery plan for the endangered Neosho mucket. The draft recovery plan includes specific recovery objectives and criteria that must be met in order for us to delist this species under the Endangered Species Act. We request review and comment on this draft recovery plan from local, State, and Federal agencies; Tribes; and the public.

DATES: In order to be considered, comments on the draft recovery plan must be received on or before October 16, 2018.

ADDRESSES:

Obtaining Documents: If you wish to review this draft recovery plan or a list of the references cited in this notice, you may obtain copies by contacting Melvin Tobin, U.S. Fish and Wildlife Service, Arkansas Ecological Services Field Office, 110 S. Amity Road, Suite 300, Conway, AR 72032; tel. (501) 513–4473; or by visiting the Service's Arkansas Field Office website at *http://www.fws.gov/arkansas-es.*

Submitting Comments: If you wish to comment on the draft recovery plan, you may submit your written comments by one of the following methods:

U.S. Mail or Hand-Delivery: Arkansas Ecological Services Field Office (address above).

Fax: 501–513–4480, attn. ''Neosho Mucket Draft Recovery Plan Comment.''

Email: chris_davidson@fws.gov. Please include ''Neosho Mucket Draft Recovery Plan Comment'' in the subject line.

For additional information about submitting comments, see *Request for Public Comments*, below.

FOR FURTHER INFORMATION CONTACT: Melvin Tobin, by telephone at 501–513–4473, or via email at *melvin_tobin@fws.gov.*

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the draft recovery plan for the endangered Neosho mucket (*Lampsilis rafinesqueana*). The draft recovery plan includes specific recovery objectives and criteria that must be met in order for us to delist this species under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). We request review and comment on this draft recovery plan from local, State, and Federal agencies; Tribes; and the public.

Background

The Neosho mucket is a freshwater mussel. The shell is up to 5 inches (18 cm) long. The species is sexually dimorphic, as is typical of *Lampsilis.* The mantle lure is well developed in young females 2–5 years of age, but may be less developed in older individuals (Oesch 1984; McMurray *et al.* 2012).

Neosho mucket glochidia (larvae) are obligate parasites on smallmouth bass (*Micropterus dolomieu*), largemouth bass (*Micropterus salmoides*), and spotted bass (*Micropterus punctulatus*) (Barnhart and Roberts 1997; Service 2005). The Neosho mucket spawns in late April and May, and female brooding occurs May through August. Little is known about habitat requirements of Neosho mucket. It is associated with shallow riffles and runs comprising gravel substrate and moderate-to-swift currents. The species is most often found in areas with swift current, but in Shoal Creek and the Illinois River it prefers nearshore areas or areas out of the main current (Oesch 1984; Obermeyer 2000). The Neosho mucket does not occur in reservoirs lacking riverine characteristics (Obermeyer *et al.* 1997b).

The ESA specifies five factors for listing species as endangered or threatened. The Neosho mucket is threatened primarily by the destruction, modification, or curtailment of its habitat or range (Listing Factor A of the ESA). Specific threats include impoundment, sedimentation, chemical contaminants, mining, the inadequacy of existing regulatory mechanisms, population fragmentation and isolation, invasive nonindigenous species, and water temperature. Climate change (Listing Factor E) is also likely to have adverse effects on the species due to alteration of hydrologic cycles of rivers that support Neosho mucket, but the extent or magnitude of this threat has not been quantified at this time. We determined that other existing

regulatory mechanisms were inadequate to reduce these threats (Listing Factor D).

As a result of these threats, the Neosho mucket was listed as endangered on the Federal List of Endangered and Threatened Wildlife in title 50 of the Code of Federal Regulations (50 CFR 17.11) on September 17, 2013 (78 FR 57076). A total of 483 river miles (777 river kilometers) in seven rivers and one creek (Elk, Fall, Illinois, Neosho, Spring, North Fork Spring, and Verdigris Rivers and Shoal Creek) has been designated as critical habitat for the Neosho mucket (80 FR 24692, April 30, 2015). Critical habitat as set forth in 50 CFR 17.95(f) is located in Benton and Washington Counties, Arkansas; Allen, Cherokee, Coffey, Elk, Greenwood, Labette, Montgomery, Neosho, Wilson, and Woodson Counties, Kansas; Jasper, Lawrence, McDonald, and Newton Counties, Missouri; and Adair, Cherokee, and Delaware Counties, Oklahoma.

Recovery Plan

Section 4(f) of the ESA requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species. Recovery plans describe actions considered necessary for conservation of the species, establish recovery criteria, and estimate time and cost for implementing recovery measures. Section 4(f) of the ESA also requires us to provide public notice and an opportunity for public review and comment during recovery plan development. We will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. We and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

The goal of this recovery plan is to ensure the long-term viability of the Neosho mucket in the wild to the point that it can be removed (''delisted'') from the Federal List of Endangered and Threatened Wildlife. To achieve this goal, it will be necessary to establish naturally self-sustaining populations with healthy long-term demographic traits and trends. We are defining the following reasonable delisting criteria based on the best available information on this species. These criteria will be reevaluated as new information becomes available:

Recovery Criteria

The Neosho mucket will be considered for delisting when:

(1) Two of four targeted river basins (Illinois, Verdigris, Neosho, and Spring River basins) contain viable populations with positive or stable basin-wide population trend, as evidenced by a population number measured with sufficient precision to detect change of ±25 percent (Factors A, D, and E);

(2) Spatial distribution of natural or stocked aggregations distributed throughout the basin is sufficient to protect against local catastrophic or stochastic events (Factors A and E);

(3) All life stages are supported by sufficient habitat quantity and quality (see Primary Constituent Elements in the *Species Biological Report for Neosho Mucket*) and appropriate presence and abundance of fish hosts necessary for recruitment (Factors A, D, and E); and

(4) Threats and causes of decline have been reduced or eliminated (Factors A, D, and E).

A viable population is defined as a wild, naturally reproducing population that is able to persist and maintain sufficient genetic variation to evolve and respond to natural changes and stochastic events without further human intervention. Viable populations are expected to be large and genetically diverse, include at least five age classes with at least one cohort ≤7 years of age, and recruit at sufficient rates to maintain or increase population size.

Request for Public Comments

We request written comments on the draft recovery plan. We will consider all comments we receive by the date specified in **DATES** prior to final approval of the plan.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533 (f).

Dated: August 10, 2018.

Mike Oetker,

Acting Regional Director, Southeast Region.

[FR Doc. 2018–17753 Filed 8–16–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendments in the State of Oklahoma

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The State of Oklahoma entered into compact amendments with the Absentee Shawnee Tribe, Cherokee Nation, Chickasaw Nation, Citizen Potawatomi Nation, Eastern Shawnee Tribe of Oklahoma, Iowa Tribe of Oklahoma, Kaw Nation, Muscogee (Creek) Nation, Seneca-Cayuga Nation, Wichita and Affiliated Tribes, and Wyandotte Nation of Oklahoma governing certain forms of class III gaming; this notice announces the approval of the State of Oklahoma Gaming Compact Non-house-Banked Table Games Supplement between the State of Oklahoma and the Absentee Shawnee Tribe, Cherokee Nation, Citizen Potawatomi Nation, Eastern Shawnee Tribe of Oklahoma, Iowa Tribe of Oklahoma, Kaw Nation, Muscogee (Creek) Nation, Seneca-Cayuga Nation, Wichita and Affiliated Tribes, and Wyandotte Nation.

DATES: The compact amendments take effect on August 17, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by IGRA and 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The compact amendments authorize the Tribes to engage in certain additional class III gaming activities, provide for the application of existing revenue sharing agreements to the additional forms of class III gaming, and designate how the State will distribute revenue sharing funds.

Dated: August 9, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–17729 Filed 8–16–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AAKC001030/ A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendments in the State of Oklahoma

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The State of Oklahoma entered into compact amendments with the Choctaw Nation of Oklahoma and with the Fort Sill Apache Tribe of Oklahoma governing certain forms of class III gaming; this notice announces the approval of the State of Oklahoma Gaming Compact Non-house-Banked Table Games Supplement between the State of Oklahoma and the Choctaw Nation of Oklahoma and the Fort Sill Apache Tribe of Oklahoma.

DATES: The compact amendments take effect on August 17, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by IGRA and 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The compact amendments authorize the Tribes to engage in certain additional class III gaming activities, provide for the application of existing revenue sharing agreements to the additional forms of class III gaming, and designate how the State will distribute revenue sharing funds.

Dated: August 6, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–17728 Filed 8–16–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AAKC001030/ A0A501010.999900 253G]

Rate Adjustments for Indian Irrigation Projects

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) owns or has an interest in irrigation projects located on or associated with various Indian reservations throughout the United States. We are required to establish irrigation assessment rates to recover the costs to administer, operate, maintain, and rehabilitate these projects. We are notifying you that we have adjusted the irrigation assessment rates at several of our irrigation projects and facilities to reflect current costs of administration, operation, maintenance, and rehabilitation.

DATES: The irrigation assessment rates are current as of January 1, 2018.

FOR FURTHER INFORMATION CONTACT: For details about a particular BIA irrigation project or facility, please use the tables in the **SUPPLEMENTARY INFORMATION** section to identify contacts at the regional or local office at which the project or facility is located.

SUPPLEMENTARY INFORMATION: A Notice of Proposed Rate Adjustment was published in the **Federal Register** on January 18, 2018 (83 FR 2662) to propose adjustments to the irrigation assessment rates at several BIA irrigation projects. The public and interested parties were provided an opportunity to submit written comments during the 60-day period that ended March 19, 2018.

Did BIA defer or change any proposed rate increases?

Yes. The 2019 Operation and Maintenance (O&M) rate for the Wind River Irrigation Project, Units 2, 3, and 4, was proposed in the **Federal Register** at $25.00 per acre. After further review, BIA decided to change the rate to $24.50. Instead of raising the rate by $1.00, the rate will only increase by $.50. Because the rate increased by $1.50 over the two previous years, BIA decided the full $1.00 increase for the 2019 O&M rate is not appropriate. Hence, this notice of rate adjustments reflects a 2019 O&M rate of $24.50 per acre for Units 2, 3, and 4.

Did BIA receive any comments on the proposed irrigation assessment rate adjustments?

Yes. BIA received twelve (12) written comments related to the proposed irrigation rate adjustment for the Flathead Indian Irrigation Project and Wind River Irrigation Project.

What issues were of concern to the commenters?

Commenters raised concerns on the proposed rates about the following issues:

The Following Comments are Specific to the Flathead Indian Irrigation Project (FIIP)

Written comments relating to the proposed rate adjustment were received by letter. BIA's summary of the issues and BIA's responses are provided below.

Comment: Several commenters state a general opposition to the 2019 rate increase, along with a number of specific concerns. These include: A concern that BIA is pursuing a rate increase prior to the FIIP manager's annual meeting with the individual irrigation districts, and concerns with how FIIP management chooses to expend funds obtained through irrigation rate assessments.

Response: As noted when rates were proposed in the **Federal Register** on January 18, 2018 (83 FR 2662), BIA is required to establish irrigation assessment rates that recover the costs to administer, operate, maintain, and rehabilitate our projects. As owner of FIIP, it is BIA's responsibility to ensure adequate resources are made available to meet the requirements noted above. BIA's authority to assess rates dates back to the Act of May 29, 1908, codified at 25 U.S.C. 381 *et seq.,* and is addressed in BIA's regulations at 25 CFR part 171. Additionally, the repayment contracts between the irrigation districts and the Department of the Interior explicitly state that operation and maintenance expenses ''shall be paid . . . as provided . . . by rules made or to be made . . . by the Secretary of the Interior.'' The procedures followed by BIA in adjusting its irrigation assessment rates are consistent with applicable law and past practice.

Regarding the timing of this **Federal Register** notice, BIA makes every effort to publish notice of irrigation O&M rate adjustments prior to the issuance of irrigation bills for the upcoming season, and that process requires BIA to solicit comments on proposed rate adjustments on a timeline that will allow it to

publish by then. The BIA-wide effort seeking comments on proposed irrigation rate adjustments is separate from the Project-specific meetings that are conducted by individual Project Managers consistent with each Project's Operations and Management Guidelines.

Regarding concerns with how FIIP management expends funds, each Project Manager has discretion to assess priorities and address those priorities, subject to available funding. As discussed in more detail below, BIA chose not to implement the full, recommended $7.50 increase in 2017, choosing instead to impose a $3.00 increase. As a result, the FIIP Project Manager had less funding available to address key priorities. It is anticipated that the proposed $4.50 increase will provide the FIIP Project Manager with opportunities to address additional priorities.

Comment: One commenter states an opposition to the $4.50 per acre 2019 O&M rate increase, alleging that BIA has not met BIA operating standards by not meeting monthly with the three irrigation districts and not meeting with the three districts to discuss O&M costs, water storage, and other issues.

Response: The status of the FIIP budget and the need to increase rates were communicated to the Flathead Joint Board of Control (FJBC) and irrigation districts as early as 2014 and have been discussed with the irrigation districts, FJBC, and CSKT numerous times since then. BIA publicly noticed its intent to increase assessment rates in both 2015 and 2016 (see Proposed Rate Adjustments published in the **Federal Register** on June 11, 2015 (80 FR 33279, 33283) and August 5, 2016 (81 FR 51927, 51931)). In January 2017, the FIIP Project Manager met with the FJBC to discuss the proposed 2018 increase, which at the time was proposed to be $7.50. As discussed below, for a number of reasons, BIA chose to implement only a $3.00 increase in 2018, but made it clear that the full $7.50 was warranted and that the remaining $4.50 increase would be included in the 2019 rates. This information was provided at an April 11, 2017 water user meeting and reiterated in meetings with the FJBC on May 9, 2017, June 13, 2017, and July 11, 2017.

The BIA's Operations and Management Guidelines require only an annual meeting with the FJBC. This meeting took place on April 11, 2017. These Guidelines also allow FIIP management to meet with individual irrigation districts on an ad hoc basis; to that end, the FIIP Project Manager met with the chairmen of the three individual irrigation districts on June 15, 2017 to discuss the $4.50 rate increase. The FIIP Project Manager also met with the FJBC on September 12, 2017 and October 10, 2017, but the FJBC did not discuss the rate increase at those meetings.

Comment: One commenter protests the $4.50 per acre increase, stating that farmers will be faced with a 29% increase in irrigation costs in two years. The commenter further contends that BIA has not provided a justification or proposal for utilizing the increase.

Response: The costs associated with operating and maintaining the FIIP consistently exceed the amount paid to the FIIP through O&M assessments. Even during the timeframe when the Cooperative Management Entity operated the FIIP, the O&M assessment rate was increased twice, in 2010 and 2011. Since re-assumption, BIA has made clear the need to increase FIIP assessments rates to address O&M needs, and has publicly noticed the need to raise rates in both 2015 and 2016. The only reason rate increases were not implemented then was as a result of the timeframe necessary to communicate an increase to the counties that collect the O&M assessments. Rate increases have been needed for some time, and FIIP's ability to address its operation and maintenance needs have been severely compromised by not increasing rates since 2011.

In 2017, BIA proposed to increase the 2018 rate by $7.50 and explained in the **Federal Register** notice on April 21, 2017 (82 FR 18770) that the entire $7.50 increase was justified due to the increased costs associated with administering, operating, maintaining, and rehabilitating the FIIP. Because of the timing of the 2017 **Federal Register** proposed rate notice, BIA agreed to impose only a $3.00 increase in 2018 and memorialized that increase in the final rate notice published on August 11, 2017 (82 FR 37604, 37605). At the time, however, BIA made clear that the additional $4.50 would be included in its 2019 rates.

The Following Comments Are Specific to the Wind River Irrigation Project (WRIP)

Written comments relating to the proposed rate adjustment were received by letter. The BIA's summary of the issues and BIA's responses are provided below.

Comment: One commenter objects to increased O&M fees that may idle tribal and allotted lands and decrease the financial viability of agricultural operations.

Response: BIA's projects are important economic contributors to the local communities they serve, and they contribute millions of dollars in crop value annually. Unfortunately, the costs associated with operating and maintaining an irrigation project may increase independently of prices and costs that are realized by the irrigators. Historically, BIA tempered irrigation rates to demonstrate sensitivity to the economic impact on water users, but that past practice resulted in a rate deficiency at some irrigation projects. Therefore, funding to operate and maintain these projects needs to come from the water users served by those projects.

BIA's irrigation program has been the subject of serval Office of Inspector General (OIG) and U.S. Government Accountability Office (GAO) audits. In the most recent OIG audit, No. 96–I–641, March 1996, the OIG concluded:

Operation and maintenance revenues were insufficient to maintain the projects, and some projects had deteriorated to the extent that their continued capability to deliver water was in doubt. This occurred because operation and maintenance rates were not based on the full cost of delivering irrigation water, including the costs of systematically rehabilitating and replacing project facilities and equipment, and because project personnel did not seek regular rate increases to cover the full cost of project operation.

A previous OIG audit performed on one of BIA's largest irrigation projects, the Wapato Irrigation Project, No. 95–I–1402, September 1995, reached the same conclusion.

To address the issues noted in these audits, BIA must systematically review and evaluate irrigation assessment rates and adjust them, when necessary, to reflect the full cost to operate and perform all appropriate maintenance on the irrigation project or facility infrastructure to ensure safe and reliable operation. If this review and adjustment is not accomplished, a rate deficiency can accumulate over time. Rate deficiencies force BIA to raise irrigation assessment rates in larger increments over shorter periods than would have been otherwise necessary.

BIA has projected this proposed rate increase for several years, and anticipated increasing the assessment rates in both 2018 and 2019. The Wind River Irrigation Project (WRIP) Operations and Maintenance (O&M) budget was prepared in accordance with BIA financial guidelines. The intent of the increases is for maintenance of a

reserve fund for contingencies or emergencies.

Based on increased costs associated with administering, operating, maintaining, and rehabilitating WRIP, the need for the proposed rate increase is clear and justified for both 2018 and 2019. For those farm units where BIA determines that our irrigation facilities are not capable of delivering adequate irrigation water, an Annual Assessment Waiver can be granted to waive the O&M assessment.

Comment: Commenters state that no rate increases should occur on WRIP. Specifically, some commenters oppose Unit 6's rate increase because the Ray Canal Water Users Association (RCWUA) efficiently operates the project through a cooperative agreement.

Response: As explained in the previous response, BIA can no longer temper irrigation rates. BIA is required to establish irrigation assessment rates that recover the costs to administer, operate, maintain, and rehabilitate our projects. As owner of WRIP, it is BIA's responsibility to ensure adequate resources are made available to meet the requirements noted above. BIA's authority to assess rates dates back to the Act of May 29, 1908, codified at 25 U.S.C. 381 *et seq.,* and is addressed in BIA's regulations at 25 CFR part 171. In accordance with 25 CFR 171.500, upcoming annual costs are to be estimated through a budgeting process that factors in all categories, including maintenance of a reserve fund.

Of the six WRIP rates, BIA does not set the rates for LeClair District or Riverton Valley Irrigation District. Of the remaining four WRIP rates, BIA is raising each Unit's 2017 rate by $1.00 over the course of two years. Rates for three Units (Unit 6, Crow Heart Unit, and A Canal Unit) are increasing by $1.00 in 2018; these three Units' rates will not increase in 2019. The remaining rate for Units 2, 3, and 4 will be raised by $1 over the course of two years: $0.50 increase in 2018 and $.50 increase in 2019. The rate increases will replenish WRIP's reserve fund; as explained below, the reserve fund is for contingencies or emergencies.

Regarding Unit 6 specifically, RCWUA bases its annual budget on the 85% collection rate minus the BIA direct service cost. The BIA direct service cost is $3.50 per acre and based on a cost per acre of direct services BIA provides to Unit 6 (Ray Canal water users), which includes: (1) Administrative functions for two full-time Accounting Technicians; (2) general office per acre cost; (3) 7.5% of the Project Manager's per acre cost; and (4) 8% of the Equipment Operator's per acre cost. With respect to the last item, BIA's Equipment Operators operate and maintain Washakie Dam, which provides water to the Ray Canal Diversion structure. The Equipment Operators also clean trash racks and maintain the diversion structure for Ray Canal. Operation and maintenance of Washakie Dam and the Ray Canal Diversion structure is captured in BIA's direct service cost of $3.50 per acre.

Although RCWUA may be functioning within its budget to provide O&M within Unit 6, BIA must assess rates based on the entire WRIP. BIA must increase the rate to (1) reflect the full cost of operating and performing all maintenance on the irrigation project or facility infrastructure and (2) maintain a reserve fund to cover emergencies, including critical repairs to avoid potential system failures that occurred in 2017. The reserve fund is used as needed for any Unit within WRIP, including Unit 6. Although BIA receives some non-water user funding for irrigation rehabilitation, each irrigation project needs to maintain a reserve fund for emergencies and equipment purchases. The BIA National Irrigation Handbook's Emergency Reserve Fund Guidelines recommends a reserve of 40% of the annual O&M costs, which is calculated by averaging five years of costs. For WRIP, the recommended reserve amount is $310,000. In addition, irrigation projects should maintain a sinking fund to meet future expenditures for replacement of equipment and vehicles. Currently, the reserve fund and sinking fund combined total is $280,000. The WRIP rate increases will bring in just over $28,000 in 2018 and over $36,000 in the following years for replenishment of WRIP's reserve and sinking funds. Thus, BIA views the modest rate increase here to be necessary and reasonable.

Comment: Commenters expressed a position that the repair costs (both past and future) of the washout of the 37C chute project should not be passed on to the RCWUA water users.

Response: Because of flooding that resulted from the melting of the extensive snowpack that occurred in 2017, a major structure was damaged, a main canal was put at risk of failure, and 37C chute was damaged. RCWUA did not incur any of the costs associated with the 37C chute project. BIA has and will continue to use both O&M funds and the WRIP reserve fund for repairs from the flooding. BIA, Eastern Shoshone Tribe, and Northern Arapaho Tribe requested and secured non-water user funding sources (federal and Tribal funds) to supplement the costs associated with the repair of 37C chute project. Reserve funding may also be used for the structure's repair. Accordingly, BIA must increase O&M rates to replenish the reserve fund to prepare for inevitable failures or damage. Without the necessary O&M rate increases, lack of adequate funds could result in the inability of the project to maintain irrigation system components and deliver water.

Comment: Two commenters state an opposition to the proposed rate adjustments because the Project has only had one BIA part-time secretary. Given that a BIA project position has been vacant for years, salaries from vacant positions should offset any proposed increases.

Response: Presently, WRIP is operating with one full-time Accounting Technician and an Acting Irrigation Project Manager. BIA intends to fill two vacant positions: Accounting Technician and Irrigation Project Manager. We believe that these personnel expenditures are reasonable and appropriate, and well within BIA's authority to manage its personnel to assure that its water deliver obligations are satisfied. Any remaining funds will be utilized toward flood damage and deferred maintenance. Thus, water users will see a significant portion of the increase returned to them in form of repairs and increased maintenance.

Comment: One commenter objects to the proposed rate adjustments because BIA fails to renew leases and act on leasing in a timely manner, which leaves a large amount of agricultural land vacant on WRIP.

Response: Leasing functions fall under the Agency Realty Office, while leases on Tribal land require Tribal approval. Upon receipt of leasing information from the Agency Realty Office, BIA's WRIP staff efficiently perform data entry for O&M billing compilation.

Does this notice affect me?

This notice affects you if you own or lease land within the assessable acreage of one of our irrigation projects or if you have a carriage agreement with one of our irrigation projects.

Where can I get information on the regulatory and legal citations in this notice?

You can contact the appropriate office(s) stated in the tables for the irrigation project that serves you, or you can use the internet site for the Government Printing Office at *www.gpo.gov.*

What authorizes you to issue this notice?

Our authority to issue this notice is vested in the Secretary of the Interior (Secretary) by 5 U.S.C. 301 and the Act of August 14, 1914 (38 Stat. 583; 25 U.S.C. 385). The Secretary has in turn delegated this authority to the Assistant Secretary—Indian Affairs under Part 209, Chapter 8.1A, of the Department of the Interior's Departmental Manual.

Whom can I contact for further information?

The following tables are the regional and project/agency contacts for our irrigation facilities.

Project name	Project/agency contacts
Northwest Region Contacts	
Bodie Shaw, Acting Regional Director, Bureau of Indian Affairs, Northwest Regional Office, 911 NE 11th Avenue, Portland, OR 97232–4169, Telephone: (503) 231–6702.	
Flathead Indian Irrigation Project	Pete Plant, Acting Superintendent, Pete Plant, Irrigation Project Manager, P.O. Box 40, Pablo, MT 59855, Telephones: (406) 675–2700 ext. 1300 Superintendent, (406) 745–2661 ext. 2 Project Manager.
Fort Hall Irrigation Project	David Bollinger, Irrigation Project Manager, Building #2 Bannock Ave., Fort Hall, ID 83203–0220, Telephone: (208) 238–6264.
Wapato Irrigation Project	David Shaw, Superintendent, Larry Nelson, Acting Project Administrator, P.O. Box 220, Wapato, WA 98951–0220, Telephones: (509) 865–2421 Superintendent, (509) 877–3155 Acting Project Administrator.
Rocky Mountain Region Contacts	
Susan Messerly, Acting Regional Director, Bureau of Indian Affairs, Rocky Mountain Regional Office, 2021 4th Avenue North, Billings, MT 59101, Telephone: (406) 247–7943.	
Blackfeet Irrigation Project	Thedis Crowe, Superintendent, Greg Tatsey, Irrigation Project Manager, Box 880, Browning, MT 59417, Telephones: (406) 338–7544, Superintendent, (406) 338–7519, Irrigation Project Manager.
Crow Irrigation Project	Michael Addy, Acting Superintendent, Jim Gappa, Acting Irrigation Project Manager, P.O. Box 69, Crow Agency, MT 59022, Telephones: (406) 638–2672, Superintendent, (406) 247–7998, Acting Irrigation Project Manager.
Fort Belknap Irrigation Project	Dave Hopkins, Acting Superintendent, Jim Gappa, Acting Irrigation Project Manager (BIA), (Project operation & maintenance contracted to Tribes), R.R.1, Box 980, Harlem, MT 59526, Telephones: (406) 353–2901, Superintendent, (406) 353–8454, Irrigation Project Manager (Tribal Office).
Fort Peck Irrigation Project	Howard Beemer, Superintendent, Huber Wright, Acting Irrigation Project Manager, P.O. Box 637, Poplar, MT 59255, Telephones: (406) 768–5312, Superintendent, (406) 653–1752, Irrigation Project Manager.
Wind River Irrigation Project	Norma Gourneau, Superintendent, Jim Gappa, Acting Irrigation Project Manager, P.O. Box 158, Fort Washakie, WY 82514, Telephones: (307) 332–7810, Superintendent, (406) 247–7998, Acting Irrigation Project Manager.
Southwest Region Contacts	
John Halliday, Acting Regional Director, Bureau of Indian Affairs, Southwest Regional Office, 1001 Indian School Road, Albuquerque, NM 87104, Telephone: (505) 563–3100.	
Pine River Irrigation Project	Priscilla Bancroft, Superintendent, Vickie Begay, Irrigation Project Manager, P.O. Box 315, Ignacio, CO 81137–0315, Telephones: (970) 563–4511, Superintendent, (970) 563–9484, Irrigation Project Manager.
Western Region Contacts	
Bryan Bowker, Regional Director, Bureau of Indian Affairs, Western Regional Office, 2600 N Central Ave., 4th Floor Mailroom, Phoenix, AZ 85004, Telephone: (602) 379–6600.	
Colorado River Irrigation Project	Kellie Youngbear Superintendent, Gary Colvin, Irrigation Project Manager, 12124 1st Avenue, Parker, AZ 85344, Telephone: (928) 669–7111.
Duck Valley Irrigation Project	Joseph McDade, Superintendent (Project operation & management compacted to Tribes), 2719 Argent Ave., Suite 4, Gateway Plaza, Elko, NV 89801, Telephone: (775) 738–5165, (208) 759–3100, (Tribal Office).
Yuma Project, Indian Unit	Denni Shields, Superintendent, 256 South Second Avenue, Suite D, Yuma, AZ 85364, Telephone: (928) 782–1202.
San Carlos Irrigation Project (Indian Works and Joint Works).	Ferris Begay, Project Manager, Clarence Begay, Irrigation Manager, 13805 N Arizona Boulevard, Coolidge, AZ 85128, Telephone: (520) 723–6225.
Uintah Irrigation Project	Antonio Pingree, Acting Superintendent, Ken Asay, Irrigation System Manager, P.O. Box 130, Fort Duchesne, UT 84026, Telephone: (435) 722–4300, (435) 722–4344.
Walker River Irrigation Project	Robert Eben, Superintendent, 311 E Washington Street, Carson City, NV 89701, Telephone: (775) 887–3500.

What irrigation assessments or charges are adjusted by this notice?

The rate table below contains the final rates for the 2018 and 2019 calendar years for all irrigation projects where we recover costs of administering, operating, maintaining, and rehabilitating them. An asterisk immediately following the rate category notes the irrigation projects where 2018 rates are different from the 2019 rates.

Project name	Rate category	Final 2017 rate	Final 2018 rate	Final 2019 rate
Northwest Region Rate Table				
Flathead Indian Irrigation Project (See Note #1).	Basic-per acre—A*	$26.00	$29.00	$33.50
	Basic-per acre—B*	13.00	14.50	16.75
	Minimum Charge per tract	75.00	75.00	75.00
Fort Hall Irrigation Project	Basic per acre*	54.00	56.00	58.00
	Minimum Charge per tract*	38.50	39.00	40.00
Fort Hall Irrigation Project—Minor Units	Basic per acre*	32.50	35.00	36.50
	Minimum Charge per tract*	38.50	39.00	40.00
Fort Hall Irrigation Project—Michaud	Basic per acre*	57.50	59.50	62.00
	Pressure per acre*	88.50	92.50	98.00
	Minimum Charge per tract*	38.50	39.00	40.00
Wapato Irrigation Project—Toppenish/Simcoe Units.	Minimum Charge per bill	25.00	25.00	25.00
	Basic per acre	25.00	25.00	25.00
Wapato Irrigation Project—Ahtanum Units	Minimum Charge per bill	30.00	30.00	30.00
	Basic per acre	30.00	30.00	30.00
Wapato Irrigation Project—Satus Unit	Minimum Charge per bill	79.00	79.00	79.00
	"A" Basic per acre	79.00	79.00	79.00
	"B" Basic per acre	85.00	85.00	85.00
Wapato Irrigation Project—Additional Works	Minimum Charge per bill	78.00	80.00	80.00
	Basic per acre	78.00	80.00	80.00
Wapato Irrigation Project—Water Rental	Minimum Charge	86.00	86.00	86.00
	Basic per acre	86.00	86.00	86.00
Rocky Mountain Region Rate Table				
Blackfeet Irrigation Project	Basic-per acre	20.00	20.00	20.00
Crow Irrigation Project—Willow Creek O&M (includes Agency, Lodge Grass #1, Lodge Grass #2, Reno, Upper Little Horn, and Forty Mile Units).	Basic-per acre	28.00	28.00	28.00
Crow Irrigation Project—All Others (includes Bighorn, Soap Creek, and Pryor Units).	Basic-per acre	28.00	28.00	28.00
Crow Irrigation Project—Two Leggins Unit	Basic-per acre	14.00	14.00	14.00
Crow Irrigation Two Leggins Drainage District	Basic-per acre	2.00	2.00	2.00
Fort Belknap Irrigation Project	Basic-per acre	16.00	16.00	16.00
Fort Peck Irrigation Project	Basic-per acre*	26.50	26.50	27.00
Wind River Irrigation Project—Units 2, 3 and 4.	Basic-per acre*	23.50	24.00	24.50
Wind River Irrigation Project—Unit 6	Basic-per acre	21.00	22.00	22.00
Wind River Irrigation Project—LeClair District (see Note #2).	Basic-per acre	47.00	47.00	47.00
Wind River Irrigation Project—Crow Heart Unit.	Basic-per acre	15.50	16.50	16.50
Wind River Irrigation Project—A Canal Unit	Basic-per acre	15.50	16.50	16.50
Wind River Irrigation Project—Riverton Valley Irrigation District (see Note #2).	Basic-per acre	30.65	30.65	30.65
Southwest Region Rate Table				
Pine River Irrigation Project	Minimum Charge per tract	50.00	50.00	50.00
	Basic-per acre*	19.00	20.00	21.00
Western Region Rate Table				
Colorado River Irrigation Project	Basic per acre up to 5.75 acre-feet	54.00	54.00	54.00
	Excess Water per acre-foot over 5.75 acre-feet.	17.000	17.00	17.00
Duck Valley Irrigation Project (See Note #3)	Basic per acre	5.30	5.30	(+)
Yuma Project, Indian Unit (See Note #4)	Basic per acre up to 5.0 acre-feet	118.50	147.00	(+)
	Excess Water per acre-foot over 5.0 acre-feet.	27.50	30.00	(+)
	Basic per acre up to 5.0 acre-feet (Ranch 5)	118.50	147.00	(+)

San Carlos Irrigation Project (Joint Works) (See Note #5).	Basic per acre*	25.00	27.90	31.25
	Final 2017, 2018, 2019 Construction Water Rate Schedule:			
		Off project construction	On project construction—gravity water	On project construction—pump water
	Administrative Fee	300.00	300.00	300.00.
	Usage Fee	250.00 per month.	No Fee	100.00 per acre foot.
	Excess Water Rate†	5.00 per 1,000 gal.	No Charge	No Charge.

Project name	Rate category	Final 2017 rate	Final 2018 rate	Final 2019 rate
San Carlos Irrigation Project (Indian Works) (See Note #6).	Basic per acre*	$81.00	$87.60	$95.40
Uintah Irrigation Project	Basic per acre*	18.00	20.00	21.00
	Minimum Bill	25.00	25.00	25.00
Walker River Irrigation Project	Basic per acre	31.00	31.00	31.00

+ These rates have not yet been determined; BIA will publish a separate notice for these rates at a later date.
† The excess water rate applies to all water used in excess of 50,000 gallons in any one month.
* Notes irrigation projects where 2018 rates are different from 2019 rates.
Note #1: Federal Register Notice on January 18, 2018 (83 FR 2665), finalized the 2018 rate for the Flathead Indian Irrigation Project.
Note #2: These O&M rates may vary yearly based upon the budget submitted by the LeClair District and the Riverton Valley Irrigation District.
Note #3: The annual O&M rate is established by the Shoshone-Paiute Tribes who perform O&M under a self-governance compact.
Note #4: The O&M rate for the Yuma Project, Indian Unit has two components. The first component of the O&M rate is established by the Bureau of Reclamation (BOR), the owner and operator of the Project. BOR's rate, which is based upon the annual budget submitted by BOR, is 143.50 for 2018; and has not been established for 2019. The second component of the O&M rate is established by BIA to cover administrative costs, which includes billing and collections for the Project. The 2018 and 2019 BIA rate component is 3.50/acre.
Note #5: Federal Register Notice on August 11, 2017 (82 FR 37608), established the final 2018 rate for the San Carlos Irrigation Project. The construction water rate schedule identifies the fees assessed for use of irrigation water for non-irrigation purposes.
Note #6: The 2018 and 2019 O&M rates for the San Carlos Irrigation Project—Indian Works has three components. The first component is the O&M rate established by the San Carlos Irrigation Project—Indian Works, the owner and operator of the Project; this rate is 50.00 per acre each year. The second component is for the O&M rate established by the San Carlos Irrigation Project—Joint Works and is determined to be 27.90 per acre for 2018 and 31.25 per acre for 2019. The third component is the O&M rate established by the San Carlos Irrigation Project Joint Control Board and is 9.70 per acre for 2018 and 14.15 per acre for 2019.

Consultation and Coordination With Tribal Governments (Executive Order 13175)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this notice under the Department's consultation policy and under the criteria of Executive Order 13175 and have determined there to be substantial direct effects on federally recognized Tribes because the irrigation projects are located on or associated with Indian reservations. To fulfill its consultation responsibility to Tribes and Tribal organizations, BIA communicates, coordinates, and consults on a continuing basis with these entities on issues of water delivery, water availability, and costs of administration, operation, maintenance, and rehabilitation of projects that concern them. This is accomplished at the individual irrigation project by project, agency, and regional representatives, as appropriate, in accordance with local protocol and procedures. This notice is one component of our overall coordination and consultation process to provide notice to, and request comments from, these entities when we adjust irrigation assessment rates.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (Executive Order 13211)

The rate adjustments are not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Regulatory Planning and Review (Executive Order 12866)

These rate adjustments are not a significant regulatory action and do not need to be reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

These rate adjustments are not a rule for the purposes of the Regulatory Flexibility Act because they establish ''a rule of particular applicability relating to rates.'' 5 U.S.C. 601(2).

Unfunded Mandates Reform Act of 1995

These rate adjustments do not impose an unfunded mandate on state, local, or Tribal governments in the aggregate, or on the private sector, of more than $130 million per year. They do not have a significant or unique effect on state, local, or Tribal governments or the private sector. Therefore, the Department is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Takings (Executive Order 12630)

These rate adjustments do not effect a taking of private property or otherwise have ''takings'' implications under Executive Order 12630. The rate adjustments do not deprive the public, state, or local governments of rights or property.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, these rate adjustments do not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement because they will not affect the States, the relationship

between the national government and the States, or the distribution of power and responsibilities among various levels of government. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This notice complies with the requirements of Executive Order 12988. Specifically, in issuing this notice, the Department has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct as required by section 3 of Executive Order 12988.

Paperwork Reduction Act of 1995

These rate adjustments do not affect the collections of information which have been approved by the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), under the Paperwork Reduction Act of 1995. The OMB Control Number is 1076–0141 and expires June 30, 2019.

National Environmental Policy Act

The Department has determined that these rate adjustments do not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required under the National Environmental Policy Act of 1969, 42 U.S.C. 4321–4370(d), pursuant to 43 CFR 46.210(i). In addition, the rate adjustments do not present any of the 12 extraordinary circumstances listed at 43 CFR 46.215.

Data Quality Act

In developing this notice, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

Dated: August 13, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–17724 Filed 8–16–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X 1109AF LLUT930000 L16100000.DS0000.LXSSJ0640000]

Notice of Availability of the Grand Staircase-Escalante National Monument-Grand Staircase, Kaiparowits, and Escalante Canyon Units and Federal Lands Previously Included in the Monument That Are Excluded From the Boundaries Draft Resource Management Plans and Associated Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Grand Staircase-Escalante National Monument (GSENM) and Kanab Field Office (KFO) have prepared Draft Resource Management Plans (RMPs) and a Draft Environmental Impact Statement (EIS) for the GSENM Grand Staircase, Kaiparowits, and Escalante Canyons Units and Federal lands excluded from the Monument by Proclamation 9682 and by this notice are announcing the opening of the public comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft RMPs/Draft EIS within 90 days of the date the Environmental Protection Agency publishes its Notice of Availability of the Draft RMPs/Draft EIS in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases and/or mailings.

ADDRESSES: You may submit comments on the Draft RMPs/Draft EIS by either of the following methods:

- *Website: https://goo.gl/EHvhbc*
- *Mail:* 669 S Hwy. 89A, Kanab, UT 84741, Attn: Matt Betenson

Copies of the Draft RMPs/Draft EIS are available at the following locations:

- Bureau of Land Management, Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah
- Escalante Interagency Visitor Center, 755 West Main, Escalante, Utah
- Kanab Field Office, 669 South Highway 89A, Kanab, Utah

The Draft RMPs/Draft EIS and accompanying background documents are available on the ePlanning website at: *https://goo.gl/EHvhbc.*

FOR FURTHER INFORMATION CONTACT: Matt Betenson, Associate Monument Manager, telephone (435) 644–1200; address 669 S Hwy. 89A, Kanab, UT 84741; email *BLM_UT_CCD_monuments@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question for the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: On December 4, 2017, President Donald Trump signed Presidential Proclamation 9682 modifying the boundaries of the GSENM as established by Proclamation 6920 to exclude from designation and reservation approximately 861,974 acres of land. Lands that remain part of the GSENM are included in three units, known as the Grand Staircase, Kaiparowits, and Escalante Canyons Units and are reserved for the care and management of the objects of historic and scientific interest described in Proclamation 6920, as modified by Proclamation 9682. Lands that are excluded from the Monument boundaries are now referred to as the Kanab-Escalante Planning Area (KEPA) and are managed in accordance with the BLM's multiple-use mandate.

The planning area is located in Kane and Garfield Counties, Utah, and encompasses approximately 1.86 million acres of public land. For the GSENM Grand Staircase, Kaiparowits, and Escalante Canyons Units, this planning effort, is needed to identify goals, objectives, and management actions necessary for the conservation, protection, restoration, or enhancement of the resources, objects, and values identified in Proclamation 6920, as modified by Proclamation 9682. For lands excluded from the monument, this planning effort is needed to determine to identify goals, objectives, and management actions necessary to ensure that public lands and their various resource values are utilized in the combination that will best meet the present and future needs of the American people.

The entire planning area is currently managed by the BLM and under the Grand Staircase-Escalante National Monument Management Plan (BLM 1999), as amended. This planning effort would replace the existing Monument Management Plan with four new RMPs.

Within the Draft EIS, the BLM is also considering alternatives related to livestock Grazing on 318,000 acres of land within the Glen Canyon National Recreation Area, 65,500 acres in the Kanab Field Office and 2,300 acres in the Arizona Strip Field Office. The EIS includes information regarding the environmental consequences of implementing various livestock grazing management actions on resources in these areas. At the completion of this planning process, the National Park Service, who is cooperating with the BLM on preparation of the NEPA analysis, may adopt the EIS and prepare a separate decision related to livestock grazing for lands under NPS authority.

The BLM reviewed public scoping comments to identify planning issues that directed the formulation of alternatives and framed the scope of analysis in the Draft RMPs/Draft EIS. Issues identified include management of recreation and access; paleontological and cultural resources; livestock grazing; mineral resources; and wildlife, water, vegetation, and soil resources. This planning effort also considers management of lands with wilderness characteristics and designation of Areas of Critical Environmental Concern (ACECs).

The Draft RMPs/Draft EIS evaluate four alternatives in detail. Alternative A is the No Action alternative, which is a continuation of existing decisions in the Monument Management Plan. Alternative B generally focuses on protection of resources (*e.g.,* wildlife, vegetation, cultural, etc.) while providing for targeted resource use (*e.g.,* rights-of-way, travel, mineral development). Alternative C generally represents a balance of resource protection and resource use. Alternative D generally focuses on maximizing resource use (*e.g.,* rights-of-way, minerals development, livestock grazing) while still providing for resource protection as required by applicable regulations, laws, policies, plans, and guidance, including protection of Monument objects within the GSENM Units. The BLM has identified Alternative D as the preferred alternative for purposes of public comment and review. Identification of this alternative, however, does not represent final agency direction, and the Proposed RMPs/Final EIS may include management actions described in the other analyzed alternatives.

Pursuant to 43 CFR 1610.7–2(b), the BLM is required to publish a notice in the **Federal Register** listing each ACEC proposed and specifying the resource use limitations which would occur if the ACEC were formally designated. This notice announces a concurrent public comment period for potential ACECs. There are no ACECs under Alternative A. There are 14 potential ACECs under Alternative B (totaling 308,044 acres), 5 potential ACECs under Alternative C (totaling 130,997 acres), and no potential ACECs under Alternative D. Pertinent information regarding ACECs, including proposed designation acreage and resource use limitations are included below:

Potential ACEC	Alternative B (acres)	Alternative C (acres)	Relevant and important values	Resource use limitations
Alvey Wash	30,460	Not Designated	Historic and Cultural Values.	• Prohibit exclusive commercial mineral material sites. • Prohibit community mineral material pits larger than five acres in size. • Surface facilities incident to underground mining would be required to avoid known and document archaeological sites. • Stipulations would be necessary to mitigate adverse effects of subsidence. • NSO for fluid mineral leasing. • No rock climbing allowed within 100 meters of archaeological structures. • No casual use collection of fossils or other paleontological materials. • Require inventories of all paleontological resources prior to surface disturbing activities to document significant invertebrate and paleobotanical fossil sites, not just vertebrates.
Bulldog Bench	361	Not Designated	Historic and Cultural Values.	• No casual use collection of fossils or other paleontological materials. • Require inventories of all paleontological resources prior to surface disturbing activities to document significant invertebrate and paleobotanical fossil sites, not just vertebrates.
Butler Valley	15,899	Not Designated	Scenic and Natural Process or System.	• Manage as VRM Class II. • No collection of BLM or State sensitive plants without a research permit. • Prohibit vegetation treatments that are likely to harm, or will not benefit, special status species plants in known suitable habitat.
Circle Cliffs	26,706	26,706	Historic and Cultural, Scenic, and Fish and Wildlife Resources.	• Prohibit exclusive commercial mineral material sites. • Prohibit community mineral material pits larger than five acres in size. • NSO for fluid mineral leasing. • No Casual Collection of petrified Wood. • Avoid surface disturbance and placement of facilities near concentrations of petrified wood or in situ logs.
Cockscomb East	42,182	32,683	Fish and Wildlife Resources, Natural Process or Systems, Scenic, and Historic and Cultural Value.	• No collection of BLM or State sensitive plants without a research permit. • Prohibit vegetation treatments that are likely to harm, or will not benefit, special status species plants in known suitable habitat. • Manage as VRM Class II. • No casual use collection of fossils or other paleontological materials. • Require inventories of all paleontological resources prior to surface disturbing activities to document significant invertebrate and paleobotanical fossil sites, not just vertebrates. • Do not designate new OHV routes. OHV use limited to designated routes.

Potential ACEC	Alternative B (acres)	Alternative C (acres)	Relevant and important values	Resource use limitations
Cockscomb West	40,476	40,476	Natural Process or Systems, Scenic, and Historic and Cultural Values.	• Prohibit exclusive commercial mineral material sites. • Prohibit community mineral material pits larger than five acres in size. • NSO for fluid mineral leasing (Alternative B). • CSU for fluid mineral leasing (Alternative C). • Avoid vegetation treatments that disturb soils in previously untreated areas that are either Semidesert Shallow Loam (Pinyon-Juniper) or Semidesert Shallow Gypsum (Mormontea) Ecological Sites; Limit method to hand-thinning (lop and scatter). • No collection of BLM or State sensitive plants without a research permit. • Manage as VRM Class II.
Collet Top	9,218	Not Designated	Historic and Cultural Values, Scenic, and Natural Process or Systems.	• Prohibit exclusive commercial mineral material sites. • Prohibit community mineral material pits larger than five acres in size. • NSO for fluid mineral leasing. • Surface facilities incident to underground mining would be required to avoid known and document archaeological sites. • Stipulations would be necessary to mitigate adverse effects of subsidence. • No rock climbing allowed within 100 meters of archaeological structures. • Manage as VRM Class II. • No collection of BLM or State sensitive plants without a research permit.
Henderson/Pardner	12,259	Not Designated	Scenic and Historic and Cultural Values.	• Manage as VRM Class II. • No casual use collection of fossils or other paleontological materials. • Require inventories of all paleontological resources prior to surface disturbing activities to document significant invertebrate and paleobotanical fossil sites, not just vertebrates.
Hole in the Rock Trail	61,064	Not Designated	Historic and Cultural Values and Natural Process or System.	• Manage all areas outside WSAs VRM Class II. • Prohibit exclusive commercial mineral material sites. • Prohibit community mineral material pits larger than 5 acres in size. • NSO for fluid mineral leasing. • No collection of BLM or State sensitive plants without a research permit.
Paria River	180	Not Designated	Scenic, Historic and Cultural Values, Fish Wildlife, Natural Process or System.	• Manage all areas outside WSAs VRM Class II. • Closed or limited to designated routes.
Scorpion Flat/Dry Fork	30,691	Not Designated	Scenic	• Manage all areas outside WSAs VRM Class II.
Straight Cliffs/Fifty Mile Bench.	21,357	12,270	Scenic and Historical and Cultural Values.	• Prohibit exclusive commercial mineral material sites. • Prohibit community mineral material pits larger than five acres in size. • NSO for fluid mineral leasing (Alternative B). • CSU for fluid mineral leasing (Alternative C). • Surface facilities incident to underground mining would be required to avoid known and document archaeological sites. • Stipulations would be necessary to mitigate adverse effects of subsidence. • No rock climbing allowed within 100 meters of archaeological structures. • Manage as VRM Class II.
Tibbet Head	19,079	19,079	Historical and Cultural Values and Natural process or System.	• No collection of BLM or State sensitive plants without a research permit. No casual use collection of fossils or other paleontological materials. • Require inventories of all paleontological resources prior to surface disturbing activities to document significant invertebrate and paleobotanical fossil sites, not just vertebrates.
Wahweap Hoodoos	130	Not Designated	Natural Systems or Process.	• Recommend withdrawing from mineral entry. • No rock climbing or rappelling within 100 meters of any hoodoo formation.

The application of the Federal coal unsuitability criteria to portions of the Southern Kaiparowits in the lands excluded from the monument is included in the Draft RMP/Draft EIS. As required by 43 CFR 3461.2–1(a)(2), the public is invited to comment on the results of the application of the criteria and the process used to derive these results.

BLM Utah is soliciting comments on the entire Draft RMPs/Draft EIS. Please note that public comments and information submitted including names, street addresses, and email addresses of persons who submit comments will be available for public review and disclosure at addresses provided in the **ADDRESSES** section of this notice during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may request to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10 and 43 CFR 1610.2.

Edwin L. Roberson,

State Director.

[FR Doc. 2018–17751 Filed 8–16–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X 1109AF LLUT930000 L16100000.DS0000.LXSSJ0650000]

Notice of Availability of the Draft Bears Ears National Monument Indian Creek and Shash Jáa Units Monument Management Plans and Associated Environmental Impact Statement, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Canyon Country District Office, in coordination with the United States Forest Service (USFS), Manti-La Sal National Forest, has prepared Draft Monument Management Plans (MMPs) and an Environmental Impact Statement (EIS) for the Bears Ears National Monument (BENM) Indian Creek and Shash Jáa Units. By this Notice, the BLM is announcing the opening of the public comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the BENM Draft MMPs/Draft EIS within 90 days of the date the Environmental Protection Agency publishes its Notice of Availability of the BENM Draft MMPs/Draft EIS in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases and/or mailings.

ADDRESSES: You may submit comments on the BENM Draft MMPs/EIS by either of these methods:

- *Email: blm_ut_monticello_monuments@blm.gov*
- *Mail:* BLM, Canyon Country District Office, 82 East Dogwood, Moab, Utah 84532, Attn: Lance Porter

Copies of the BENM Draft MMPs/Draft EIS are available at the following locations:

- Bureau of Land Management, Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah
- Bureau of Land Management, Monticello Field Office, 365 North Main, Monticello, Utah
- Bureau of Land Management, Canyon Country District Office, 82 E Dogwood, Moab, Utah
- Manti-La-Sal National Forest, 559 West Price River Drive, Price, Utah

The BENM Draft MMPs/Draft EIS and accompanying background documents are available on the ePlanning website at: *https://goo.gl/uLrEae.*

FOR FURTHER INFORMATION CONTACT: Lance Porter, District Manager, BLM Canyon Country District Office, 82 East Dogwood, Moab, UT 84532, telephone 435–259–2100 or email *l50porte@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question for the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: On December 4, 2017, President Donald Trump signed Proclamation 9681 modifying the Bears Ears National Monument designated by Proclamation 9558 to exclude from its designation and reservation approximately 1,150,860 acres of land. The revised BENM boundary includes two units—Shash Jáa and Indian Creek Units—that are reserved for the care and management of the objects of historic and scientific interest within their boundaries. The planning area is located entirely in San Juan County, Utah and encompasses 169,289 acres of BLM-managed lands and 32,587 acres of National Forest System Lands. All of the National Forest System Lands are within the Shash Jáa Unit.

The BLM is the lead agency for the preparation of the EIS, and the Forest Service is participating as a cooperating agency.

This planning effort is needed to identify goals, objectives, and management actions necessary for the conservation, protection, restoration, or enhancement of the resources, objects, and values identified in Proclamation 9558, as modified by Proclamation 9681. The BENM is jointly managed by the BLM and USFS under the Monticello Resource Management Plan (BLM 2008), as amended, and the Manti La-Sal Land and Resource Management Plan (LRMP), as amended (USFS 1986). The MMPs would replace the existing Monticello RMP for the BLM-administered lands within the BENM, and would amend the existing Manti La-Sal LRMP for USFS-administered lands within the BENM.

Each agency will continue to manage their lands within the monument pursuant to their respective applicable legal authorities. The responsible official for the BLM is the Utah State Director; the responsible official for the USFS is the Manti-La Sal Forest Supervisor. The USFS intends to use the BLM's EIS to make its decision for the part of the Shash Jáa Unit MMP it administers. The USFS will use the BLM's administrative review procedures, as provided by the USFS 2012 Planning Rule, at 36 CFR 219.59(b).

The BLM and USFS have reviewed public scoping comments to identify planning issues that directed the formulation of alternatives and framed the scope of analysis in the Draft MMPs/Draft EIS. Issues identified include management of cultural resources, including protection of American Indian sacred sites, traditional cultural properties, and access by members of Indian tribes for traditional cultural and customary uses; recreation and access; livestock grazing; and wildlife, water, vegetation, and soil resources. This planning effort also considers management of lands with wilderness characteristics.

The Draft MMPs/Draft EIS evaluate four alternatives in detail. Alternative A is the No Action alternative, which is a continuation of existing decisions in the Monticello RMP and in the Manti-La Sal Forest Plan, to the extent that those decisions are compatible with the proclamations. Alternative B emphasizes resource protection and conservation. It is the alternative which imposes the greatest restrictions on recreation and other uses. The BLM and USFS would take a more active management approach to ensure that objects and values are conserved, protected and restored. Alternative C represents a balance among levels of restriction on recreation and other uses and emphasizes adaptive management to protect the long-term sustainability of Monument objects and values while providing for other multiple uses. Alternative D is the alternative with the least restrictive management prescriptions and utilizes a more passive management strategy, with the aim of minimizing the number of changes in the BENM. The agencies would focus on management actions that preserve objects and values but do not alter the existing character of the landscape or limit future agency discretion.

The BLM and USFS have identified Alternative D as the preferred

alternative for purposes of public comment and review. Identification of this alternative, however, does not represent final agency direction, and the Proposed MMPs/Final EIS may include management actions described in the other analyzed alternatives.

BLM Utah and the USFS are soliciting comments on the entire Draft MMPs/Draft EIS. Please note that public comments and information submitted including names, street addresses, and email addresses of persons who submit comments will be available for public review and disclosure at addresses provided in the **ADDRESSES** section of this notice during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may request to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, and 36 CFR 219.59.

Edwin L. Roberson,

State Director.

[FR Doc. 2018–17750 Filed 8–16–18; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed extension for the collection of the ''BLS Data Sharing Program.'' A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before October 16, 2018.

ADDRESSES: Send comments to Erin Good, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE, Washington, DC 20212. Written comments may be transmitted by fax to 202–691–5111. (This is not a toll free number.)

FOR FURTHER INFORMATION CONTACT: Erin Good, BLS Clearance Officer, 202–691–7763. (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

An important aspect of the mission of the BLS is to disseminate to the public the maximum amount of information possible. Not all data are publicly available because of the importance of maintaining the confidentiality of BLS data. However, the BLS has opportunities available on a limited basis for eligible researchers to access confidential data for purposes of conducting valid statistical analyses that further the mission of the BLS as permitted in the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA). The BLS makes confidential data available to eligible researchers through three major programs:

1. The Census of Fatal Occupational Injuries (CFOI), as part of the BLS occupational safety and health statistics program, compiles a count of all fatal work injuries occurring in the U.S. in each calendar year. Multiple sources are used in order to provide as complete and accurate information concerning workplace fatalities as possible. A research file containing CFOI data is made available offsite to eligible researchers.

2. The National Longitudinal Surveys of Youth (NLSY) is designed to document the transition from school to work and into adulthood. The NLSY collects extensive information about youths' labor market behavior and educational experiences over time. The NLSY includes three different cohorts: The National Longitudinal Survey of Youth 1979 (NLSY79), the NLSY79 Young Adult Survey, and the National Longitudinal Survey of Youth 1997 (NLSY97). NLSY data beyond the public use data are made available in greater detail through an offsite program to eligible researchers.

3. Additionally, the BLS makes available data from several employment, compensation, prices, and working conditions surveys to eligible researchers for onsite use. Eligible visiting researchers can access these data in researcher rooms at the BLS national office in Washington, DC or at a Federal Statistical Research Data Center (FSRDC).

II. Current Action

Office of Management and Budget clearance is being sought for the BLS Data Sharing Program. In order to provide access to confidential data, the BLS must determine that the researcher's project will be exclusively statistical in nature and that the researcher is eligible based on guidelines set out in CIPSEA, the Office of Management and Budget (OMB) implementation guidance on CIPSEA, and BLS policy. This information collection provides the vehicle through which the BLS will obtain the necessary details to ensure all researchers and projects comply with appropriate laws and policies.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Type of Review: Revision.

Agency: Bureau of Labor Statistics.

Title: BLS Data Sharing Program.

OMB Number: 1220–0180.

Affected Public: Individuals.

Form	Total respondents	Frequency	Total responses	Average time per response (minutes)	Estimated total burden hours
CFOI Application	5	On occasion	5	35	2.9
NLSY Application	126	On occasion	126	30	63
Visiting Researcher Application	30	On occasion	30	30	15
Totals	161		161		80.9

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, on August 10, 2018.

Eric Molina,

Acting Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2018–17718 Filed 8–16–18; 8:45 am]

BILLING CODE 4510–24–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of August 20, 27, September 3, 10, 17, 24, 2018.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of August 20, 2018

There are no meetings scheduled for the week of August 20, 2018.

Week of August 27, 2018—Tentative

There are no meetings scheduled for the week of August 27, 2018.

Week of September 3, 2018—Tentative

There are no meetings scheduled for the week of September 3, 2018.

Week of September 10, 2018—Tentative

Monday, September 10, 2018

10:00 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

Week of September 17, 2018—Tentative

There are no meetings scheduled for the week of September 17, 2018.

Week of September 24, 2018—Tentative

Thursday, September 27, 2018

10:00 a.m. Strategic Programmatic Overview of the Operating Reactors Business Line (Public)

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* Braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or you may email *Patricia.Jimenez@nrc.gov* or *Wendy.Moore@nrc.gov.*

Dated: August 15, 2018.

Glenn Ellmers,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2018–17879 Filed 8–15–18; 11:15 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Partitions of Eligible Multiemployer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Partitions of Eligible Multiemployer Plans. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before October 16, 2018.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email:* paperwork.comments@pbgc.gov.
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to OMB control number 1212–0068. All comments received will be posted without change to PBGC's website, *http://www.pbgc.gov,* including any personal information provided.

Copies of the collections of information may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, or calling 202–326–4040 during normal business hours. TTY users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4040. PBGC's regulations on

multiemployer plans may be accessed on PBGC's website at *http://www.pbgc.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026; 202–326–4400, extension 6563. (TTY users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4400, extension 6563.)

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Partitions of Eligible Multiemployer Plans (29 CFR part 4233) (OMB control number 1212–0068; expires December 31, 2018). This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

Sections 4233(a) and (b) of the Employee Retirement Income Security Act of 1974 (ERISA) allow a plan sponsor of a multiemployer plan to apply to PBGC for a partition of the plan and state the criteria that PBGC uses to determine a plan's eligibility for a partition.

PBGC's regulation on Partitions of Eligible Multiemployer Plans (29 CFR part 4233) sets forth the procedures for applying for a partition, the information required to be included in a partition application, and notices to interested parties of the application.

PBGC needs the information to determine whether a plan is eligible for partition and whether a proposed partition would comply with the statutory conditions required before PGBC may order a partition.

The collection of information under the regulation has been approved by OMB control number 1212–0068 (expires December 31, 2018). PBGC intends to request that OMB extend its approval for another three years. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC estimates that there will be six applications for partition each year for which plan sponsors submit applications under this regulation. The total estimated annual burden of the collection of information is 78 hours and $239,400.

PBGC is soliciting public comments to—

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2018–17749 Filed 8–16–18; 8:45 am]

BILLING CODE 7709–02–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2017–232; CP2017–241; CP2017–243; CP2017–244; CP2017–247; CP2017–251; CP2017–257]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 21, 2018 and August 22, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2017–232; *Filing Title:* Notice of the United States Postal Service of Filing Modification Three to a Global Plus 1D Negotiated Service Agreement; *Filing Acceptance Date:* August 13, 2018; *Filing Authority:* 39

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* August 21, 2018.

2. *Docket No(s).:* CP2017–241; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Plus 1D Negotiated Service Agreement; *Filing Acceptance Date:* August 13, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 21, 2018.

3. *Docket No(s).:* CP2017–243; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Plus 1D Negotiated Service Agreement; *Filing Acceptance Date:* August 13, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 21, 2018.

4. *Docket No(s).:* CP2017–244; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Plus 1D Negotiated Service Agreement; *Filing Acceptance Date:* August 13, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 21, 2018.

5. *Docket No(s).:* CP2017–247; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Plus 1D Negotiated Service Agreement; *Filing Acceptance Date:* August 13, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Lyudmila Y. Bzhilyanskaya; *Comments Due:* August 21, 2018.

6. *Docket No(s).:* CP2017–251; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Plus 1D Negotiated Service Agreement; *Filing Acceptance Date:* August 13, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* August 22, 2018.

7. *Docket No(s).:* CP2017–257; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Plus 1D Negotiated Service Agreement; *Filing Acceptance Date:* August 13, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Lyudmila Y. Bzhilyanskaya; *Comments Due:* August 22, 2018.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–17791 Filed 8–16–18; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83834; File No. SR–NASDAQ–2018–067]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete and Replace the Current Rules on Arbitration

August 13, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 9, 2018, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete the current rules on arbitration (''Current Arbitration Rules''), currently under the 10000 Series (Rules 10001 through 10102), and adopt the Nasdaq ISE, LLC (''ISE'') rules on arbitration in Chapter 18 of the ISE's rulebook (''Proposed Arbitration Rules'') into General 6 in the Exchange's rulebook's (''Rulebook'') shell structure.[3]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to delete the rules on arbitration, currently under the 10000 Series (Rules 10001 through 10102), and adopt the ISE rules on arbitration in Chapter 18 of the ISE's rulebook into General 6 in the Exchange's Rulebook.

The Exchange adopted the Current Arbitration Rules to ensure a fair and efficient manner in which to handle any dispute, claim or controversy arising out of, or in connection with, the business of any Member of the Exchange. To help administer the process of dispute resolution, the Exchange and FINRA are parties to a Regulatory Contract, pursuant to which FINRA has agreed to perform certain functions and provide access to certain services, including: member regulation and registration; non-real time market surveillance; examinations and investigations; and dispute resolution. FINRA currently operates the largest securities dispute resolution forum in the United States,[4] and has given the Exchange access to these services. Under the Current Arbitration Rules, Members and associated persons of a Member are subject to the FINRA Code of Arbitration Procedure.

Because the Affiliated Exchanges are also parties to similar Regulatory Contracts with FINRA that make their members and associated persons of such members subject to the FINRA Code of Arbitration Procedure, the Exchange believes it is pertinent that a common set of rules on arbitration be included in the General section of the Rulebook's shell. These rules will, pursuant to subsequent filings, then replace the existing arbitration rules for each of the Affiliated Exchanges.

As part of the process of harmonizing these rules, staff evaluated the corresponding rules on arbitration at each of the Affiliated Exchanges. Staff have determined that the Proposed Arbitration Rules are the easiest to read and the most accessible, and do not

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Recently, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, Nasdaq BX, Inc.; Nasdaq PHLX LLC; Nasdaq ISE, LLC; Nasdaq GEMX, LLC; and Nasdaq MRX, LLC (''Affiliated Exchanges''). The shell structure currently contains eight (8) Chapters which, once complete, will apply a common set of rules to the Affiliated Exchanges. *See* Securities Exchange Act Release No. 82175 (November 29, 2017), 82 FR 57494 (December 5, 2017) (SR–NASDAQ–2017–125).

[4] *http://www.finra.org/arbitration-and-mediation.*

detract from, or omit, any of the substance of the Current Arbitration Rules.

Therefore, the Exchange will adopt the Proposed Arbitration Rules and place them under the ''General 6 Arbitration'' of the shell's ''General Equity and Options Rules'' section. As mentioned, these rules are already in place on ISE, and also apply to Nasdaq GEMX, LLC and Nasdaq MRX, LLC, which incorporate Chapter 18 of the ISE Rules by reference. Subsequently, the other Affiliated Exchanges plan to adopt these rules also.

The relocation and harmonization of the arbitration rules is part of the Exchange's continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges.[5] The Exchange believes that the adoption and placement of the Proposed Arbitration Rules to their new location in the shell will facilitate the use of the Rulebook by Members [6] of the Exchange who are members of other Affiliated Exchanges. Moreover, the proposed changes are of a conforming nature and will not amend the substance of the adopted rules other than to update the language to that of the Proposed Arbitration Rules, and to make conforming cross-reference changes.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by promoting efficiency and conformity of the Exchange's processes with those of the Affiliated Exchanges and to make the Exchange's Rulebook easier to read and more accessible to its Members. The Exchange believes that the adoption and harmonization of the arbitration rules and cross-reference updates are of a non-substantive nature.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose a burden on competition because, as previously stated, they are (i) of a non-substantive nature, (ii) intended to harmonize the Exchange's rules with those of its Affiliated Exchanges, and (iii) intended to organize the Rulebook in a way that it will ease the Members' navigation and reading of the rules across the Affiliated Exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [9] and subparagraph (f)(6) of Rule 19b–4 thereunder.[10]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2018–067 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2018–067. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet wedbsite (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2018–067 and should be submitted on or before September 7, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2018–17737 Filed 8–16–18; 8:45 am]

BILLING CODE 8011–01–P

[5] *See* footnote 3.

[6] Exchange Rule 0120(i).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has requested a waiver of this requirement.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83836; File No. SR–NYSE–2018–31]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Require Certain Member Organizations To Participate in Scheduled Market-Wide Circuit Breaker Testing

August 13, 2018.

I. Introduction

On June 26, 2018, New York Stock Exchange LLC (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to require certain member organizations to participate in scheduled market-wide circuit breaker testing. On July 5, 2018, the Exchange filed Amendment No. 1 to the proposed rule change, which supersedes the original filing in its entirety.[3] The proposed rule change, as amended by Amendment No. 1, was published for comment in the **Federal Register** on July 11, 2018.[4] The Commission has received no comment letters on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to amend NYSE Rule 49 to require certain member organizations to participate in scheduled Market-Wide Circuit Breaker (''MWCB'') testing.[5]

The Securities Information Processors (''SIPs'') for the U.S. equity markets have established a quarterly MWCB testing schedule.[6] On the scheduled dates, the Consolidated Tape Association Plan (''CTA Plan'') and the Consolidated Quotation Plan (''CQ'' Plan'') (collectively ''the CTA/CQ Plans''),[7] along with the Nasdaq/UTP Plan,[8] conduct MWCB testing that allows market participants across the securities industry to test their ability to receive messages associated with MWCBs, including decline status, halt, and resume messages. Market participants are also able to participate in testing of re-opening auctions following market-wide circuit breaker halts.

The Exchange states that quarterly MWCB testing is critical to ensure that securities markets halt trading and subsequently re-open in a manner consistent with the MWCB rules.[9] To that end, the Exchange states that certain member organizations should be required to participate in scheduled MWCB tests. The proposed rule would provide the Exchange with authority to require participation by certain member organizations in industry-wide tests to validate that their processing in the event of MWCB is as expected within their systems.

The Exchange also proposes new Rule 49(c)(1), which would provide that each member organization notified of its obligation to participate in mandatory testing pursuant to standards established under paragraphs (b)(1) and (3) of Rule 49 [10] would also be required to participate in scheduled MWCB testing in the manner and frequency specified by the Exchange. The Exchange proposes that future SCI Notices would also include notification to member organizations of their obligation to participate in a scheduled MWCB test.[11]

Finally, proposed Rule 49(c)(2) would provide that member organizations not required to participate in a scheduled MWCB test pursuant to standards established in paragraphs (b)(1) and (3) of Rule 49 would be permitted to participate in a scheduled MWCB test.

The Exchange proposes to implement the proposed rule change at the same time that the Exchange notifies member organizations of required participation in the 2019 Regulation SCI industry test.[12] The 2019 SCI Notice would identify the member organizations that would be required to participate in scheduled MWCB testing. Member organizations notified in the 2019 SCI Notice of their obligation to participate in a scheduled MWCB test would be required to participate in that test on at least one of the testing dates established by the SIPs.[13]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange proposed to improve the clarity of the proposal and elaborate on the Exchange's statement on burden on competition. *See* Letter from Martha Redding, Associate General Counsel, NYSE, to Brent J. Fields, Secretary, Commission (Jul. 9, 2018), *available at https://www.sec.gov/comments/sr-nyse-2018-31/nyse201831-4016966-167312.pdf.*

[4] *See* Securities Exchange Act Release No. 83601 (Jul. 6, 2018), 83 FR 32172 (Jul. 11, 2018) (''Notice'').

[5] The securities and futures exchanges have procedures for coordinated cross-market trading halts if a severe market price decline reaches levels that may exhaust market liquidity. These procedures, known as market-wide circuit breakers, may halt trading temporarily or, under extreme circumstances, close the markets before the normal close of the trading session. Market-wide circuit breakers provide for cross-market trading halts during a severe market decline as measured by a single-day decrease in the S&P 500 Index. A cross-market trading halt can be triggered at three circuit-breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). These triggers are set by the markets at levels that are calculated daily based on the prior day's closing price of the S&P 500 Index.

[6] *See, e.g., https://www.nyse.com/publicdocs/ctaplan/notifications/trader-update/CTS_CQS%202018_Failover%20Testing_Q1.pdf; https://www.nasdaqtrader.com/TraderNews.aspx?id=utp2017-15.*

[7] The CTA/CQ Plans govern the collection, consolidation, processing, and dissemination of last sale and quotation information for Network A and Network B securities. Network A refers to securities listed on NYSE and Network B refers to securities listed on exchanges other than the Nasdaq Stock Market LLC (''Nasdaq'').

[8] The Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis (''Nasdaq/UTP Plan'') governs the collection, consolidation, processing, and dissemination of last sale and quotation information for Network C securities. Network C refers to securities listed on Nasdaq.

[9] Pursuant to NYSE Rule 80B (Trading Halts Due to Extraordinary Market Volatility), a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit-breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 circuit breaker after 9:30 a.m. ET and before 3:25 p.m. ET would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. ET would not halt market-wide trading. A market decline that triggers a Level 3 circuit breaker, at any time during the trading day, would halt market-wide trading for the remainder of the trading day.

[10] In 2015, the Exchange adopted rules to require certain member organizations to participate in testing of the operation of the Exchange's business continuity and disaster recovery plans in connection with Regulation Systems Compliance and Integrity (''Regulation SCI''). Paragraph (b)(1) of Rule 49 establishes standards for the designation by the Exchange of member organizations that are necessary to participate in business continuity and disaster recovery plans testing pursuant to Regulation SCI. *See* Securities Exchange Act Release No. 76346 (Nov. 4, 2015), 80 FR 69765 (Nov. 10, 2015). The Exchange believes that, because member organizations required to participate in Regulation SCI testing have already been identified as essential for the maintenance of a fair and orderly market, these same member organizations should also be required to participate in scheduled MWCB testing. *See* Notice, *supra* note 4, 83 FR at 32173.

[11] The Exchange states that the annual Regulation SCI test is currently conducted in October of each calendar year and that it provides at least (3) months advance notice to member organizations that are required to participate in such SCI testing (''SCI Notice'').

[12] The Exchange states that member organizations were notified in April 2018 of their required participation in the Regulation SCI testing scheduled for October 13, 2018. The Exchange notes that, while it encourages all member organizations to participate in MWCB testing voluntarily, implementing the new rule in 2019 would provide member organizations with sufficient time to prepare for a scheduled MWCB test. *See* Notice, *supra* note 4, 83 FR at 32173 n. 8.

[13] *See supra,* note 6 and accompanying text.

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[14] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[15] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and that the rules not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Commission also finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(8) of the Act,[16] which requires that the rules of an exchange not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As indicated above, the Commission has received no comment letters addressing the proposed rule change.

The Commission believes that amending NYSE Rule 49 to require certain member organizations to participate in scheduled MWCB testing would enable the Exchange, participating member organizations, and others to assess the readiness of participating member organizations to respond in the event of unanticipated market volatility. Member organizations required to participate in MWCB testing pursuant to the proposal would be designated as such using the same standards used by the Exchange in determining which member organizations are subject to mandatory Regulation SCI testing. Because these member organizations have been designated by the Exchange as essential to the maintenance of a fair and orderly market, their demonstrated ability to halt and subsequently re-open trading in a manner consistent with the MWCB rules should contribute to the fairness and orderliness of the market for the benefit of all market participants. The Commission therefore believes that the proposal, as modified by Amendment No. 1, is designed to remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and to protect investors and the public interest.

Accordingly, for the reasons discussed above, the Commission believes that the Exchange's proposal, as modified by Amendment No. 1, is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[17] that the proposed rule change (SR–NYSE–2018–31), as modified by Amendment No.1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2018–17743 Filed 8–16–18; 8:45 am]

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[14] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78f(b)(8).

[17] 15 U.S.C. 78s(b)(2).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83832; File No. SR–ICC–2018–006]

Self-Regulatory Organizations; ICE Clear Credit LLC; Order Approving Proposed Rule Change Relating To Amending the ICC Clearing Rules Regarding Mark-to-Market Margin

August 13, 2018.

I. Introduction

On June 13, 2018, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the ICC Clearing Rules (the ''ICC Rules'') [3] to more clearly characterize Mark-to-Market Margin payments as settled-to-market rather than collateralized-to-market. The proposed rule change was published in the **Federal Register** on June 29, 2018.[4] The Commission has not received any comments on the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *Available at https://www.theice.com/publicdocs/clear_credit/ICE_Clear_Credit_Rules.pdf.* Capitalized terms used herein but not otherwise defined have the meaning set forth in the ICC Rules.

II. Description of the Proposed Rule Change

The proposed rule change would revise Chapters 4, 8, and 20 of the ICC Rules to more clearly characterize Mark-to-Market Margin payments as settlement payments (''settled-to-market'') rather than collateral (''collateralized-to-market'').[5] The proposed rule change would not change the manner in which Mark-to-Market Margin is calculated, or other current ICC operational practices.[6] Rather, the proposed rule change would revise terminology to further clarify the legal characterization that payments of Mark-to-Market Margin represent settlement rather than collateral payments.[7] ICC states that these clarifying changes are the result of ICC's analysis of the legal characterization of Mark-to-Market Margin payments, at the request of its Clearing Participants (''CPs'').[8]

The proposed rule change would revise Rule 401 to reference Mark-to-Market Margin Balance, a new term that is defined in Rule 404 to mean the aggregate amount of Mark-to-Market Margin paid or received.[9] The new definition would be used in several calculations to describe specifics pertaining to the Mark-to-Market Margin calculation.[10] For example, the proposed rule change would amend Rule 401(a), which governs House Margin, to state that ICC calculates a net amount of Mark-to-Market Margin by subtracting a CP's Mark-to-Market Margin Balance from a CP's Mark-to-Market Margin Requirement.[11] The proposed rule change would make corresponding changes to reference

[4] Securities Exchange Act Release No. 34–83513 (June 25, 2018), 83 FR 30802 (June 29, 2018) (SR–ICC–2018–006) (''Notice'').

[5] Under the settled-to-market model, the transfer of Mark-to-Market Margin constitutes a settlement of the contract's outstanding exposure, with the receiving party taking outright title to the Mark-to-Market Margin and the transferring party retaining no rights to such margin. Under the collateralized-to-market model, the transfer of Mark-to-Market Margin constitutes a pledge of collateral, such that the transferring party has a right to reclaim the collateral and the receiving party has an obligation to return the collateral. For further explanation of the settled-to-market model and collateralized-to-market model, *see* Notice, 83 FR at 30803.

[6] Notice, 83 FR at 30803.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] Notice, 83 FR at 30803.

Mark-to-Market Margin Balance in Rule 401(b)(ii), which covers Client-Related Mark-to-Market Margin.[12]

As stated above, the proposed rule change would not modify the current calculation of Mark-to-Market Margin, or other operational practices, but, instead, would replace certain specifics relating to ICC's Mark-to-Market Margin calculation with the new defined term Mark-to-Market Margin Balance.[13] In addition, the proposed rule change would not change the manner in which Initial Margin is calculated, posted and held.[14]

Further, the proposed rule change would revise Rule 401(g) to specify that amounts ICC currently pays to CPs as interest on any Mark-to-Market Margin would no longer be considered interest but instead would be treated as a new payment obligation between ICC and CPs and referred to as the ''price alignment amount.'' [15] A price alignment amount would be economically equivalent to the ''interest'' that ICC pays or charges a CP for any net Mark-to-Market Margin transferred between the parties under current Rule 401(g).[16] Because the term interest may be more typically associated with collateral, however, the proposed rule change would refer to such an amount as price alignment to avoid confusion over the proper characterization of Mark-to-Market Margin as settlement payments.[17] ICC states that such change would not affect ICC's operations because ICC would continue to pay or charge a CP an amount, which would serve the same purpose and would be calculated identically, for any net Mark-to-Market Margin transferred between the parties.[18]

The proposed rule change would also clarify in proposed revisions to Rule 401(g) that the rate ICC may pay or charge a CP for a price alignment amount on any Mark-to-Market Margin or interest on any Initial Margin in the form of cash may be negative. This proposed revision is intended by ICC to more clearly address the effect negative market rate environments could have on how such amounts might be paid or charged by ICC to CPs.[19]

The proposed rule change would add and clarify references to amounts that ICC will continue to treat as collateral to avoid confusion over the proper characterization of Mark-to-Market Margin under the ICC Rules. Specifically, the proposed rule change would update Rule 401(h) to provide that CPs may substitute, in accordance with the ICC Procedures and applicable law, Eligible Margin only for an amount of Initial Margin.[20] CPs would no longer be able to substitute Eligible Margin for Mark-to-Market Margin because under the proposed rule change, ICC would take outright title to the Mark-to-Market Margin and CPs would retain no substitution or other rights to such Mark-to-Market Margin. The proposed changes to Rule 402, which governs ICC's rights with respect to the use of margin, would exclude Mark-to-Market Margin from subsections (a) and (b), would remove details relating to Mark-to-Market Margin from subsection (b), and would specify subsection (c)'s applicability to Initial Margin. Because ICC's rights with respect to Mark-to-Market Margin would now be set out in Rule 402(e), it would no longer be necessary to refer to Mark-to-Market Margin in Rule 402(a) and (b). To avoid uncertainty, the proposed rule change would clarify that the requirements set forth in Rule 406(c) regarding collateral for Client-Related Positions apply to Initial Margin.[21]

The proposed rule change would similarly add and clarify references to amounts that ICC would treat as settled to avoid confusion over the proper characterization of Mark-to-Market Margin under the ICC Rules. The proposed rule change would add language to Rule 402(e) to describe ICC's rights with respect to Mark-to-Market Margin and more clearly state that Mark-to-Market Margin payments constitute a settlement. The proposed rule change would also update Rule 401(l) to refer to settlement finality in relation to Mark-to-Market Margin.[22] Further, the proposed rule change would add new subsection (c) to Rule 404 to define Mark-to-Market Margin Balance as a sum equal to the Mark-to-Market Margin value transferred by the CP to ICC minus the Mark-to-Market Margin value transferred by ICC to the CP.[23]

Finally, the proposed rule change would make clarifications and conforming changes to Chapters 8 and 20 of the ICC Rules. The proposed rule change would revise Rule 801(a)(i), which describes how ICC calculates a CP's Required Contribution to the General Guaranty Fund, to refer to the transfer of Mark-to-Market Margin.[24] This change would characterize Mark-to-Market Margin as settled, rather than collateral, by referring to the amount of Mark-to-Market Margin transferred to ICC in respect of a defaulting CP's positions. The proposed rule change would not change ICC's calculation of a CP's Required Contribution, which would continue to take into account the expected loss to ICC associated with a CP's default after the application of Initial Margin and Mark-to-Market Margin.[25]

The proposed rule change would also replace, in the defined term MTM in Rule 808, the phrase ''amount of MTM held by any Participant or ICE Clear Credit'' with a conforming reference to the new defined term Mark-to-Market Margin Balance.[26] This proposed change would not alter the operation of Rule 808, which describes how and when ICC would implement Reduced Gains Distributions.

The proposed rule change would replace terminology in Rule 810(e) that is commonly used in conjunction with collateral by changing the words ''posted'' to ''transferred'' and removing the phrase ''and be offset against''. This change would avoid confusion over the proper characterization of Mark-to-Market Margin as settlement payments.[27] This proposed change would not alter the operation of Rule 810, which describes ICC's termination of clearing operations.

Finally, the proposed rule change would clarify in Rule 20–605(c)(i)(B), which specifies the resources to be used to cover losses with respect to Client-Related Positions, that ICC would use the defaulting CP's Client-Related Mark-to-Market Margin, to the extent not previously applied to pay Mark-to-Market Margin to other CPs.[28] Because Mark-to-Market Margin would be settled with ICC, ICC would obtain outright title to the Mark-to-Market Margin and would be able to use the Mark-to-Market Margin for purposes other than collateralizing a CP's position, in accordance with ICC's Rules and applicable regulatory requirements. The proposed rule change would make this point clear and therefore clarify that Mark-to-Market Margin payments constitute settlement rather than collateral.

[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] Notice, 83 FR at 30803.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] Notice, 83 FR at 30803.
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] Notice, 83 FR at 30803.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[29] For the reasons given below, the Commission finds that the proposal is consistent with Section 17A(b)(3)(F) of the Act [30] and Rules 17Ad–22(b)(2) and 17Ad–22(d)(1) thereunder.[31]

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICC be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, as well as to assure the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible, and, in general, to protect investors and the public interest.[32]

As described above, the proposed rule change would revise Chapters 4, 8, and 20 of the ICC Rules to more clearly characterize Mark-to-Market Margin payments as settlement payments rather than collateral. To facilitate this characterization, the proposed rule change would introduce a new definition, Mark-to-Market Margin Balance, and a new concept, price alignment amount. Moreover, the proposed rule change would update the terminology used in certain rules, and the application of certain rules to Mark-to-Market Margin, in light of the characterization of Mark-to-Market Margin payments as settlement payments rather than collateral. The proposed rule change would not change the manner in which Mark-to-Market Margin is calculated, or other current ICC operational practices.

The Commission believes that by clarifying the treatment of Mark-to-Market Margin payments, the proposed rule change would help ensure that Mark-to-Market margin is treated as settled payments rather than collateral, consistent with ICC's intention. In doing so, the Commission further believes the proposed rule change would clarify that ICC has all rights and outright title to such Mark-to-Market Margin. The Commission believes the proposed rule change would clarify ICC's interest in and rights to Mark-to-Market Margin, thereby supporting ICC's ability to use Mark-to-Market Margin to cover credit and market losses.

The Commission further believes that in this regard the proposed rule change would remove potential confusion regarding the treatment of Mark-to-Market Margin, thereby helping to improve the operation and effectiveness of ICC's margin system. Given that an effective margin system is necessary to manage ICC's credit exposures to its CPs and the risks associated with clearing security based swap-related portfolios, the Commission believes that the proposed rule change would help improve ICC's ability to avoid the losses that could result from the mismanagement of credit exposures and the risks associated with clearing security based swap-related portfolios. Because such losses could disrupt ICC's ability to promptly and accurately clear security based swap transactions, the Commission believes that the proposed rule change, by improving the operation and effectiveness of ICC's margin system, would thereby help promote the prompt and accurate clearance and settlement of securities transactions.

Similarly, given that mismanagement of ICC's credit exposures to its CPs and the risks associated with clearing security based swap-related portfolios could cause ICC to realize losses on such portfolios and threaten ICC's ability to operate, thereby threatening access to securities and funds in ICC's control, the Commission believes that the proposed rule change would help assure the safeguarding of securities and funds which are in the custody or control of the ICC or for which it is responsible. Finally, for both of these reasons, the Commission believes the Framework would, in general, protect investors and the public interest.

Therefore, the Commission finds that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, assure the safeguarding of securities and funds in ICC's custody and control, and, in general, protect investors and the public interest, consistent with the Section 17A(b)(3)(F) of the Act.[33]

B. Consistency With Rule 17Ad–22(b)(2)

Rule 17Ad–22(b)(2) requires that ICC establish, implement, maintain and enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions and use risk-based models and parameters to set margin requirements and review such margin requirements and the related risk-based models and parameters at least monthly.[34]

As described above, the proposed rule change would revise Chapters 4, 8, and 20 of the ICC Rules to more clearly characterize Mark-to-Market Margin payments as settlement payments rather than collateral. Specifically, the Proposed Rule Change would revise Rule 401 to reference Mark-to-Market Margin Balance, a new term that is defined in Rule 404 to mean the aggregate amount of Mark-to-Market Margin paid or received. The new definition would be used in Rule 401(a), regarding House Margin, which would be revised to state that ICC calculates a net amount of Mark-to-Market Margin by subtracting a CP's Mark-to-Market Margin Balance from a CP's Mark-to-Market Margin Requirement. Moreover, under the proposed revised Rule 401(g), ICC would pay or charge a CP price alignment, which would be economically equivalent to interest, on any Mark-to-Market Margin and interest on any cash Initial Margin at a rate that may be negative. The proposed rule change would not modify the current calculation of Mark-to-Market Margin, or other operational practices, but, instead, would replace certain specifics relating to ICC's Mark-to-Market Margin calculation with the new defined term Mark-to-Market Margin Balance.

The Commission believes that by clarifying the treatment of Mark-to-Market Margin payments, the proposed rule change would help ensure that Mark-to-Market margin is treated as settled payments rather than collateral. The Commission believes that in this regard the proposed rule change would help ensure that the margin system is operating consistently for all CPs and in a manner that is consistent with ICC's view on the treatment of Mark-to-Market Margin by confirming that all Mark-to-Market Margin would be treated as settlement payments. In doing so, the Commission further believes the proposed rule change would clarify that ICC has all rights and outright title to such Mark-to-Market Margin. The Commission believes the proposed rule change would thereby clarify ICC's interest in and rights to Mark-to-Market Margin, thereby supporting ICC's ability to use Mark-to-Market to cover credit and market losses. The Commission therefore believes the proposed rule change would help ICC maintain and

[29] 15 U.S.C. 78s(b)(2)(C).

[30] 15 U.S.C. 78q–1(b)(3)(F).

[31] 17 CFR 240.17Ad–22(b)(2), (d)(1).

[32] 15 U.S.C. 78q–1(b)(3)(F).

[33] 15 U.S.C. 78q–1(b)(3)(F).

[34] 17 CFR 240.17Ad–22(b)(2).

enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions.

Moreover, as noted above, the proposed rule change resulted from a request by CPs for ICC to confirm it treats Mark-to-Market Margin as settlement payments. CPs therefore may hesitate to post Mark-to-Market Margin if ICC does not consistently treat such margin as settlement payments. Thus, the Commission believes the proposed rule change would help ICC enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions.

Therefore, for the above reasons the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(b)(2).[35]

C. Consistency With Rule 17Ad–22(d)(1)

Rule 17Ad–22(d)(1) requires that ICC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, transparent, and enforceable legal framework for each aspect of its activities in all relevant jurisdictions.[36]

As discussed above, the proposed rule change would revise Chapters 4, 8, and 20 of the ICC Rules to more clearly characterize Mark-to-Market Margin payments as settlement payments rather than collateral. The proposed rule change would also revise terminology to further clarify the legal characterization that payments of Mark-to-Market Margin represent settlement rather than collateral payments. These clarifying changes are the result of ICC's analysis of the legal characterization of Mark-to-Market Margin payments, at the request of its CPs.

Thus, ICC intends to treat Mark-to-Market Margin payments as settled rather than collateral, and the Commission believes that the proposed rule change's clarifications and additions would help ensure that ICC's margin system operates consistently with this intention. The Commission further believes that the proposed rule change would help ensure that the margin system is operating consistently for all CPs by confirming that all Mark-to-Market Margin would be treated as settlement payments. In ensuring the consistent treatment of Mark-to-Market Margin, the Commission believes that the proposed rule change would help ensure that the policies and procedures underlying ICC's margin system provide a well-founded, transparent, and enforceable legal framework.

Therefore, for the above reasons the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(d)(1).[37]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act[38] and Rules 17Ad–22(b)(2) and 17Ad–22(d)(1) thereunder.[39]

It is therefore ordered pursuant to Section 19(b)(2) of the Act[40] that the proposed rule change (SR–ICC–2018–006) be, and hereby is, approved.[41]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2018–17741 Filed 8–16–18; 8:45 am]

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[35] 17 CFR 240.17Ad–22(b)(2).

[36] 17 CFR 240.17Ad–22(d)(1).

[37] 17 CFR 240.17Ad–22(d)(1).

[38] 15 U.S.C. 78q–1(b)(3)(F).

[39] 17 CFR 240.17Ad–22(b)(2), (d)(1).

[40] 15 U.S.C. 78s(b)(2).

[41] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83833; File No. SR–BX–2018–037]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Section 7018(a) of the Exchange's Rules

August 13, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2018, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction fees at Rule 7018(a), as described further below.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on August 1, 2018.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's transaction fees at Rule 7018 to (i) adjust the volume threshold for a credit associated with orders that access liquidity that are entered by members that access liquidity equal to or in excess of a certain percentage of their [sic] total Consolidated Volume[3] for a month; and (ii) adding two credit tiers for orders entered by members that, during a given month, have a total volume (accessing and providing liquidity) equal to or exceeding 0.50% of total Consolidated Volume, at least 20% more volume during that month (as a percentage of Consolidated Volume) than the member's total volume in July 2018, and where at least 30% of that 20% increase in volume arises from adding liquidity.

[3] Pursuant to Rule 7018(a), the term ''Consolidated Volume'' means the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot.

First Change

The Exchange operates on the ''taker-maker'' model, whereby it pays credits to members that take liquidity and charges fees to members that provide liquidity. Currently, the Exchange offers several different credits for orders that access liquidity on the Exchange. Among these credits, the Exchange pays a credit of $0.0015 per share executed for an order that accesses liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) entered by a member that accesses liquidity equal to or exceeding 0.075% of total Consolidated Volume during a month. The Exchange proposes to decrease the Consolidated Volume threshold applicable to this credit to 0.065% of total Consolidated Volume during a month. The Exchange recently had increased this threshold to 0.075%,[4] but it has since determined that this level is too high. It now proposes to recalibrate the threshold downward to make it easier for firms to reach the Consolidated Volume threshold necessary to qualify for the credit.

Second Change

The Exchange presently offers several credits for members whose orders remove liquidity from the Exchange. Among these credits, the Exchange offers a $0.0018 per share executed credit for orders that access liquidity in securities in Tapes A and C (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) that are entered by a member that: (i) Accesses liquidity equal to or exceeding 0.20% of total Consolidated Volume during a month; and (ii) accesses 20% more liquidity as a percentage of Consolidated Volume than the member accessed in May 2018. The Exchange also offers a $0.0019 per share executed credit for orders that access liquidity in securities in Tape B (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) that are entered by a member that: (i) Accesses liquidity equal to or exceeding 0.20% of total Consolidated Volume during a month; and (ii) accesses 20% more liquidity as a percentage of Consolidated Volume than the member accessed in May 2018.

The Exchange now plans to add two new tiers that will also entitle members to receive credits of $0.0018 and $0.0019 per share executed. The first of these new tiers will offer a member a $0.0018 per share executed credit for its orders that access liquidity in securities in Tapes A and C (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) to the extent that the member, during a given month: (i) Has a total volume (including both providing and accessing liquidity) that is equal to or exceeds 0.20% [sic] of total Consolidated Volume during that month; (ii) has a total volume that is at least 20% greater (as a percentage of Consolidated Volume) than its total volume in July 2018; and (iii) of the 20% or more increase in total volume described above, at least 30% is attributable to adding liquidity. The second tier will offer a member a $0.0019 per share executed credit for orders that access liquidity in securities in Tape B (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) to members that satisfy these same three conditions.

An example of how these two new credits will work is as follows. Firm X adds and removes 0.60% of total Consolidated Volume in securities in Tape A in July 2018. In August 2018, Firm X adds and removes 0.72% of total Consolidated Volume in securities in the same Tape. The increase in total volume as a percentage of total Consolidated Volume from July to August is 0.12%—which is an increase of approximately [sic] 20%. If at least 30% of that 0.12% increase (0.036%) is attributable to Firm X adding liquidity, then Firm X will qualify for a $0.0018 per share executed credit for its orders that access liquidity in securities in Tape A (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price).

The Exchange proposes to add these credits to provide new and stronger incentive for members to increase their total volume of activity on the Exchange, provided that at least a certain percentage of that increase in total volume arises from adding liquidity. The Exchange also proposes a higher credit for increasing volume in Tape B than it does in Tapes A or C to specifically target Tape B securities, where the Exchange has seen less activity than it has in Tape A and C securities.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [7]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [8] (''NetCoalition'') the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[9] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [10]

Further, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [11] Although the court

[4] *See* Securities Exchange Act Release No. 34–83680 (July 20, 2018), 83 FR 35502 (July 26, 2018) (SR–BX–2018–032).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[8] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[9] *See NetCoalition,* at 534–535.

[10] *Id.* at 537.

[11] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR

and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

First Change

The Exchange believes that it is reasonable to decrease the Consolidated Volume threshold on its credit for orders that access liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with Midpoint pegging [sic]) entered by members that access liquidity equal to or exceeding 0.075% of total Consolidated Volume during a month. The Exchange must, from time to time, assess the effectiveness of its credits in achieving their intended objectives and adjust the levels of such credits based on the Exchange's observations of market participant behavior. In this instance, the Exchange recently had increased the Consolidated Volume threshold to provide a stronger incentive to market participants to improve the market, but the Exchange has since determined that this increase was too high and that the threshold needs to be recalibrated downward to 0.065% to ensure that firms can continue to qualify for the credit. The Exchange believes that the proposed decrease is equitable and is not unfairly discriminatory because it will apply to all similarly situated member firms.

Second Change

Likewise, the Exchange believes that its proposal is reasonable to add new credits for orders that access liquidity (excluding orders with Midpoint pegging and those that receive price improvement and execute against an order with a non-displayed price) that are entered by members that, in a given month, remove and access [sic] liquidity equal to or in excess of 0.50% of Consolidated Volume during the month, have a total volume (as a percentage of Consolidated Volume) that is 20% greater than it was in July 2018, and where at least 30% of the 20% increase in total volume (as a percentage of Consolidated Volume) arises from adding liquidity. This proposal is reasonable because it will provide new and stronger incentive for members to improve the market by both adding and removing liquidity from the Exchange. It will also incent them to increase the extent of this activity on the Exchange relative to their activity levels as of July 2018. The Exchange believes it is reasonable, equitable, and not unfairly discriminatory to propose a higher credit to members that increase volume in securities in Tape B than those that do so in securities in Tapes A and C because the Exchange has experienced less activity in Tape B securities relative to Tapes A and C securities and it wishes to specifically target increased activity with respect to Tape B securities. The Exchange also believes that these proposals are equitable and not unfairly discriminatory because they will apply to all similarly situated member firms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and credits to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee or credit changes in this market may impose any burden on competition is extremely limited.

In this instance, the Exchange's proposals to add to or modify its credits do not impose a burden on competition because these proposals are reflective of the Exchange's overall efforts to provide greater incentives to market participants that it believes will improve the market, to the benefit of all participants. The Exchange does not believe that any of the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets. Moreover, because there are numerous competitive alternatives to the use of the Exchange, it is likely that BX will lose market share as a result of the changes if they are unattractive to market participants.

Likewise, the Exchange's proposed credits and credit amendments do not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. Again, if the proposed credits are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposal will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2018–037 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2018–037. This file number should be included on the subject line if email is used. To help the Commission process and review your

74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2018–037 and should be submitted on or before September 7, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2018–17742 Filed 8–16–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83830; File No. SR–ISE–2018–66]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Schedule of Fees Relating to Crossing Orders and Responses to Crossing Orders in Index Options on the Nasdaq 100 Reduced Value Index

August 13, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2018, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Schedule of Fees to provide further explanation on how the Exchange charges Crossing Orders and Responses to Crossing Orders in index options on the Nasdaq 100 Reduced Value Index (''NQX'').

The text of the proposed rule change is available on the Exchange's website at *http://ise.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange recently adopted transaction fees and rebates for adding or removing liquidity from ISE (*i.e.,* maker/taker fees and rebates) in NQX options, which apply to executions in both the regular and complex order book, according to the following schedule: [3]

Market participant	Maker fee/rebate	Taker fee/rebate
Market Maker	($0.25)	$0.00
Market Maker (for orders sent by Electronic Access Members)	(0.25)	0.00
Non-Nasdaq ISE Market Maker (FarMM)	0.25	0.25
Firm Proprietary/Broker-Dealer	0.25	0.25
Professional Customer	0.25	0.25
Priority Customer	0.00	0.00

In SR–ISE–2018–61, the Exchange stated that the above pricing would apply to all executions in NQX, including Non-Priority Customer [4] Crossing Orders [5] in NQX. The Exchange now proposes to clarify that the taker fee applies to Crossing Orders (*i.e.,* both the originating and contra side of the order) in NQX as well as responses to such orders by noting the following in Section III.B: ''Fee will also apply to the originating and contra side of Crossing Orders, and to Responses to Crossing Orders.'' [6]

The Exchange does not seek to amend the manner in which Crossing Orders in NQX and responses thereto are currently charged, rather the Exchange

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 83639 (July 16, 2018) (SR–ISE–2018–61).

[4] ''Non-Priority Customers'' include Market Makers, Non-Nasdaq ISE Market Makers, Firm Proprietary/Broker-Dealers, and Professional Customers.

[5] A ''Crossing Order'' is an order executed in the Exchange's Facilitation Mechanism, Solicited Order Mechanism, Price Improvement Mechanism (PIM) or submitted as a Qualified Contingent Cross order. For purposes of the fee schedule, orders executed in the Block Order Mechanism are also considered Crossing Orders.

[6] ''Responses to Crossing Order'' is any contra-side interest submitted after the commencement of an auction in the Exchange's Facilitation Mechanism, Solicited Order Mechanism, Block Order Mechanism or PIM.

seeks to more clearly state in its Schedule of Fees that taker pricing applies for such orders. While the Exchange is not aware of any member confusion with respect to this fee, the Exchange believes this specificity will help preclude any potential confusion in how its fees will apply.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[8] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed language relating to the application of taker fees to Crossing Orders and Responses to Crossing Orders in NQX is reasonable because the proposed rule text will bring greater transparency to the manner in which the Exchange charges NQX orders submitted in ISE's various crossing mechanisms. As discussed above, the Exchange charges members the applicable taker fee to both the originating and contra side of Crossing Orders in NQX as well charging the NQX taker pricing for Responses to Crossing Orders. The Exchange believes it is reasonable and appropriate to charge taker and not maker pricing for these orders because the Exchange seeks to encourage market making activity in NQX by providing the $0.25 per contract maker rebate to Market Maker orders that post liquidity in the Exchange's new proprietary product during the initial months of trading. Furthermore, the manner in which the Exchange applies the NQX taker fees in Section III.B is not changing with this proposal, and the proposed changes are intended to bring greater clarity to ISE's Schedule of Fees, to the benefit of all market participants.

The Exchange's proposal to add the clarifying language is also equitable and not unfairly discriminatory because the Exchange will continue to apply the taker fees for Crossing Orders and Responses to Crossing Orders in NQX in a uniform manner for all similarly situated participants. The Exchange also believes that it is equitable and not unfairly discriminatory to assess no taker fees to Market Maker Crossing Orders and Responses to Crossing Orders in NQX as compared to other Non-Priority Customers, who are currently assessed the $0.25 per contract taker fee for such orders. Market Makers, unlike other market participants, take on a number of obligations, including quoting obligations, that other market participants do not have. Further, the Exchange believes that it is equitable and not unfairly discriminatory to assess no transaction fees to Priority Customer[9] Crossing Orders and Responses to Crossing Orders in NQX because Priority Customer order flow enhances liquidity on the Exchange for the benefit of all market participants. Priority Customer liquidity provides more trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the proposal is intended to eliminate ambiguity from the Schedule of Fees by further explaining how ISE charges the originating and contra side of Crossing Orders in NQX as well as Responses to Crossing Orders in NQX. The proposal does not amend the current manner in which the Exchange assesses fees for Crossing Orders and Responses to Crossing Orders in NQX, and the Exchange will continue to assess the applicable taker fees in Section III.B for such NQX orders in a uniform manner to all market participants. For the foregoing reasons, the Exchange believes that the proposed changes do not impose an undue burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4) and (5).

[9] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Rule 100(a)(37A).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[10] and Rule 19b–4(f)(2)[11] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2018–66 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2018–66. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2018–66 and should be submitted on or before September 7, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2018–17738 Filed 8–16–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83835; File No. SR–PEARL–2018–15]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to the Exchange Rule 514 Priority on the Exchange

August 13, 2018.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2018, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 514, Priority on the Exchange.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 514, Priority on the Exchange. Specifically, the Exchange proposes to amend subsection (c), Self-Trade Protection, to broaden the protection afforded under the current rule by giving Members[3] the option to have this protection apply at the market participant identifier (''MPID'')[4] level (*i.e.,* currently existing functionality), or at the firm level. The Exchange believes that this enhancement will provide helpful flexibility for market making firms that wish to prevent trading against all orders entered by their firm under any MPID, instead of just those entered under the same MPID.

Currently, the rule prevents orders entered by a Market Maker[5] via the MEO Interface[6] or the FIX Interface[7] using the same MPID from executing against orders entered on the opposite side of the market by the same Market Maker using the same MPID via the MEO Interface or the FIX Interface.[8] In such a case, the System[9] will cancel the oldest of the orders back to the entering party prior to execution.

Members of the Exchange may either be Market Makers or Electronic Exchange Members.[10] Each Market Maker and Electronic Exchange Member is assigned an MPID by the Exchange for identification purposes. A Member may have multiple Market Maker MPIDs on the Exchange, therefore the possibility exists that a Member may cross its own Market Maker's orders.[11]

The Exchange now proposes to allow members to choose to have this protection applied at either the MPID level, as currently implemented, or at the member firm level. If members choose to have this protection applied at the member firm level, the System will prohibit orders entered from different MPIDs within the Member's firm from trading against one another. The Exchange believes that the proposed enhancement will provide Members with more tailored self-trade functionality that will allow Members to manage their trading as appropriate based on the Member's business needs. While the Exchange believes that some firms will want to restrict trading interest from the same MPID, (as currently implemented), the Exchange believes that other firms will find it helpful to apply self-trade protection across all MPIDs of the same firm.

The Exchange note that similar functionality also exists on the Nasdaq Stock Market (''NASDAQ'') which prevents self-trades by MPID, or alternatively, if selected by the member, self-trade protection for all MPIDs of the firm.[12] Cboe BZX Exchange (''CboeBZX'') also has a similar rule in place which provides members the ability to apply Match Trade Prevention (''MTP'') modifiers (CboeBZX's version

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of MIAX PEARL Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] The term ''MPID'' means unique market participant identifier. *See* Exchange Rule 100.

[5] The term ''Market Maker'' or ''MM'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the MIAX PEARL Rules. *See* Exchange Rule 100.

[6] The term ''MEO Interface'' means a binary order interface used for submitting certain order types (as set forth in Rule 516) to the MIAX PEARL System. *See* Exchange Rule 100.

[7] The term ''FIX Interface'' means the Financial Information Exchange interface used for submitting certain order types (as set forth in Rule 516) to the MIAX PEARL System. *See* Exchange Rule 100.

[8] *See* Exchange Rule 514(c)(1).

[9] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[10] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[11] The Exchange notes that if requested by an EEM, orders entered by an EEM via the MEO Interface using the same MPID will not be executed against orders entered on the opposite side of the market by the same EEM using the same MPID via the MEO Interface. In such a case, the System will cancel the oldest of the orders back to the entering party prior to execution. *See* Exchange Rule 514(c)(2).

[12] *See* Nasdaq Stock Market Rule, Chapter VI, Sec. 18(c)(1).

of self-trade protection) based on MPID, Exchange Member, trading group, or Exchange Sponsored Participant identifiers.[13]

The Exchange will announce the implementation date of this functionality via a Regulatory Circular prior to the functionality being available on the Exchange.

2. Statutory Basis

MIAX PEARL believes that its proposed rule changes are consistent with Section 6(b) of the Act[14] in general, and furthers the objectives of Section 6(b)(5) of the Act[15] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes the proposed changes promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system by providing Market Makers with additional flexibility to configure self-trade protections offered by the Exchange. Currently, all Market Makers are provided functionality that prevents orders entered by a Market Maker via the MEO Interface or the FIX Interface using the same MPID from executing against orders entered on the opposite side of the market by the same Market Maker using the same MPID via the MEO Interface or the FIX Interface. While this functionality is helpful, some members would prefer not to trade with orders entered under different MPIDs of the same firm. Therefore, the Exchange is proposing to provide Exchange Members flexibility with respect to how self-trade protections are implemented. Members may continue to use the current functionality, while members who prefer to prevent self-trades across different MPIDs within the same firm will now be provided with functionality that allows them to do so.

Similar functionality exists on the Nasdaq Stock Market and CboeBZX[16] and the Exchange believes that the flexibility to apply self-trade protection at either the MPID or firm level would be useful to Members of MIAX PEARL. The Exchange also believes that the proposed rule change is designed to promote just and equitable principles of trade and will remove impediments to and perfect the mechanisms of a free and open market as it will enhance self-trade protections provided to MIAX PEARL Market Makers similar to those protections provided on other markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX PEARL does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to enhance the Exchange's current self-trade protection, and will benefit members that wish to protect their orders from trading with orders from other Market Makers within the same firm, rather than the more limited MPID standard currently in use. The new functionality, which is similar to functionality already provided on CboeBZX, is also completely voluntary, and members that wish to use the current functionality may continue to do so. The Exchange does not believe that providing more flexibility to members will have any significant impact on competition. Conversely, the Exchange believes that the proposed rule change will foster competition as Market Makers may send more orders to the Exchange knowing that there is no chance that they will trade with their own orders on the other side of the market. This could result in more order flow and more liquidity on the Exchange.

The Exchange does not believe that the proposed rule change will impose any burden on intra-market competition as self-trade protection is available to all Market Makers on the Exchange. Further, the Exchange does not believe that the proposed rule change will impose any burden on inter-market competition, and rather could potentially promote inter-market competition and result in more competitive order flow to the Exchange by more widely preventing Market Makers from trading with their own orders.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[17] and Rule 19b–4(f)(6)[18] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2018–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–PEARL–2018–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the

[13] *See* Cboe BZX Exchange Rule 11.9(f).

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *See supra* note 12 and 13.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–PEARL–2018–15 and should be submitted on or before September 7, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2018–17740 Filed 8–16–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83831; File No. SR–CboeBYX–2018–014]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Make Permanent Rule 11.24, Which Sets Forth the Exchange's Pilot Retail Price Improvement Program

August 13, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 30, 2018, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to make permanent Rule 11.24, which sets forth the Exchange's pilot Retail Price Improvement Program.

The text of the proposed rule change is available at the Exchange's website at *www.markets.cboe.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule 11.24 to make permanent the Retail Price Improvement Program (the ''Program''), which is currently offered on a pilot basis. The Exchange has operated the pilot for a six year period and believes that it has been successful in its stated goal of providing price improvement opportunities to retail investors. The analysis conducted by the Exchange shows that retail investors have been provided a total of $4.5 million of price improvement during the 2.5 year period reviewed from January 2016 through June 2018. In addition, the Exchange's analysis shows that the Program has provided these benefits to retail investors without having an adverse impact on the broader market. The proposal provides an analysis of the economic benefits to retail investors and the marketplace flowing from operation of the Program, which the Exchange believes supports making the Program permanent.

Background

In November 2012, the Commission approved the Program on a pilot basis.[3] The Program is designed to attract retail order flow to the Exchange, and allow such order flow to receive potential price improvement. The Program is currently limited to trades occurring at prices equal to or greater than $1.00 per share.[4] Under the Program, a class of market participant called a Retail Member Organization (''RMO'') is eligible to submit certain retail order flow (''Retail Orders'') to the Exchange. Users[5] are permitted to provide potential price improvement for Retail Orders[6] in the form of non-displayed interest that is better than the national best bid that is a Protected Quotation (''Protected NBB'') or the national best offer that is a Protected Quotation (''Protected NBO'', and together with the Protected NBB, the ''Protected NBBO'').[7] The Program was approved by the Commission on a pilot basis running one-year from the date of implementation.[8] The Commission approved the Program on November 27, 2012.[9] The Exchange implemented the Program on January 11, 2013, and has extended the pilot period five times.[10]

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 68303 (November 27, 2012), 77 FR 71652 (December 3, 2012) (''RPI Approval Order'') (SR–BYX–2012–019).

[4] The Exchange will periodically notify the membership regarding the securities included in the Program through an information circular.

[5] A ''User'' is defined in Rule 1.5(cc) as any member or sponsored participant of the Exchange who is authorized to obtain access to the System.

[6] A ''Retail Order'' is defined in Rule 11.24(a)(2) as an agency order that originates from a natural person and is submitted to the Exchange by a RMO, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any computerized methodology. *See* Rule 11.24(a)(2).

[7] The term Protected Quotation is defined in BYX Rule 1.5(t) and has the same meaning as is set forth in Regulation NMS Rule 600(b)(58). The terms Protected NBB and Protected NBO are defined in BYX Rule 1.5(s). The Protected NBB is the best-priced protected bid and the Protected NBO is the best-priced protected offer. Generally, the Protected NBB and Protected NBO and the national best bid (''NBB'') and national best offer (''NBO'', together with the NBB, the ''NBBO'') will be the same. However, a market center is not required to route to the NBB or NBO if that market center is subject to an exception under Regulation NMS Rule 611(b)(1) or if such NBB or NBO is otherwise not available for an automatic execution. In such case, the Protected NBB or Protected NBO would be the best-priced protected bid or offer to which a market center must route interest pursuant to Regulation NMS Rule 611.

[8] *See* RPI Approval Order, *supra* note 3 at 71652.

[9] *Id.*

[10] *See* Securities Exchange Act Release Nos. 71249 (January 7, 2014), 79 FR 2229 (January 13, 2014) (SR–BYX–2014–001); 74111 (January 22, 2015), 80 FR 4598 (January 28, 2015) (SR–BYX–2015–05); 76965 (January 22, 2016), 81 FR 4682 (January 27, 2016) (SR–BYX–2016–01); 78180 (June

The pilot period for the Program is scheduled to expire on July 31, 2018.[11] The Exchange believes that the Program has been successful in its goal of providing price improvement to Retail Orders, and is therefore proposing to amend Rule 11.24 to make this pilot permanent so that retail investors can continue to reap the benefits of the Program.[12]

The SEC approved the Program on a pilot basis, in part, because it concluded, ''the Program is reasonably designed to benefit retail investors by providing price improvement to retail order flow.'' [13] The Commission also found that ''while the Program would treat retail order flow differently from order flow submitted by other market participants, such segmentation would not be inconsistent with Section 6(b)(5) of the Act, which requires that the rules of an exchange are not designed to permit unfair discrimination.'' [14] As the SEC acknowledged, the retail order segmentation was designed to create greater retail order flow competition and thereby increase the amount of this flow to transparent and well-regulated exchanges. This would help to ensure that retail investors benefit from competitive price improvement that exchange-based liquidity providers provide. As discussed below, the Exchange believes that the Program data supports the conclusion that it provides valuable price [sic] to retail investors that they may not otherwise have received, and that it is therefore appropriate to make the Program permanent.

Definitions

The Exchange adopted the following definitions under Rule 11.24(a):

First, the term ''Retail Member Organization'' is defined as a Member (or a division thereof) that has been approved by the Exchange to submit Retail Orders.

Second, the term ''Retail Order'' is defined as an agency order or riskless principal that meets the criteria of FINRA Rule 5320.03 [15] that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. A Retail Order is an Immediate or Cancel (''IOC'') Order and shall operate in accordance with Rule 11.24(f). A Retail Order may be an odd lot, round lot, or mixed lot.

Finally, the term ''Retail Price Improvement Order'' or ''RPI Order'' consists of non-displayed interest on the Exchange that is priced better than the Protected NBB or Protected NBO by at least $0.001 and that is identified as such (''RPI interest'').[16] The System [17] will monitor whether RPI buy or sell interest, adjusted by any offset and subject to the ceiling or floor price, is eligible to interact with incoming Retail Orders. An RPI Order remains non-displayed in its entirety (the buy or sell interest, the offset, and the ceiling or floor). An RPI Order may also be entered in a sub-penny increment with an explicit limit price. Any User is permitted, but not required, to submit RPI Orders. An RPI Order may be an odd lot, round lot or mixed lot.

The price of an RPI Order is determined by a User's entry of the following into the Exchange: (1) RPI buy or sell interest; (2) an offset, if any; and (3) a ceiling or floor price. RPI Orders submitted with an offset are similar to other peg orders available to Users in that the order is tied or ''pegged'' to a certain price, and would have its price automatically set and adjusted upon changes in the Protected NBBO, both upon entry and any time thereafter. RPI buy or sell interest is typically entered to track the Protected NBBO, that is, RPI Orders are typically submitted with an offset. The offset is a predetermined amount by which the User is willing to improve the Protected NBBO, subject to a ceiling or floor price. The ceiling or floor price is the amount above or below which the User does not wish to trade. RPI Orders in their entirety (the buy or sell interest, the offset, and the ceiling or floor) will remain non-displayed. The Exchange also allows Users to enter RPI Orders that establish the exact limit price, which is similar to a non-displayed limit order currently accepted by the Exchange except the Exchange accepts sub-penny limit prices on RPI Orders in increments of $0.001. The Exchange monitors whether RPI buy or sell interest, adjusted by any offset and subject to the ceiling or floor price, is eligible to interact with incoming Retail Orders.

Users and RMOs may enter odd lots, round lots or mixed lots as RPI Orders and as Retail Orders respectively. As discussed below, RPI Orders are ranked and allocated according to price and time of entry into the System consistent with Rule 11.12 and therefore without regard to whether the size entered is an odd lot, round lot or mixed lot amount. Similarly, Retail Orders interact with RPI Orders according to the Priority and Allocation rules of the Program and without regard to whether they are odd lots, round lots or mixed lots. Finally, Retail Orders are designated as Type 1 or Type 2 without regard to the size of the order.

RPI Orders interact with Retail Orders as follows. Assume a User enters RPI sell interest with an offset of $0.001 and a floor of $10.10 while the Protected NBO is $10.11. The RPI Order could interact with an incoming buy Retail Order at $10.109. If, however, the Protected NBO was $10.10, the RPI Order could not interact with the Retail Order because the price required to deliver the minimum $0.001 price improvement ($10.099) would violate the User's floor of $10.10. If a User otherwise enters an offset greater than the minimum required price improvement and the offset would produce a price that would violate the User's floor, the offset would be applied only to the extent that it respects the User's floor. By way of illustration, assume RPI buy interest is entered with an offset of $0.005 and a ceiling of $10.112 while the Protected NBB is at $10.11. The RPI Order could interact with an incoming sell Retail Order at $10.112, because it would produce the required price improvement without violating the User's ceiling, but it could not interact above the $10.112 ceiling. Finally, if a User enters an RPI Order

28, 2016), 81 FR 43306 (July 1, 2016) (SR–BYX–2016–15); 81368 (August 10, 2017), 82 FR 38960 (August 16, 2017) (SR–BYX–2017–18).

[11] Concurrently with the filing of this proposed rule change, the Exchange is filing to extend the current pilot period until the earlier of approval of the filing to make this rule permanent (*i.e.,* this proposed rule change) or December 31, 2018.

[12] The Program will continue to only apply to trades occurring at prices equal to or greater than $1.00 per share.

[13] *See* RPI Approval Order, *supra* note 3 at 71655.

[14] *Id.*

[15] FINRA Rule 5320.03 clarifies that an RMO may enter Retail Orders on a riskless principal basis, provided that (i) the entry of such riskless principal orders meet the requirements of FINRA Rule 5320.03, including that the RMO maintains supervisory systems to reconstruct, in a time-[sic] sequenced manner, all Retail Orders that are entered on a riskless principal basis; and (ii) the RMO submits a report, contemporaneously with the execution of the facilitated order, that identifies the trade as riskless principal.

[16] Exchange systems prevent Retail Orders from interacting with RPI Orders if the RPI Order is not priced at least $0.001 better than the Protected NBBO. The Exchange notes, however, that price improvement of $0.001 would be a minimum requirement and Users could enter RPI Orders that better the Protected NBBO by more than $0.001. Exchange systems will accept RPI Orders without a minimum price improvement value; however, such interest will execute at its floor or ceiling price only if such floor or ceiling price is better than the Protected NBBO by $0.001 or more.

[17] The ''System'' is defined in BYX Rule 1.5(aa) as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.''

without an offset (*i.e.,* an explicitly priced limit order), the RPI Order will interact with Retail Orders at the level of the User's limit price as long as the minimum required price improvement is produced. Accordingly, if RPI sell interest is entered with a limit price of $10.098 and no offset while the Protected NBO is $10.11, the RPI Order could interact with the Retail Order at $10.098, producing $0.012 of price improvement. The System will not cancel RPI interest when it is not eligible to interact with incoming Retail Orders; such RPI interest will remain in the System and may become eligible again to interact with Retail Orders depending on the Protected NBBO.

RMO Qualifications and Application Process

Under Rule 11.24(b), any Member may qualify as an RMO if it conducts a retail business or routes retail orders on behalf of another broker-dealer. For purposes of Rule 11.24(b), conducting a retail business shall include carrying retail customer accounts on a fully disclosed basis. Any Member that wishes to obtain RMO status is required to submit: (1) An application form; (2) supporting documentation sufficient to demonstrate the retail nature and characteristics of the applicant's order flow; and (3) an attestation, in a form prescribed by the Exchange, that substantially all orders submitted as Retail Orders will qualify as such under Rule 11.24.[18] The Exchange shall notify the applicant of its decision in writing.

An RMO is required to have written policies and procedures reasonably designed to assure that it will only designate orders as Retail Orders if all requirements of a Retail Order are met. Such written policies and procedures must require the Member to (i) exercise due diligence before entering a Retail Order to assure that entry as a Retail Order is in compliance with the requirements of this rule, and (ii) monitor whether orders entered as Retail Orders meet the applicable requirements. If the RMO represents Retail Orders from another broker-dealer customer, the RMO's supervisory procedures must be reasonably designed to assure that the orders it receives from such broker-dealer customer that it designates as Retail Orders meet the definition of a Retail Order. The RMO must (i) obtain an annual written representation, in a form acceptable to the Exchange, from each broker-dealer customer that sends it orders to be designated as Retail Orders that entry of such orders as Retail Orders will be in compliance with the requirements of this rule, and (ii) monitor whether its broker-dealer customers' Retail Order flow continues to meet the applicable requirements.[19]

If the Exchange disapproves the application, the Exchange provides a written notice to the Member. The disapproved applicant could appeal the disapproval by the Exchange as provided in Rule 11.24(d), and/or reapply for RMO status 90 days after the disapproval notice is issued by the Exchange. An RMO also could voluntarily withdraw from such status at any time by giving written notice to the Exchange.

Failure of RMO To Abide by Retail Order Requirements

Rule 11.24(c) addresses an RMO's failure to abide by Retail Order requirements. If an RMO designates orders submitted to the Exchange as Retail Orders and the Exchange determines, in its sole discretion, that those orders fail to meet any of the requirements of Retail Orders, the Exchange may disqualify a Member from its status as an RMO. When disqualification determinations are made, the Exchange provides a written disqualification notice to the Member. A disqualified RMO may appeal the disqualification as provided in Rule 11.24(d) and/or reapply for RMO status 90 days after the disqualification notice is issued by the Exchange.

Appeal of Disapproval or Disqualification

Rule 11.24(d) provides appeal rights to Members. If a Member disputes the Exchange's decision to disapprove it as an RMO under Rule 11.24(b) or disqualify it under Rule 11.24(c), such Member (''appellant'') may request, within five business days after notice of the decision is issued by the Exchange, that the Retail Price Improvement Program Panel (''RPI Panel'') review the decision to determine if it was correct.

The RPI Panel consists of the Exchange's Chief Regulatory Officer (''CRO''), or a designee of the CRO, and two officers of the Exchange designated by the Chief Operating Officer (''COO''). The RPI Panel reviews the facts and render [sic] a decision within the time frame prescribed by the Exchange. The RPI Panel may overturn or modify an action taken by the Exchange and all determinations by the RPI Panel constitute final action by the Exchange on the matter at issue.

Retail Liquidity Identifier

Under Rule 11.24(e), the Exchange disseminates an identifier when RPI interest priced at least $0.001 better than the Exchange's Protected Bid or Protected Offer for a particular security is available in the System (''Retail Liquidity Identifier''). The Retail Liquidity Identifier is disseminated through consolidated data streams (*i.e.,* pursuant to the Consolidated Tape Association Plan/Consolidated Quotation Plan, or CTA/CQ, for Tape A and Tape B securities, and the Nasdaq UTP Plan for Tape C securities) as well as through proprietary Exchange data feeds.[20] The Retail Liquidity Identifier reflects the symbol and the side (buy or sell) of the RPI interest, but does not include the price or size of the RPI interest. In particular, CQ and UTP quoting outputs include a field for codes related to the Retail Liquidity Identifier. The codes indicate RPI interest that is priced better than the Exchange's Protected Bid or Protected Offer by at least the minimum level of price improvement as required by the Program.

Retail Order Designations

Under Rule 11.24(f), an RMO can designate how a Retail Order would interact with available contra-side interest as follows:

A Type 1-designated Retail Order will interact with available contra-side RPI Orders and other price improving contra-side interest but will not interact with other available contra-side interest in the System that is not offering price improvement or route to other markets. The portion of a Type 1-designated Retail Order that does not execute against contra-side RPI Orders or other price improving liquidity will be immediately and automatically cancelled.

A Type 2-designated Retail Order will interact first with available contra-side RPI Orders and other price improving liquidity and then any remaining

[18] For example, a prospective RMO could be required to provide sample marketing literature, website screenshots, other publicly disclosed materials describing the retail nature of their order flow, and such other documentation and information as the Exchange may require to obtain reasonable assurance that the applicant's order flow would meet the requirements of the Retail Order definition.

[19] The Exchange or another self-regulatory organization on behalf of the Exchange will review an RMO's compliance with these requirements through an exam-based review of the RMO's internal controls.

[20] The Exchange notes that the Retail Liquidity Identifier for Tape A and Tape B securities are disseminated pursuant to the CTA/CQ Plan. The identifier is also available through the consolidated public market data stream for Tape C securities. The processor for the Nasdaq UTP quotation stream disseminates the Retail Liquidity Identifier and analogous identifiers from other market centers that operate programs similar to the RPI Program.

portion of the Retail Order will be executed as an Immediate-or-Cancel (''IOC'') Order pursuant to Rule 11.9(b)(1). A Type 2-designated Retail Order can either be submitted as a BYX Only Order [21] or as an order eligible for routing pursuant to Rule 11.13(a)(2).

Priority and Order Allocation

Under Rule 11.24(g), competing RPI Orders in the same security are ranked and allocated according to price then time of entry into the System. Executions occur in price/time priority in accordance with Rule 11.12. Any remaining unexecuted RPI interest remains available to interact with other incoming Retail Orders if such interest is at an eligible price. Any remaining unexecuted portion of the Retail Order will cancel or execute in accordance with Rule 11.24(f). The following example illustrates this method:

- Protected NBBO for security ABC is $10.00–$10.05
- User 1 enters an RPI Order to buy ABC at $10.015 for 500
- User 2 then enters an RPI Order to buy ABC at $10.02 for 500
- User 3 then enters an RPI Order to buy ABC at $10.035 for 500

An incoming Retail Order to sell ABC for 1,000 executes first against User 3's bid for 500 at $10.035, because it is the best priced bid, then against User 2's bid for 500 at $10.02, because it is the next best priced bid. User 1 is not filled because the entire size of the Retail Order to sell 1,000 is depleted. The Retail Order executes against RPI Orders in price/time priority.

However, assume the same facts above, except that User 2's RPI Order to buy ABC at $10.02 is for 100. The incoming Retail Order to sell 1,000 executes first against User 3's bid for 500 at $10.035, because it is the best priced bid, then against User 2's bid for 100 at $10.02, because it is the next best priced bid. User 1 then receives an execution for 400 of its bid for 500 at $10.015, at which point the entire size of the Retail Order to sell 1,000 is depleted.

As a final example, assume the same facts as above, except that User 3's order was not an RPI Order to buy ABC at $10.035, but rather, a non-displayed order to buy ABC at $10.03. The result would be similar to the result immediately above, in that the incoming Retail Order to sell 1,000 executes first against User 3's bid for 500 at $10.03, because it is the best priced bid, then against User 2's bid for 100 at $10.02, because it is the next best priced bid. User 1 then receives an execution for 400 of its bid for 500 at $10.015, at which point the entire size of the Retail Order to sell 1,000 is depleted.

Eligible Securities

All Regulation NMS securities traded on the Exchange are eligible for inclusion in the RPI Program. The Exchange limits the Program to trades occurring at prices equal to or greater than $1.00 per share. Toward that end, Exchange trade validation systems prevent the interaction of RPI buy or sell interest (adjusted by any offset) and Retail Orders at a price below $1.00 per share.[22] For example, if there is RPI buy interest tracking the Protected NBB at $0.99 with an offset of $0.001 and a ceiling of $1.02, Exchange trade validation systems would prevent the execution of the RPI Order at $0.991 with a sell Retail Order with a limit of $0.99. However, if the Retail Order was Type 2 as defined the Program,[23] it would be able to interact at $0.99 with liquidity outside the Program in the Exchange's order book. In addition to facilitating an orderly [24] and operationally intuitive program, the Exchange believes that limiting the Program to trades equal to or greater than $1.00 per share enabled it better to focus its efforts to monitor price competition and to assess any indications that data disseminated under the Program is potentially disadvantaging retail orders. As part of that review, the Exchange produced data throughout the pilot, which included statistics about participation, the frequency and level of price improvement provided by the Program, and any effects on the broader market structure.

Rationale for Making the Program Pilot Permanent

The Exchange established the Program in an attempt to attract retail order flow to the Exchange by providing an opportunity for price improvement to such order flow. The Exchange believes that the Program promotes transparent competition for retail order flow by allowing Exchange members to submit RPI Orders to interact with Retail Orders. Such competition promotes efficiency by facilitating the price discovery process and generating additional investor interest in trading securities, thereby promoting capital formation and retail investment opportunities. The Program will continue to be limited to trades occurring at prices equal to or greater than $1.00 per share.

In accordance with its filing establishing the pilot, the Exchange did ''produce data throughout the pilot, which will include statistics about participation, the frequency and level of price improvement provided by the Program, and any effects on the broader market structure.'' [25] The Exchange has fulfilled this obligation through the reports and assessments it has submitted to the Commission since the implementation of the pilot Program. The Exchange believes that the data provided to the Commission to date, as well as the data being provided in this proposed rule change, support the continued operation of the Program on a permanent basis.

The SEC stated in the RPI Approval Order that the Program could promote competition for retail order flow among execution venues, and that this could benefit retail investors by creating additional well-regulated and transparent price improvement opportunities for marketable retail order flow, most of which is currently executed in the Over-the-Counter (''OTC'') markets without ever reaching a public exchange.[26] The Exchange believes that it has achieved its goal of attracting retail order flow to the Exchange. As the Exchange's analysis of the Program data below demonstrates, there has been consistent retail investor interest in the Program, which has provided tangible price improvement to those retail investors through a competitive pricing process over the course of the pilot. The data also demonstrates that the Program had an overall negligible impact on broader market quality outside of the Program. The Exchange has not received any

[21] A BYX Only Order is defined in BYX Rule 11.9(c)(4) and includes orders that are not eligible for routing to other trading centers.

[22] As discussed above, the price of an RPI is determined by a User's entry of buy or sell interest, an offset (if any) and a ceiling or floor price. RPI sell or buy interest typically tracks the Protected NBBO.

[23] Type 2 Retail Orders are treated as IOC orders that execute against displayed and non-displayed liquidity in the Exchange's order book where there is no available liquidity in the Program. Type 2 Retail Orders can either be designated as eligible for routing or as BYX Only Orders, and thus non-routable, as described above.

[24] Given the limitation, the Program would have no impact on the minimum pricing increment for orders priced less than $1.00 and therefore no effect on the potential of markets executing those orders to lock or cross. In addition, the non-displayed nature of the liquidity in the Program simply has no potential to disrupt displayed, protected quotes. In any event, the Program would do nothing to change the obligation of exchanges to avoid and reconcile locked and crossed markets under NMS Rule 610(d).

[25] RPI Approval Order, 77 FR at 71655.

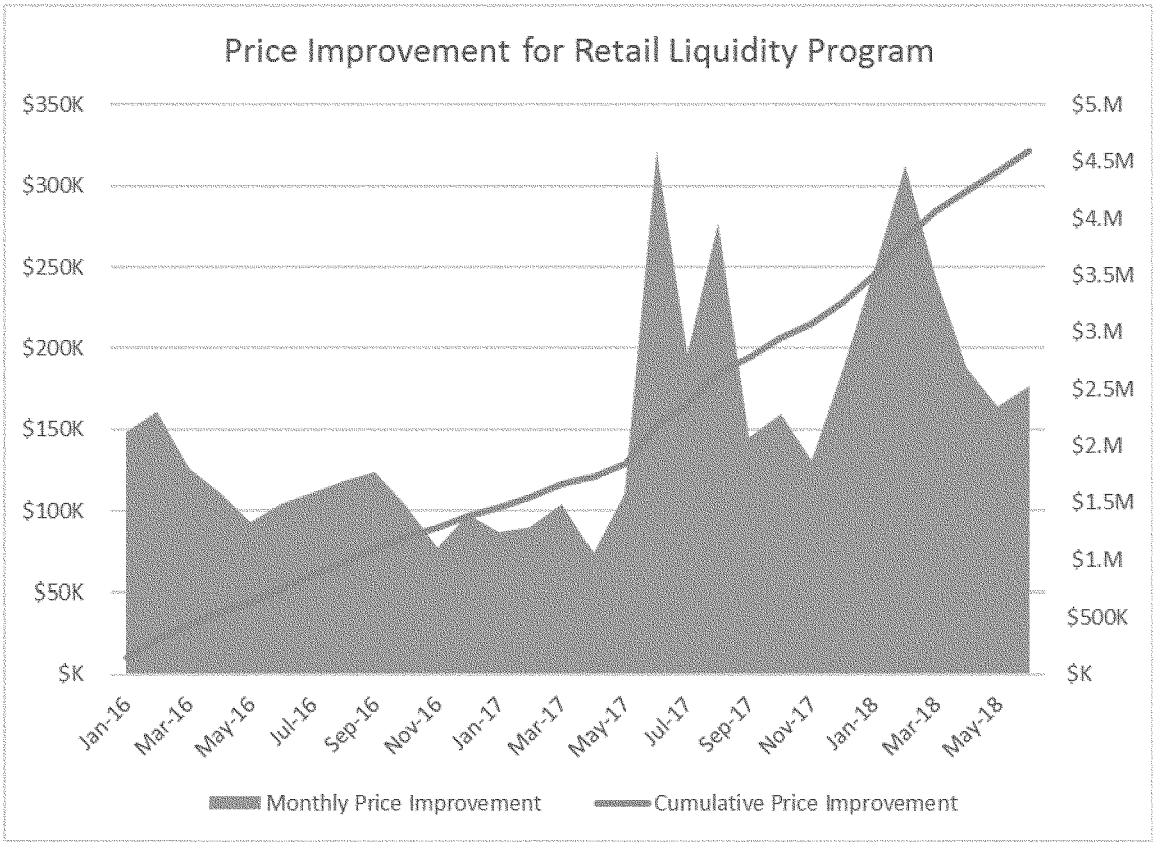
[26] *Id.*

complaints or negative feedback concerning the Program.

I. Overall Analysis of the Program

Brokers route retail orders to a wide range of different trading systems. The Program offers a transparent and well-regulated option, providing meaningful competition and price improvement. As explained above, the purpose of the Program is to attract retail order flow to the Exchange by providing an opportunity for retail investors to receive price improvement. The Exchange believes that the Program has satisfied this goal, having provided a total of $4.5 million of price improvement, or approximately $153,000 per month, in the last 2.5 years. Furthermore, while the amount of price improvement provided in the Program varies month to month, the amount of price improvement provided in recent months has generally increased relative to prior months due to additional participation in the Program by market participants with retail order flow. The Exchange believes that this supports permanent approval of the pilot as retail investors continue to reap the benefits afforded by the Program. The amount of monthly and cumulative price improvement provided in the Program is illustrated in Chart 1 below.

Chart 1: Price Improvement Summary



Furthermore, Retail Order volume executed in the Program accounted for between 0.86% and 2.32% of total BYX volume from January 2017 to June 2018, as shown in Chart 2 below, and between 0.05% and 0.11% of total consolidated volume, as shown in Chart 3 below. Despite its size relative to total volume executed on the Exchange or the broader market, the Program has continued to provide considerable price improvement each month to retail investors that participated in the Program. In addition, the Exchange believes that the relatively modest volume executed in the Program relative to total BYX volume and total consolidated volume limits the potential impact of the Program on broader market quality on the Exchange.[27] The Exchange therefore believes that the Program has demonstrated the effectiveness of a transparent, on-exchange retail order price improvement functionality, notwithstanding that the majority of retail volume is still traded off-exchange.

[27] The Exchange has also performed an analysis of the impact of the Program on other market quality indicators, which found that the Program did not have a significant impact on market quality in the broader market. *See* Section III below.

Chart 2: RPI Volume as a Percentage of Total BYX Volume

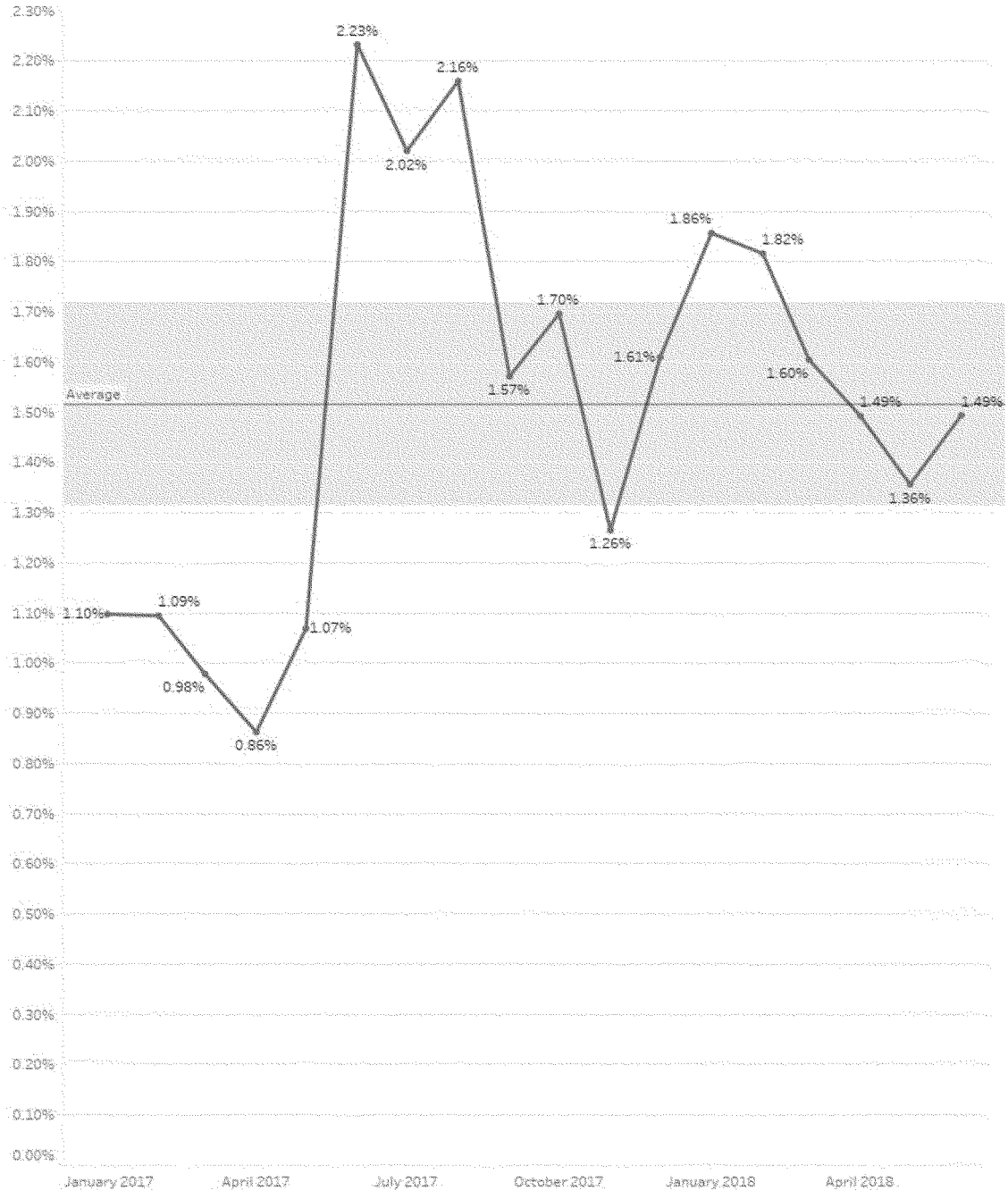
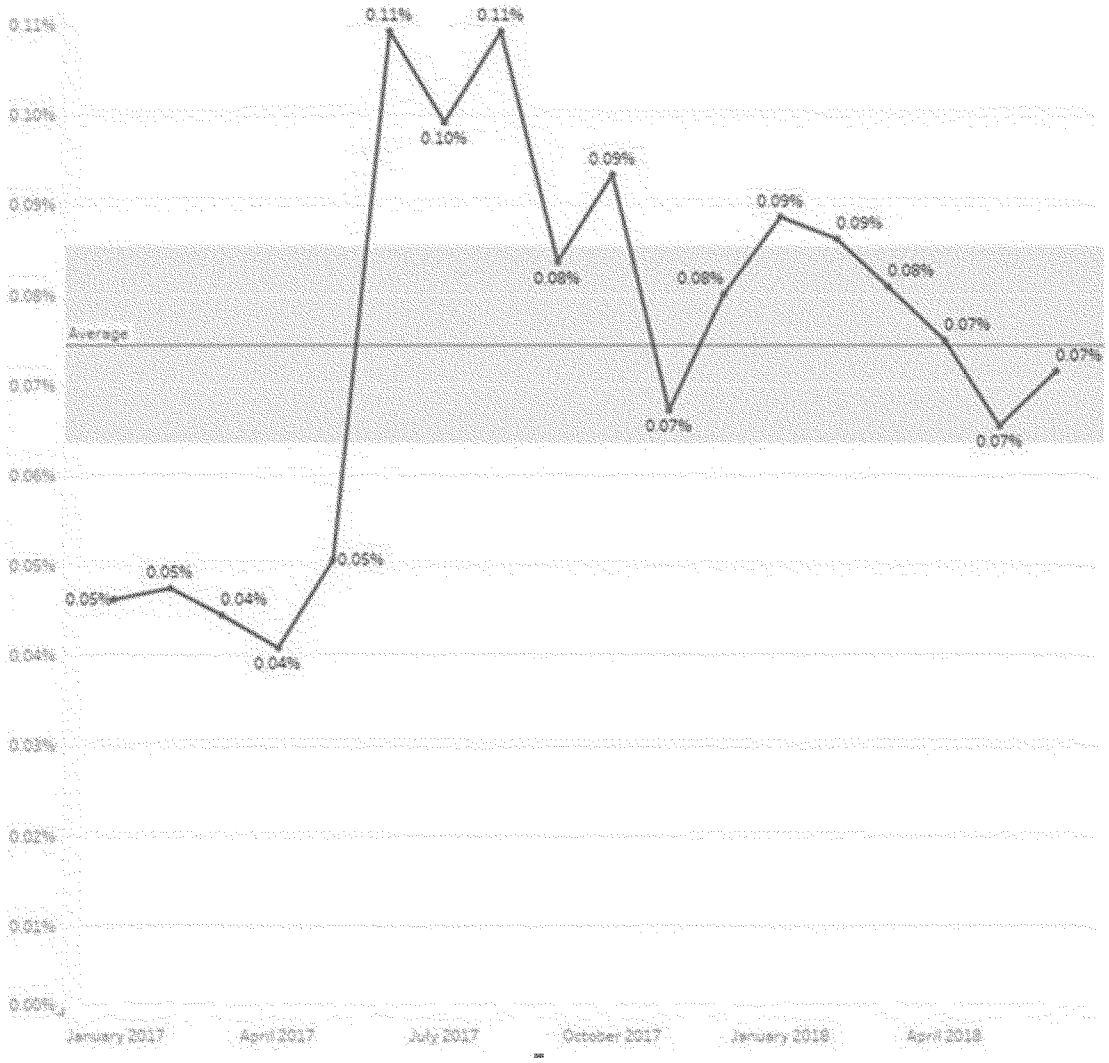


Chart 3: RPI Volume as a Percentage of Total Consolidated Volume



Retail Orders are routed by sophisticated brokers using systems that seek the highest fill rates and amounts of price improvement. These brokers have many choices of execution venues for this order flow. When they choose to route to the Program, they have determined that it is the best opportunity for fill rate and price improvement at that time. As shown in Table 1 below, Retail Order average daily volume (''ADV'') executed in the Program averaged between 2 and 7 million shares from January 2016 to June 2018. Increased volatility in February 2018 likely contributed to the increased Retail Order shares executed in the Program that month. Fill rates for the majority of the period studied ranged from 11%–19% with fill rates declining below 10% starting in December 2017, likely due to additional participation in the Program that resulted in a significant increase in the Retail Order volume entered on the Exchange. Retail Orders also continue to receive more than the minimum $0.001 price improvement required of a liquidity providing RPI Order, with the monthly average price improvement provided to Retail Orders ranging from $0.0011–$0.0014 per share, and the monthly effective/quoted spread ratio ranging from 0.77–0.90. The Exchange believes that this data supports permanent approval of the Program as this would allow retail investors to continue to execute their orders with price improvement in the Program.

TABLE 1—SUMMARY STATISTICS ON THE PROGRAM

Date	Retail shares executed ADV	Retail orders placed ADV	Effective spread BPS	Quoted spread BPS	Effective/ quoted spread ratio	Price improvement	Fill rate (%)
Jan-16	4,666,052	20,560	19	22	0.89	$0.0011	16.09
Feb-16	4,083,670	18,025	19	22	0.87	0.0011	16.10
Mar-16	3,474,997	15,103	21	24	0.90	0.0011	17.50
Apr-16	3,216,923	14,126	18	21	0.88	0.0011	19.23
May-16	2,912,160	12,980	18	21	0.87	0.0011	19.73

TABLE 1—SUMMARY STATISTICS ON THE PROGRAM—Continued

Date	Retail shares executed ADV	Retail orders placed ADV	Effective spread BPS	Quoted spread BPS	Effective/ quoted spread ratio	Price improvement	Fill rate (%)
Jun-16	3,144,024	13,924	16	18	0.89	0.0011	19.65
Jul-16	4,009,916	17,257	18	20	0.90	0.0011	19.97
Aug-16	3,906,624	17,135	19	21	0.90	0.0011	17.66
Sep-16	4,887,221	20,708	17	19	0.88	0.0011	17.28
Oct-16	3,595,900	15,922	24	27	0.90	0.0012	17.19
Nov-16	2,273,885	8,972	29	33	0.88	0.0013	12.71
Dec-16	3,192,065	12,768	36	41	0.88	0.0013	14.82
Jan-17	3,122,721	16,951	31	36	0.88	0.0013	16.09
Feb-17	3,262,046	21,151	31	35	0.88	0.0013	14.71
Mar-17	3,068,930	20,921	33	38	0.88	0.0014	13.85
Apr-17	2,680,646	18,518	34	38	0.88	0.0013	13.97
May-17	3,407,603	23,437	29	33	0.87	0.0013	16.88
Jun-17	7,896,833	46,398	28	32	0.88	0.0013	17.07
Jul-17	5,966,961	36,717	27	31	0.88	0.0012	16.43
Aug-17	6,467,615	38,608	23	26	0.88	0.0013	16.24
Sep-17	5,237,243	33,314	27	31	0.87	0.0013	15.76
Oct-17	5,702,759	33,578	34	40	0.84	0.0012	16.77
Nov-17	4,427,779	62,352	33	40	0.83	0.0012	11.61
Dec-17	5,131,502	142,810	34	41	0.84	0.0012	8.30
Jan-18	6,359,122	167,730	29	36	0.82	0.0013	7.98
Feb-18	7,230,230	227,980	21	27	0.79	0.0012	8.29
Mar-18	5,967,844	202,050	23	31	0.73	0.0011	7.69
Apr-18	4,976,642	178,009	20	27	0.75	0.0011	7.90
May-18	4,367,743	169,085	23	28	0.83	0.0011	7.02
Jun-18	5,211,044	202,601	23	31	0.77	0.0011	7.19

II. Analysis of Retail Orders by Order Size

Tables 2, 3, and 4 show the distribution of Retail Orders entered and executed in the Program for the period from January 2017 to June 2018. As shown in Table 2, a majority of all Retail Orders entered to participate in the Program from January 2016 to June 2018 were for a round lot or fewer shares. Specifically, Retail Orders of one round lot or fewer shares accounted for an average of approximately 56% of the total number of Retail Orders entered. More than 73% of Retail Orders entered were for 300 shares or less. Very large orders of more than 7,500 shares accounted for only 1.9% of Retail Orders submitted to the Program but accounted for a significant portion (approximately 40%) of the shares entered, as shown in Table 3. In addition, despite lower fill rates, large orders account for a reasonable portion (approximately 9%) of the shares executed in the Program, as shown in Table 4. The Program also receives a significantly large number of odd lot and single lot sized shares, which could be representative of retail marketable orders from retail customers. By providing price improvement to these orders, retail customers would continue to benefit from the Program.

TABLE 2—DISTRIBUTION OF RETAIL ORDERS ENTERED BY ORDER SIZE

Date	≤100 (%)	101–300 (%)	301–500 (%)	501–1,000 (%)	1,001–2,000 (%)	2,001–4,000 (%)	4,001–7,500 (%)	7,500–15,000 (%)	>15,000 (%)
Jan-17	44.90	18.45	8.60	10.12	6.84	4.90	3.10	1.93	1.16
Feb-17	47.80	18.04	8.21	9.61	6.27	4.41	2.82	1.75	1.09
Mar-17	47.60	17.76	8.16	9.67	6.36	4.60	3.01	1.78	1.05
Apr-17	48.82	17.30	7.88	9.48	6.19	4.61	2.88	1.82	1.02
May-17	52.39	18.69	7.13	8.13	5.21	3.81	2.40	1.41	0.83
Jun-17	55.32	13.89	6.67	8.08	5.35	4.47	3.24	2.03	0.95
Jul-17	53.18	15.12	7.32	8.85	5.86	4.12	2.71	1.79	1.05
Aug-17	49.41	16.53	8.00	9.65	6.33	4.49	2.75	1.76	1.08
Sep-17	49.88	16.51	7.94	9.50	6.27	4.49	2.71	1.71	1.00
Oct-17	49.92	16.17	7.73	9.45	6.49	4.67	2.76	1.79	1.02
Nov-17	61.01	17.66	5.65	6.33	3.86	2.54	1.39	0.98	0.59
Dec-17	61.48	18.49	6.31	6.65	3.40	1.97	0.93	0.49	0.28
Jan-18	61.20	17.06	6.54	7.14	3.84	2.25	1.06	0.58	0.33
Feb-18	66.63	15.79	5.61	5.80	2.98	1.70	0.80	0.43	0.25
Mar-18	66.11	15.39	5.82	6.22	3.25	1.76	0.78	0.41	0.24
Apr-18	67.41	15.45	5.40	6.06	3.10	1.43	0.59	0.34	0.22
May-18	66.09	16.12	5.43	6.30	3.41	1.47	0.59	0.35	0.24
Jun-18	66.29	16.17	5.59	6.14	3.20	1.46	0.59	0.35	0.22

TABLE 3—DISTRIBUTION OF SHARES ENTERED BY ORDER SIZE

Date	≤100 (%)	101–300 (%)	301–500 (%)	501–1,000 (%)	1,001–2,000 (%)	2,001–4,000 (%)	4,001–7,500 (%)	7,500–15,000 (%)	>15,000 (%)
Jan-17	2.15	3.45	3.27	7.03	9.15	12.48	14.61	17.00	30.87
Feb-17	2.36	3.64	3.40	7.30	9.16	12.29	14.52	16.80	30.53

TABLE 3—DISTRIBUTION OF SHARES ENTERED BY ORDER SIZE—Continued

Date	≤100 (%)	101–300 (%)	301–500 (%)	501–1,000 (%)	1,001–2,000 (%)	2,001–4,000 (%)	4,001–7,500 (%)	7,500–15,000 (%)	>15,000 (%)
Mar-17	2.25	3.55	3.36	7.32	9.21	12.68	15.38	16.92	29.33
Apr-17	2.36	3.54	3.32	7.32	9.17	13.00	14.92	17.45	28.91
May-17	3.44	4.59	3.60	7.51	9.25	12.92	15.02	16.32	27.35
Jun-17	1.89	2.89	2.92	6.64	8.44	13.27	17.56	20.05	26.34
Jul-17	1.98	3.18	3.22	7.24	9.17	12.23	14.73	18.29	29.96
Aug-17	1.92	3.36	3.39	7.59	9.57	12.76	14.33	17.21	29.87
Sep-17	2.15	3.49	3.43	7.55	9.70	13.15	14.55	17.27	28.70
Oct-17	1.97	3.34	3.30	7.41	9.91	13.48	14.54	17.90	28.16
Nov-17	6.28	5.19	3.86	7.92	9.53	12.10	12.18	16.22	26.72
Dec-17	9.96	7.34	5.96	11.51	11.24	12.70	11.15	11.31	18.83
Jan-18	8.56	6.29	5.64	11.27	11.49	13.17	11.61	12.18	19.79
Feb-18	11.33	7.16	6.01	11.31	11.12	12.42	10.99	11.30	18.37
Mar-18	11.06	6.96	6.10	12.00	11.88	12.69	10.62	10.82	17.88
Apr-18	12.30	7.46	5.95	12.51	12.19	11.17	8.89	9.73	19.80
May-18	12.14	7.50	5.74	12.40	12.76	11.08	8.53	9.67	20.17
Jun-18	12.39	7.77	6.12	12.60	12.60	11.42	8.76	9.89	18.45

TABLE 4—DISTRIBUTION OF SHARES EXECUTED BY ORDER SIZE

Date	≤100 (%)	101–300 (%)	301–500 (%)	501–1,000 (%)	1,001–2,000 (%)	2,001–4,000 (%)	4,001–7,500 (%)	7,500–15,000 (%)	>15,000 (%)
Jan-17	11.39	14.06	10.40	18.41	15.88	12.34	8.41	5.26	3.86
Feb-17	13.96	15.27	10.48	17.77	14.54	11.44	7.82	5.15	3.60
Mar-17	14.14	14.99	10.15	17.53	14.74	11.80	8.15	5.02	3.48
Apr-17	14.69	14.83	10.01	17.80	14.84	11.55	7.85	5.00	3.42
May-17	17.86	18.10	9.98	16.46	13.17	10.48	6.94	4.23	2.78
Jun-17	9.74	11.25	8.91	16.71	14.58	14.86	12.03	7.97	3.95
Jul-17	10.37	12.33	9.91	18.84	16.17	12.75	8.96	6.56	4.11
Aug-17	9.39	12.34	10.01	18.97	16.70	13.36	8.77	6.15	4.31
Sep-17	10.60	12.93	10.22	18.87	16.28	13.00	8.56	5.74	3.79
Oct-17	9.40	12.40	10.16	19.36	17.12	13.45	8.58	5.86	3.66
Nov-17	12.42	13.48	9.27	16.56	15.84	13.24	7.98	6.63	4.56
Dec-17	14.98	15.80	10.29	16.77	14.92	11.67	6.98	5.04	3.55
Jan-18	14.27	14.96	10.28	17.53	15.27	11.90	7.12	5.16	3.50
Feb-18	16.74	15.75	10.78	17.05	14.27	11.08	6.48	4.57	3.30
Mar-18	17.27	15.97	10.58	16.87	13.81	10.51	6.66	4.63	3.70
Apr-18	17.12	15.58	10.24	16.30	13.60	10.04	6.71	5.37	5.03
May-18	18.24	16.29	10.18	15.89	12.80	9.80	6.25	5.25	5.31
Jun-18	18.93	17.28	10.59	16.16	12.96	9.64	5.66	4.95	3.84

The Exchange also analyzed fill rates across the different order size buckets and found that while fill rates are higher for smaller orders as expected, large size orders are still able to access liquidity and therefore receive price improvement in the Program. Moreover, overall fill rates indicate that market participants that provide liquidity are responding with quote depth when the contra side order is looking for a fill. While fill rates decreased starting in November 2017, the Exchange believes that this is due to new Retail Order flow being routed to the Program, rather than a decrease in the available liquidity. Monthly volume executed in the Program, as shown in Table 1, has therefore remained constant or increased since November 2017 despite the lower overall fill rates for those months. The Exchange therefore believes that the Program is an attractive option for market participants looking to fill Retail Orders with price improvement.

TABLE 5—FILL RATES

Date	≤100 (%)	101–300 (%)	301–500 (%)	501–1,000 (%)	1,001–2,000 (%)	2,001–4,000 (%)	4,001–7,500 (%)	7,500–15,000 (%)	>15,000 (%)
Jan-17	85.19	65.62	51.13	42.16	27.93	15.91	9.26	4.98	2.01
Feb-17	87.21	61.69	45.31	35.83	23.36	13.69	7.92	4.51	1.73
Mar-17	87.04	58.53	41.87	33.20	22.18	12.89	7.34	4.11	1.65
Apr-17	86.90	58.46	42.12	33.97	22.59	12.40	7.35	4.00	1.65
May-17	87.53	66.54	46.75	36.99	24.03	13.69	7.80	4.38	1.71
Jun-17	87.78	66.50	52.07	42.98	29.48	19.12	11.70	6.78	2.56
Jul-17	85.99	63.63	50.52	42.77	28.96	17.12	9.99	5.89	2.25
Aug-17	79.61	59.74	48.02	40.59	28.33	17.00	9.94	5.81	2.34
Sep-17	77.55	58.32	46.98	39.39	26.44	15.58	9.27	5.24	2.08
Oct-17	80.19	62.29	51.71	43.82	28.97	16.73	9.90	5.49	2.18
Nov-17	22.78	29.93	27.66	24.11	19.16	12.61	7.55	4.71	1.97
Dec-17	12.14	17.37	13.96	11.77	10.72	7.42	5.05	3.60	1.52
Jan-18	12.84	18.31	14.06	11.98	10.24	6.96	4.72	3.26	1.36
Feb-18	11.79	17.56	14.32	12.03	10.24	7.12	4.70	3.23	1.43
Mar-18	11.56	17.00	12.85	10.42	8.60	6.13	4.64	3.17	1.53
Apr-18	10.61	15.91	13.11	9.93	8.50	6.85	5.76	4.21	1.94
May-18	10.11	14.61	11.93	8.62	6.75	5.95	4.93	3.65	1.77
Jun-18	10.57	15.39	11.98	8.88	7.12	5.84	4.47	3.46	1.44

III. Impact of the Program on Broader Market Quality

As shown in Charts 2 and 3 above, Retail Order volume executed in the Program is a small percentage of both total volume executed on the Exchange and total consolidated volume. While the Program has better depth available for Retail Orders, it does not significantly affect the market volume of BYX. The average volume within the 95th percentile is between 1.3% and 1.7%. With the Program volume mostly below 2.5% of BYX volume, the Exchange does not believe that it is able to significantly impact BYX market quality. Nevertheless, to test the impact of the Program on broader market quality, the Exchange reviewed the correlation between metrics that are tied to overall market quality with relevant Program metrics over both 2017 and 2018. Based on this analysis, which is provided in Table 6 below, the Exchange does not believe that the Program has had any significant impact on broader market quality.

Specifically, the Exchange's analysis shows that: (1) Inside size in the broader market is not correlated with either RPI effective spreads or the percentage of volume executed in the Program, which suggests that market participants are not moving volume from the regular market to the Program as effective spreads narrow or volume executed in the Program increases; (2) effective spreads in the broader market are not correlated with the percentage of volume executed in the Program, which suggests that spreads are not widening as a result of more Retail Order flow being executed in the Program, (3) midpoint volume executed is not correlated with effective spreads in the Program, which suggests that market participants are not moving midpoint liquidity from the regular market to instead receive price improvement in the Program, and (4) displayed volume executed is not correlated with quoted spreads in the Program, which suggest that market participants are not entering non-displayed retail price improving interest in the Program as an alternative to displaying interest on an order book. The Exchange therefore believes that the Program can continue on a permanent basis—and thereby provide increased price improvement opportunities to retail investors on a transparent well-regulated exchange—without degrading market quality outside of the Program.

TABLE 6—BYX MARKET QUALITY CORRELATION ANALYSIS

	Date	
	2017	2018
Correlation of RPI Effective Spread to Average Inside Size across all Equities Exchanges[28]	−0.0145	−0.0096
Correlation of RPI Volume as a Percent of Total Volume to Average Inside Size across all Equities Exchanges	−0.0217	−0.0056
Correlation of RPI Volume as a Percent of Total Volume to Average Effective Spread across all Venues	0.1175	0.0134
Correlation of RPI Effective Spread to Total Midpoint Volume across all Venues	−0.1438	−0.1366
Correlation of RPI Quoted Spread to Total Protected Lit Volume across all Equities Exchanges	−0.1221	−0.0999

IV. Conclusion

Based on the Exchange's experience in operating the Program, and the data provided here and during the duration of the pilot, the Exchange believes that the Program has been a positive experiment in attracting retail order flow to a public exchange. The data provided by the Exchange describes a valuable service that delivers considerable price improvement in a transparent and well-regulated environment. The Program represents just a fraction of retail orders, most of which are executed off-exchange by a wide range of order handling services that have considerably more market share, and which operate pursuant to different rules and regulatory requirements. The order flow the Program attracted to the Exchange provided tangible price improvement to retail investors through a competitive and transparent pricing process unavailable in non-exchange venues. As such, despite relatively modest volumes, the Exchange believes that the Program satisfied the twin goals of attracting retail order flow to the Exchange and allowing such order flow to receive potential price improvement. Moreover, the Exchange believes that the data collected supports the conclusion that the Program did not have a negative impact on broader market quality. Although the results of the Program highlight the substantial advantages that broker-dealers retain when managing the benefits of retail order flow, the Exchange believes that the level of price improvement provided by the Program and the scant evidence that the Program negatively impacted the marketplace justifies making the Program permanent.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[29] in general, and Section 6(b)(5) of the Act,[30] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that making the pilot permanent is consistent with these principles because the Program is reasonably designed to attract retail order flow to the exchange environment, while helping to ensure that retail investors benefit from the better price that liquidity providers are willing to give their orders. During the pilot period, the Exchange has provided data and analysis to the Commission. The Exchange believes that this data and analysis, as well as the further analysis provided in this filing, show that the Program has provided the intended benefits to the market, and retail investors in particular, and is therefore consistent with the Act.

Additionally, the Exchange believes the proposed rule change is designed to facilitate transactions in securities and to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system because making the Program permanent would allow the Exchange to continue to attract retail order flow to a public exchange and allow such order flow to receive potential price improvement. The data provided by the Exchange to the Commission staff demonstrates that the Program provided tangible price improvement to retail investors through a competitive pricing process

[28] Inside size is the average bid or ask size when the venue is at the NBB or NBO.

[29] 15 U.S.C. 78f(b).

[30] 15 U.S.C. 78f(b)(5).

unavailable in non-exchange venues, and otherwise had an insignificant impact on the broader market. The Exchange believes that making the Program permanent would encourage the additional utilization of, and interaction with, the Exchange and provide retail customers with an additional venue for price discovery, liquidity, competitive quotes, and price improvement. For the same reasons, the Exchange believes that making the Program permanent would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market.

Finally, the Exchange also believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition. For all of these reasons, the Exchange believes that the proposed rule change is consistent with the Act.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that making the Program permanent would continue to promote competition for retail order flow among execution venues and contribute to the public price discovery process. The Exchange believes that the data supplied to the Commission, and experience gained over the life of the pilot, have demonstrated that the Program creates price improvement opportunities for retail orders that are equal to what would be provided under OTC internalization arrangements, thereby benefiting retail investors and increasing competition between execution venues. The Exchange also believes that making the Program permanent will promote competition between execution venues operating their own retail liquidity programs. Such competition will lead to innovation within the market, thereby increasing the quality of the national market system. Finally, the Exchange notes that it operates in a highly competitive market in which market participants can easily direct their orders to competing venues, including off-exchange venues. In such an environment, the Exchange must continually review, and consider adjusting the services it offers and the requirements it imposes to remain competitive with other U.S. equity exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CboeBYX–2018–014 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–CboeBYX–2018–014. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR-CboeBYX–2018–014 and should be submitted on or before September 7, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2018–17736 Filed 8–16–18; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15567 and #15568; HAWAII Disaster Number HI–00049]

Presidential Declaration Amendment of a Major Disaster for the State of Hawaii

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Hawaii (FEMA–4366–DR), dated 06/14/2018.

Incident: Kilauea Volcanic Eruption and Earthquakes.

Incident Period: 05/03/2018 and continuing.

DATES: Issued on 06/14/2018.

Physical Loan Application Deadline Date: 09/12/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 03/14/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

[31] 17 CFR 200.30–3(a)(12).

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Hawaii, dated 06/14/2018, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 09/12/2018.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–17745 Filed 8–16–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Changes to SBA Secondary Market Program

AGENCY: U.S. Small Business Administration.

ACTION: Notice of changes to Secondary Market Program.

SUMMARY: The purpose of this Notice is to provide the public with notification of program changes to SBA's Secondary Market Loan Pooling Program. Specifically, SBA is increasing the minimum maturity ratio for both SBA Standard Pools and Weighted-Average Coupon (WAC) Pools by 1.0%, to 95.0%. The changes described in this Notice are being made to ensure that there are sufficient funds to cover the estimated cost of the timely payment guaranty for newly formed SBA 7(a) loan pools. The changes in this Notice will be incorporated, as needed, into the SBA Secondary Market Program Guide and all other appropriate SBA Secondary Market documents.

DATES: The changes will apply to SBA 7(a) loan pools with an issue date on or after October 1, 2018.

ADDRESSES: Address comments concerning this Notice to John M. Wade, Chief Secondary Market Division, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416, or *john.wade@sba.gov.*

FOR FURTHER INFORMATION CONTACT: John M. Wade, Chief, Secondary Market Division, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416, 202–205–3647, or *john.wade@sba.gov.*

SUPPLEMENTARY INFORMATION: The Secondary Market Improvements Act of 1984 authorized SBA to guarantee the timely payment of principal and interest on Pool Certificates. A Pool Certificate represents a fractional undivided interest in a ''Pool,'' which is an aggregation of SBA guaranteed portions of loans made by SBA Lenders under section 7(a) of the Small Business Act, 15 U.S.C. 636(a). In order to support the timely payment guaranty requirement, SBA established the Master Reserve Fund (''MRF''), which serves as a mechanism to cover the cost of SBA's timely payment guaranty. Borrower payments on the guaranteed portions of pooled loans, as well as SBA guaranty payments on defaulted pooled loans, are deposited into the MRF. Funds are held in the MRF until distributions are made to investors (''Registered Holders'') of Pool Certificates. The interest earned on the borrower payments and the SBA guaranty payments deposited into the MRF supports the timely payments made to Registered Holders.

From time to time, SBA provides guidance to SBA Pool Assemblers on the required loan and pool characteristics necessary to form a Pool. These characteristics include, among other things, the minimum number of guaranteed portions of loans required to form a Pool, the allowable difference between the highest and lowest gross and net note rates of the guaranteed portions of loans in a Pool, and the minimum maturity ratio of the guaranteed portions of loans in a Pool. The minimum maturity ratio is equal to the ratio of the shortest and the longest remaining term to maturity of the guaranteed portions of loans in a Pool.

On October 1, 2017, SBA increased the minimum maturity ratio for both SBA Standard Pools and Weighted-Average Coupon (WAC) Pools to 94.0%. Based on SBA's expectations as to the performance of future Pools, SBA has determined that, in order to support the costs associated with SBA's Secondary Market Loan Pooling Program, it is necessary to further increase the minimum maturity ratio—in other words, to reduce the difference between the shortest and the longest remaining term of the guaranteed portions of loans in a Pool. SBA does not expect a 1 percentage point increase in the minimum maturity ratio to have an adverse impact on either the program or the participants in the program. SBA has monitored Pools formed over the last 18 months and has observed that many existing Pools have a minimum maturity ratio of at least 95.0%.

A higher minimum maturity ratio will decrease the difference between the amortization rates of the guaranteed portions of loans in a Pool. This will cause the cash flows from the guaranteed portions of loans in the Pool to be more homogenous, and will more closely match the amortization rate of the Pool Certificate. This is the primary driver in reducing the cost of SBA's timely payment guaranty on Pool Certificates. Therefore, effective October 1, 2018, all guaranteed portions of loans in a Pool presented for settlement with SBA's Fiscal Transfer Agent will be required to have a minimum maturity ratio of at least 95% for Standard Pools and WAC Pools. SBA is making this change pursuant to Section 5(g)(2) of the Small Business Act, 15 U.S.C. 634(g)(2).

SBA will continue to monitor loan and pool characteristics and will provide notification of additional changes as necessary. It is important to note that there is no change to SBA's obligation to honor its guaranty of the amounts owed to Registered Holders of Pool Certificates and that such guaranty continues to be backed by the full faith and credit of the United States.

This program change will be incorporated as necessary into SBA's Secondary Market Guide and all other appropriate SBA Secondary Market documents. As indicated above, this change will be effective for Pools with an issue date on or after October 1, 2018, and will modify any previous guidance regarding the minimum maturity ratio for Standard Pools or WAC Pools.

John A. Miller,

Deputy Associate Administrator, Office of Capital Access.

[FR Doc. 2018–17726 Filed 8–16–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 10507]

E.O. 13224 Designation of Qassim Abdullah Ali Ahmed, aka Qassim al-Muamen, aka Qassim Al Muamen, aka Qassim Abdullah Ali, aka Qassim Abdullah as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the person known as Qassim Abdullah Ali Ahmed, aka Qassim al-Muamen, aka Qassim Al Muamen, aka Qassim Abdullah Ali, aka Qassim Abdullah, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States. Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order

who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: July 18, 2018.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2018–17818 Filed 8–16–18; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 10509]

Review of the Designation as a Foreign Terrorist Organization of Abu Sayyaf Group (and Other Aliases)

Based upon a review of the Administrative Record assembled pursuant to Section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) (''INA''), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the aforementioned organization as a Foreign Terrorist Organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation.

Therefore, I hereby determine that the designation of the aforementioned organization as a Foreign Terrorist Organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register**.

Dated: July 23, 2018.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2018–17816 Filed 8–16–18; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 10510]

Review of the Designation as a Foreign Terrorist Organization of Boko Haram (and Other Aliases)

Based upon a review of the Administrative Record assembled pursuant to Section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) (''INA''), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the aforementioned organization as a Foreign Terrorist Organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation.

Therefore, I hereby determine that the designation of the aforementioned organization as a Foreign Terrorist Organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register.**

Dated: July 23, 2018.

Michael R. Pompeo,

Secretary of State, Department of State.

[FR Doc. 2018–17817 Filed 8–16–18; 8:45 am]

BILLING CODE 4710–AD–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 519 (Sub-No. 4)]

Notice of National Grain Car Council Meeting

AGENCY: Surface Transportation Board (Board).

ACTION: Notice of National Grain Car Council meeting.

SUMMARY: Notice is hereby given of a meeting of the National Grain Car Council (NGCC), pursuant to the Federal Advisory Committee Act.

DATES: The meeting will be held on Thursday, September 13, 2018, beginning at 1:00 p.m. (CDT), and is expected to conclude at 5:00 p.m. (CDT).

ADDRESSES: The meeting will be held at the Kansas City Marriott Downtown, 200 West 12th Street, Kansas City, MO 64105 (Phone (816) 421–6800).

FOR FURTHER INFORMATION CONTACT: Fred Forstall at (202) 245–0241 or *alfred.forstall@stb.gov.* [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.]

SUPPLEMENTARY INFORMATION: The NGCC was established by the Interstate Commerce Commission (ICC) as a working group to facilitate private-sector solutions and recommendations to the ICC (and now the Board) on matters affecting rail grain car availability and transportation. *Nat'l Grain Car Supply—Conference of Interested Parties,* EP 519 (ICC served Jan. 7, 1994).

The general purpose of this meeting is to discuss rail carrier preparedness to transport the 2018 grain harvest. Agenda items include the following: Remarks by NGCC Chair Sharon G. Clark, Board Chair Ann D. Begeman, Board Vice Chairman and NGCC Co-Chair Deb Miller; reports by member groups on expectations for the upcoming harvest, domestic and foreign markets, the supply of rail cars, and rail service; and presentations by industry analysts. The full agenda, along with other information regarding the NGCC, is posted on the Board's website at *https://www.stb.gov/stb/rail/graincar_council.html.*

The meeting is open to the public and will be conducted pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2; Federal Advisory Committee Management, 41 CFR pt. 102–3; the NGCC charter; and Board procedures.

Public Comments: Members of the public may submit written comments to the NGCC at any time. Comments should be addressed to NGCC, c/o Fred Forstall, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001 or *alfred.forstall@stb.gov.* Any further communications about this meeting will be announced through the Board's website, *www.stb.gov.*

Decided: August 13, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2018–17779 Filed 8–16–18; 8:45 am]

BILLING CODE 4915–01–P

TENNESSEE VALLEY AUTHORITY

Meeting of the Regional Energy Resource Council

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Notice of meeting.

SUMMARY: The TVA Regional Energy Resource Council (RERC) will hold a meeting on Wednesday, September 5, 2018, to discuss the scenarios and strategies that TVA has identified for the 2019 Integrated Resource Plan.

The RERC was established to advise TVA on its energy resource activities and the priority to be placed among competing objectives and values. Notice of this meeting is given under the Federal Advisory Committee Act (FACA).

DATES: The public meeting will be held on Wednesday, September 5, 2018, from 10:00 a.m. to 4:00 p.m., EDT.

ADDRESSES: The meeting will be held at the Hilton Knoxville, 501 West Church Avenue, Knoxville, Tennessee 37902, and will be open to the public. Anyone needing special access or accommodations should let the contact below know at least a week in advance.

FOR FURTHER INFORMATION CONTACT: Barbie Perdue, 865–632–6113, *baperdue@tva.gov.*

SUPPLEMENTARY INFORMATION: The meeting agenda includes the following:

1. Introductions
2. Overview of the 2019 Integrated Resource Plan (IRP) and Supplemental Environmental Impact Statement status
3. Overview of the Scenarios and Strategies identified for the 2019 IRP
4. Public Comments
5. Council Discussion and Advice

The RERC will hear opinions and views of citizens by providing a public comment session starting at 12:45 p.m., EDT, lasting up to one hour, on Wednesday, September 5, 2018. Persons wishing to speak are requested to register at the door between 11:00 a.m. and 12:00 p.m., EDT, on Wednesday, September 5, 2018, and will be called on during the public comment period. TVA will set time limits for providing oral comments, once registered. Handout materials should be limited to one printed page. Written comments are also invited and may be mailed to the Regional Energy Resource Council, Tennessee Valley Authority, 400 West Summit Hill Drive, WT–9–D, Knoxville, Tennessee 37902.

Dated: August 10, 2018.

Joseph J. Hoagland,

Vice President, Enterprise Relations and Innovation, Tennessee Valley Authority.

[FR Doc. 2018–17756 Filed 8–16–18; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2018–42]

Petition for Exemption; Summary of Petition Received; Headquarters Air Force Junior Reserve Officer Training Corps

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from 14 CFR part 61.103(a), *Eligibility requirements,* which states in pertinent part that to be eligible for a private pilot certificate, a person must be at least 17 years of age for a rating other than a glider or balloon. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 6, 2018.

ADDRESSES: Send comments identified by docket number FAA–2018–0175 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Brent Hart (202) 267–4034, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 9, 2018.

Lirio Liu,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2018–0175.

Petitioner: Headquarters Air Force Junior Reserve Officer Training Corps.

Section(s) of 14 CFR Affected: 61.103(a).

Description of Relief Sought: The United States Air Force (USAF) is seeking an exemption to allow 16-year-old Junior Reserve Officer Training Corps (JROTC) cadets to qualify for a private pilot certificate under the HQ Air Force JROTC Flight Academy scholarship program. The USAF states that it is petitioning the FAA for an exemption because the selection board can only qualify a limited number of high school sophomores due to the 17-year-old minimum age requirement for private pilot applicants. The USAF further states that the 7- to 9-week flight academy private pilot training program is accomplished between the sophomore and junior years of high school. According to the USAF, allowing 16-year-olds to qualify would increase the cadet candidate pool by 75%, thereby improving the quality of the candidates who could be selected.

[FR Doc. 2018–17769 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Rescission of Notice of Intent (NOI) To Prepare an Environmental Impact Statement (EIS)

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The FHWA is issuing this notice to advise the public that we are rescinding the September 26, 2013, NOI to prepare an EIS for a proposed project, the I–90 Tolling Project, to manage congestion and traffic flow on I–90 between I–5 and I–405, and contribute revenue to the sustainable, long-term funding for timely completion of the SR 520 Bridge Replacement and HOV Program and maintenance and future transportation improvements on I–90.

FOR FURTHER INFORMATION CONTACT: Lindsey Handel, Urban Transportation Engineer, Federal Highway Administration, Washington Division, 711 S. Capitol Way, Suite 501, Olympia, WA 98501; telephone: 360–753–9550; and email: *lindsey.handel@dot.gov.*

SUPPLEMENTARY INFORMATION: On September 26, 2013, FHWA published a Notice of Intent to prepare an EIS for the I–90 Tolling Project to manage congestion and traffic flow on I–90 between I–5 and I–405, and contribute revenue to the sustainable, long-term funding for timely completion of the SR 520 Bridge Replacement and HOV Program and maintenance and future transportation improvements on I–90. The passage of the Connecting Washington state funding package in 2015 provided sufficient funding to complete the SR 520 Bridge Replacement, eliminating part of the purpose for this project. Any future I–90 tolling projects will progress under a separate environmental review process in accordance with all applicable laws and regulations.

Issued on: August 13, 2018.

Daniel M. Mathis,

FHWA Division Administrator, Olympia, WA.

[FR Doc. 2018–17757 Filed 8–16–18; 8:45 am]

BILLING CODE 4910–RY–P

FEDERAL REGISTER

Vol. 83 Friday,

No. 160 August 17, 2018

Book 2 of 3 Books

Pages 41143–41784

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, et al.

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, and 495

[CMS–1694–F]

RIN 0938–AT27

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2019. Some of these changes implement certain statutory provisions contained in the 21st Century Cures Act and the Bipartisan Budget Act of 2018, and other legislation. We also are making changes relating to Medicare graduate medical education (GME) affiliation agreements for new urban teaching hospitals. In addition, we are providing the market basket update that will apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis, subject to these limits for FY 2019. We are updating the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2019.

In addition, we are establishing new requirements or revising existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs). We also are establishing new requirements or revising existing requirements for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (now referred to as the Promoting Interoperability Programs). In addition, we are finalizing modifications to the requirements that apply to States operating Medicaid Promoting Interoperability Programs. We are updating policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

We also are making changes relating to the required supporting documentation for an acceptable Medicare cost report submission and the supporting information for physician certification and recertification of claims.

DATES: This final rule is effective on October 1, 2018.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, MS–DRGs, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Sole Community Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment Issues.

Michele Hudson, (410) 786–4487, Mark Luxton, (410) 786–4530, and Emily Lipkin, (410) 786–3633, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, (410) 786–0110, Frontier Community Health Integration Project Demonstration Issues.

Cindy Tourison, (410) 786–1093, Hospital Readmissions Reduction Program—Readmission Measures for Hospitals Issues.

James Poyer, (410) 786–2261, Hospital Readmissions Reduction Program—Administration Issues.

Elizabeth Bainger, (410) 786–0529, Hospital-Acquired Condition Reduction Program Issues.

Joseph Clift, (410) 786–4165, Hospital-Acquired Condition Reduction Program—Measures Issues.

Grace Snyder, (410) 786–0700 and James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Reena Duseja, (410) 786–1999 and Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Kim Spalding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Joel Andress, (410) 786–5237 and Caitlin Cromer, (410) 786–3106, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Mary Pratt, (410) 786–6867, Long-Term Care Hospital Quality Data Reporting Issues.

Elizabeth Holland, (410) 786–1309, Promoting Interoperability Programs Clinical Quality Measure Related Issues.

Kathleen Johnson, (410) 786–3295 and Steven Johnson (410) 786–3332, Promoting Interoperability Programs Nonclinical Quality Measure Related Issues.

Kellie Shannon, (410) 786–0416, Acceptable Medicare Cost Report Submissions Issues.

Thomas Kessler, (410) 786–1991, Physician Certification and Recertification of Claims.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the internet at: *http://www.gpo.gov/fdsys.*

Tables Available Through the Internet on the CMS Website

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, the majority of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables, generally, will be available only through the internet. The IPPS tables for this final rule are available through the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/*

AcuteInpatientPPS/index.html. Click on the link on the left side of the screen titled, ''FY 2019 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2019 final rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1694–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified above should contact Michael Treitel at (410) 786–4552.

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This final rule makes payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it makes payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This final rule also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

We are establishing new requirements and revising existing requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare. We also are establishing new requirements and revising existing requirements for eligible professionals (EPs), eligible hospitals, and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs. We are updating policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

We are making changes relating to the supporting documentation required for an acceptable Medicare cost report submission and the supporting information for physician certification and recertification of claims.

Under various statutory authorities, we are making changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2019 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Pub. L. 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act and section 15002 of the 21st Century Cures Act, which establishes the ''Hospital

Readmissions Reduction Program.'' Under the program, payments for discharges from an ''applicable hospital'' under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare cohorts of hospitals to each other in determining the extent of excess readmissions.

- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 Percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 Percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured (minus 0.2 percentage point for FY 2018 and FY 2019); and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016, and provides for a 4-year transitional blended payment rate for discharges occurring in LTCH cost reporting periods beginning in FYs 2016 through 2019. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1886(m)(6) of the Act, as amended by section 15009 of the 21st Century Cures Act (Pub. L. 114–255), which provides for a temporary exception to the application of the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals for discharges in cost reporting periods beginning during FYs 2018 and 2019.
- Section 1886(m)(6) of the Act, as amended by section 15010 of the 21st Century Cures Act (Pub. L. 114–255), which provides for a temporary exception to the application of the site neutral payment rate under the LTCH PPS for certain LTCHs with certain discharges with severe wounds occurring in cost reporting periods beginning during FY 2018.
- Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206(c) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which provides for the establishment of a functional status quality measure in the LTCH QRP for change in mobility among inpatients requiring ventilator support.
- Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.

2. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement, in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that will foster operational efficiencies and will reduce costs, including collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures, where possible, such as electronic clinical quality measures; [3]
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities, as shown in the following table:

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections. Preventable Healthcare Harm.
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals. End of Life Care According to Preferences. Patient's Experience of Care. Patient Reported Functional Outcomes.

[1] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[2] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

[3] We refer readers to section VIII.A.9.c. of the preamble of this final rule where we discuss public comments on the potential future development and adoption of eCQMs.

Quality priority	Meaningful measure area
Promote Effective Communication and Coordination of Care	Medication Management. Admissions and Readmissions to Hospitals. Transfer of Health Information and Interoperability.
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care. Management of Chronic Conditions. Prevention, Treatment, and Management of Mental Health. Prevention and Treatment of Opioid and Substance Use Disorders. Risk Adjusted Mortality.
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care. Community Engagement.
Make Care Affordable	Appropriate Use of Healthcare. Patient-focused Episode of Care. Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers, while reducing burden and costs for clinicians and providers, as well as promoting operational efficiencies.

We received numerous comments from stakeholders regarding the Meaningful Measures Initiative and the impact of its implementation in CMS' quality programs. Many of these comments pertained to specific program proposals, and are discussed in the appropriate program-specific sections of this final rule. However, commenters also provided insights and recommendations for the ongoing development of the Meaningful Measures Initiative generally, including: ensuring transparency in public reporting and usability of publicly reported data; evaluating the benefit of individual measures to patients via use in quality programs weighed against the burden to providers of collecting and reporting that measure data; and identifying additional opportunities for alignment across CMS quality programs. We look forward to continuing to work with stakeholders to refine and further implement the Meaningful Measures Initiative, and will take commenters' insights and recommendations into account moving forward.

3. Summary of the Major Provisions

Below we provide a summary of the major provisions in this final rule. In general, these major provisions are as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the proposed changes that we included in the proposed rule issued prior to this final rule is presented in section I.D. of the preamble of this final rule.

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2019, we are making an adjustment of +0.5 percent to the standardized amount.

b. Expansion of the Postacute Care Transfer Policy

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, we are making conforming amendments to § 412.4(c) of the regulation, effective for discharges on or after October 1, 2018, to specify that if a discharge is assigned to one of the MS–DRGs subject to the postacute care transfer policy and the individual is transferred to hospice care by a hospice program, the discharge is subject to payment as a transfer case.

c. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this FY 2019 IPPS/LTCH PPS final rule, we are updating our estimates of the three factors used to determine uncompensated care payments for FY 2019. We are continuing to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in the calculation of Factor 2. We also are continuing to incorporate data from Worksheet S–10 in the calculation of hospitals' share of the aggregate amount

of uncompensated care by combining data on uncompensated care costs from Worksheet S–10 for FYs 2014 and 2015 with proxy data regarding a hospital's share of low-income insured days for FY 2013 to determine Factor 3 for FY 2019. In addition, we are using only data regarding low-income insured days for FY 2013 to determine the amount of uncompensated care payments for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers. For this final rule, we are establishing the following policies: (1) For providers with multiple cost reports, beginning in the same fiscal year, to use the longest cost report and annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) in the rare case where a provider has multiple cost reports, beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year, such that the hospital has no cost report for that fiscal year, the cost report that spans both fiscal years will be used for the latter fiscal year; and (3) to apply statistical trim methodologies to potentially aberrant cost-to-charge ratios (CCRs) and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

d. Changes to the LTCH PPS

In this final rule, we set forth changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2019. In addition, we are eliminating the 25-percent threshold policy, and under this policy, we are applying a one-time adjustment of approximately 0.9 percent to the LTCH PPS standard Federal payment rate in FY 2019 to ensure this elimination of the 25-percent threshold policy is budget neutral.

e. Reduction of Hospital Payments for Excess Readmissions

We are making changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act and further amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2018 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). In this final rule, we are establishing the applicable periods for FY 2019, FY 2020, and FY 2021. We also are codifying the definitions of dual-eligible patients, the proportion of dual-eligibles, and the applicable period for dual-eligibility.

f. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. As part of agency-wide efforts under the Meaningful Measures Initiative to use a parsimonious set of the most meaningful measures for patients, clinicians, and providers in our quality programs and the Patients Over Paperwork Initiative to reduce costs and burden and program complexity, as discussed in section I.A.2. of the preamble of this final rule, we are removing a total of 4 measures from the Hospital VBP Program, all of which will continue to be used in the Hospital IQR Program, in order to reduce the costs and complexity of tracking these measures in multiple programs. Specifically, we are removing one measure, beginning with the FY 2021 program year: (1) Elective Delivery (NQF #0469) (PC–01). We also are removing three measures from the Hospital VBP Program, effective with the effective date of this FY 2019 IPPS/LTCH PPS final rule: (1) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment); (2) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and (3) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (PN Payment) (NQF #2579). In addition, we are renaming the Clinical Care domain as the Clinical Outcomes domain, beginning with the FY 2020 program year. We also are adopting measure removal factors for the Hospital VBP Program.

We are not finalizing our proposals to remove of the following six patient safety measures: (1) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); (2) National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139); (3) American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753); (4) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia (MRSA) Outcome Measure (NQF #1716); (5) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and (6) Patient Safety and Adverse Events (Composite) (NQF #0531) (PSI 90). We are not finalizing our proposal to remove the Safety domain from the Hospital VBP Program, as we are not finalizing our proposals to remove all of the measures in this domain, and therefore we also are not finalizing changes to the domain weighting.

g. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to a hospital whose ranking in the worst-performing quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. As part of our agency-wide Patients over Paperwork and Meaningful Measures Initiatives, discussed in section I.A.2. of the preamble of this final rule, we are retaining the measures currently included in the HAC Reduction Program because the measures address a performance gap in patient safety and reduce harm caused in the delivery of care. In this final rule, we are: (1) Establishing administrative policies to collect, validate, and publicly report NHSN healthcare-associated infection (HAI) quality measure data that facilitate a seamless transition, independent of the Hospital IQR Program, beginning with January 1, 2020 infectious events; (2) changing the scoring methodology by removing domains and assigning equal weighting to each measure for which a hospital has a measure; and (3) establishing the

applicable period for FY 2021. In addition, we are summarizing comments we received regarding the potential future inclusion of additional measures, including eCQMs.

h. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year.

In this final rule, we are making several changes. As part of agency-wide efforts under the Meaningful Measures Initiative to use a parsimonious set of the most meaningful measures for patients and clinicians in our quality programs and the Patients Over Paperwork initiative to reduce burden, cost, and program complexity, as discussed in section I.A.2. of the preamble of this final rule, we are adding a new measure removal factor and removing a total of 39 measures from the Hospital IQR Program. We are finalizing a modified version of our proposal to remove 5 of those measures such that removal is delayed by 1 year. For a full list of measures being removed, we refer readers to section VIII.A.5.c. of the preamble of this final rule. Beginning with the CY 2018 reporting period/FY 2020 payment determination and subsequent years, we are removing 17 claims-based measures and two structural measures. Beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years, we are removing three chart-abstracted measures and two claims-based measures. Beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years, we are removing six chart-abstracted measures, one claims-based measure, and seven eCQMs from the Hospital IQR Program measure set. Beginning with the CY 2021 reporting period/FY 2023 payment determination, we are removing one claims-based measure.

In addition, for the CY 2019 reporting period/FY 2021 payment determination, we are: (1) Requiring the same eCQM reporting requirements that were adopted for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38355 through 38361), such that hospitals submit one, self-selected calendar quarter of 2019 data for 4 eCQMs in the Hospital IQR Program measure set; and (2) requiring that hospitals use the 2015 Edition certification criteria for CEHRT. These changes are in alignment with changes or current established policies under the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). In addition, we are summarizing public comments we received on two measures we are considering for potential future inclusion in the Hospital IQR Program, as well as on the potential future development and adoption of electronic clinical quality measures generally.

i. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The LTCH QRP is authorized by section 1886(m)(5) of the Act and applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Under the LTCH QRP, the Secretary reduces by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH fails to submit data in accordance with the LTCH QRP requirements specified for that fiscal year. As part of agency-wide efforts under the Meaningful Measures Initiative to use a parsimonious set of the most meaningful measures for patients and clinicians in our quality programs and the Patients Over Paperwork Initiative to reduce cost and burden and program complexity, as discussed in section I.A.2. of the preamble of this final rule, we are removing three measures from the LTCH QRP. We also are adopting a new measure removal factor and are codifying the measure removal factors in our regulations. In addition, we are updating our regulations to expand the methods by which an LTCH is notified of noncompliance with the requirements of the LTCH QRP for a program year and how CMS will notify an LTCH of a reconsideration decision.

j. Medicare and Medicaid Promoting Interoperability Programs (Previously Referred to as Medicare and Medicaid EHR Incentive Programs)

In this final rule, we are finalizing several changes to reduce burden, increase interoperability and improve patient electronic access to their health information under the Medicare and Medicaid Promoting Interoperability Programs (previously referred to as Medicare and Medicaid EHR Incentive Programs). Specifically, we are finalizing: (1) An EHR reporting period of a minimum of any continuous 90 days in CYs 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency; (2) modifications to our proposed performance-based scoring methodology, which consists of a smaller set of objectives as well as a smaller set of new and modified measures; (3) the removal of certain CQMs beginning with the reporting period in CY 2020 as well as the CY 2019 reporting requirements we proposed to align the CQM reporting requirements for the Promoting Interoperability Programs with the Hospital IQR Program; (4) the codification of policies for subsection (d) Puerto Rico hospitals; (5) amendments to the prior approval policy applicable in the Medicaid Promoting Interoperability Program to align with the prior approval policy for MMIS and ADP systems and to minimize burden on States; and (6) deadlines for funding availability for States to conclude the Medicaid Promoting Interoperability Program.

4. Summary of Costs and Benefits

- *Adjustment for MS–DRG Documentation and Coding Changes.* Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) For FY 2019, we are making an adjustment of +0.5 percent to the standardized amount consistent with the MACRA.
- *Expansion of the Postacute Care Transfer Policy.* Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, we are making conforming amendments to § 412.4(c) of the regulation to specify that, effective for discharges on or after October 1, 2018, if a discharge is assigned to one of the MS–DRGs subject to the postacute care transfer policy, and the individual is transferred to hospice care by a hospice program, the discharge will be subject to payment as a transfer case. We estimate that this statutory expansion to the postacute care transfer policy will reduce Medicare payments under the IPPS by approximately $240 million in FY 2019.
- *Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care.* Under section 1886(r) of the Act (as added by section

3133 of the Affordable Care Act), DSH payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment for uncompensated care is made to eligible hospitals, beginning in FY 2014. Hospitals that receive Medicare DSH payments receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, is the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments. Each hospital that receives Medicare DSH payments will receive an additional payment for uncompensated care based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2019, we are updating our estimates of the three factors used to determine uncompensated care payments. We are continuing to use uninsured estimates produced by OACT as part of the development of the NHEA in the calculation of Factor 2. We also are continuing to incorporate data from Worksheet S–10 in the calculation of hospitals' share of the aggregate amount of uncompensated care by combining data on uncompensated care costs from Worksheet S–10 for FY 2014 and FY 2015 with proxy data regarding a hospital's share of low-income insured days for FY 2013 to determine Factor 3 for FY 2019. To determine the amount of uncompensated care for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers, we are using only the data regarding low-income insured days for FY 2013. In addition, in this final rule, we are establishing the following policies: (1) For providers with multiple cost reports beginning in the same fiscal year, to use the longest cost report and annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) in the rare case where a provider has multiple cost reports beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year such that the hospital has no cost report for that fiscal year, the cost report that spans both fiscal years will be used for the latter fiscal year; and (3) to apply statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs.

We project that the amount available to distribute as payments for uncompensated care for FY 2019 will increase by approximately $1.5 billion, as compared to the estimate of overall payments, including Medicare DSH payments and uncompensated care payments, that will be distributed in FY 2018. The payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are estimated to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges.

- *Update to the LTCH PPS Payment Rates and Other Payment Policies.* Based on the best available data for the 409 LTCHs in our database, we estimate that the changes to the payment rates and factors that we present in the preamble and Addendum of this final rule, which reflect the continuation of the transition of the statutory application of the site neutral payment rate, the update to the LTCH PPS standard Federal payment rate for FY 2019, and the one-time permanent adjustment of approximately 0.9 percent to the LTCH PPS standard Federal payment rate to ensure the elimination of the 25-percent threshold policy is budget neutral, will result in an estimated increase in payments in FY 2019 of approximately $39 million.
- *Changes to the Hospital Readmissions Reduction Program.* For FY 2019 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). Overall, in this final rule, we estimate that 2,610 hospitals will have their base operating DRG payments reduced by their determined proxy FY 2019 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $566 million in FY 2019.
- *Value-Based Incentive Payments under the Hospital VBP Program.* We estimate that there will be no net financial impact to the Hospital VBP Program for the FY 2019 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2019 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2019 discharges is approximately $1.9 billion.
- *Changes to the HAC Reduction Program.* A hospital's Total HAC score and its ranking in comparison to other hospitals in any given year depend on several different factors. Any significant impact due to the HAC Reduction Program changes for FY 2019, including which hospitals will receive the adjustment, will depend on actual experience.

The removal of NHSN HAI measures from the Hospital IQR Program and the subsequent cessation of its validation processes for NHSN HAI measures and the creation of a validation process for the HAC Reduction program represent no net change in reporting burden across CMS hospital quality programs. However, with the finalization of our proposal to remove HAI chart-abstracted measures from the Hospital IQR Program, we anticipate a total burden shift of 43,200 hours and approximately $1.6 million, as a result of no longer needing to validate those HAI measures under the Hospital IQR Program and beginning the validation process under the HAC Reduction Program.

- *Changes to the Hospital Inpatient Quality Reporting (IQR) Program.* Across 3,300 IPPS hospitals, we estimate that our finalized requirements for the Hospital IQR Program in this final rule will result in the following changes to costs and burdens related to information collection for this program, compared to previously adopted requirements: (1) A total collection of information burden reduction of 1,046,138 hours and a total cost reduction of approximately $38.3 million for the CY 2019 reporting period/FY 2021 payment determination, due to the removal of ED–1, IMM–2, and VTE–6 measures; and (2) a total collection of information burden reduction of 858,000 hours and a total cost reduction of $31.3 million for the CY 2020 reporting period/FY 2022 payment determination due to the removal of ED–2; and (3) a total collection of information burden reduction of 43,200 hours and a total of $1.6 million for the CY 2021 reporting period/FY 2023 payment determination due to validation of the NHSN HAI measures no longer being conducted under the Hospital IQR Program once the HAC Reduction Program begins validating these measures, as discussed

in the preamble of this final rule for the HAC Reduction Program.

Further, we anticipate that the removal of 39 measures will result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures, as well as the tools we need to collect, validate, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs. We anticipate that our finalized policies will reduce the above-described costs.

- *Changes Related to the LTCH QRP.* In this final rule, we are removing two measures beginning with the FY 2020 LTCH QRP and one measure beginning with the FY 2021 LTCH QRP, for a total of three measures. We also are adopting a new quality measure removal factor for the LTCH QRP. We estimate that the impact of these changes is a reduction in costs of approximately $1,148 per LTCH annually or approximately $482,469 for all LTCHs annually.
- *Changes to the Medicare and Medicaid Promoting Interoperability Programs.* We believe that, overall, the finalized proposals in this final rule will reduce burden, as described in detail in section XIV.B.9. of the preamble and Appendix A, section I.N. of this final rule.

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment that considers the amount of uncompensated care beginning on October 1, 2013.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. Through and including FY 2006, an MDH received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate was exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006 through September 30, 2015 all LTCHs were paid 100 percent of the Federal rate. Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, based on a rolling effective date that is linked to the date on which a given LTCH's Federal FY 2016 cost reporting period begins, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Implemented in This Final Rule

1. Pathway for SGR Reform Act of 2013 (Pub. L. 113–67)

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) introduced new payment rules in the LTCH PPS. Under section 1206 of this law, discharges in cost reporting periods beginning on or after October 1, 2015, under the LTCH PPS, receive payment under a site neutral rate unless the discharge meets certain patient-specific criteria. In this final rule, we are continuing to update certain policies that implemented provisions under section 1206 of the Pathway for SGR Reform Act.

2. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). In this final rule, we are continuing to implement portions of section 1899B of the Act, as added by section 2(a) of the IMPACT Act, which, in part, requires LTCHs, among other post-acute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

3. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

4. The 21st Century Cures Act (Pub. L. 114–255)

The 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, contained the following provision affecting payments under the Hospital Readmissions Reduction Program,

which we are continuing to implement in this final rule:

• Section 15002, which amended section 1886(q)(3) of the Act by adding subparagraphs (D) and (E), which requires the Secretary to develop a methodology for calculating the excess readmissions adjustment factor for the Hospital Readmissions Reduction Program based on cohorts defined by the percentage of dual-eligible patients (that is, patients who are eligible for both Medicare and full-benefit Medicaid coverage) cared for by a hospital. In this final rule, we are continuing to implement changes to the payment adjustment factor to assess penalties based on a hospital's performance, relative to other hospitals treating a similar proportion of dual-eligible patients.

5. The Bipartisan Budget Act of 2018 (Pub. L. 115–123)

The Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, contains provisions affecting payments under the IPPS and the LTCH PPS, which we are implementing or continuing to implement in this final rule:

• Section 50204 amended section 1886(d)(12) of the Act to provide for certain temporary changes to the low-volume hospital payment adjustment policy for FYs 2018 through 2022. For FY 2018, this provision extends the qualifying criteria and payment adjustment formula that applied for FYs 2011 through 2017. For FYs 2019 through 2022, this provision modifies the discharge criterion and payment adjustment formula. In FY 2023 and subsequent fiscal years, the qualifying criteria and payment adjustment revert to the requirements that were in effect for FYs 2005 through 2010.

• Section 50205 extends the MDH program through FY 2022. It also provides for an eligible hospital that is located in a State with no rural area to qualify for MDH status under an expanded definition if the hospital satisfies any of the statutory criteria at section 1886(d)(8)(E)(ii)(I), (II) (as of January 1, 2018), or (III) of the Act to be reclassified as rural.

• Section 51005(a) modified section 1886(m)(6) of the Act by extending the blended payment rate for site neutral payment rate LTCH discharges for cost reporting periods beginning in FY 2016 by an additional 2 years (FYs 2018 and 2019). In addition, section 51005(b) reduces the LTCH IPPS comparable per diem amount used in the site neutral payment rate for FYs 2018 through 2026 by 4.6 percent. In this final rule, we are making conforming changes to the existing regulations.

• Section 53109 modified section 1886(d)(5)(J) of the Act to require that, beginning in FY 2019, discharges to hospice care also qualify as a postacute care transfer and are subject to payment adjustments.

D. Issuance of a Notice of Proposed Rulemaking

In the proposed rule that appeared in the **Federal Register** on May 7, 2018 (83 FR 20164), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2019 operating costs and for capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2019.

Below is a general summary of the major changes that we proposed to make in the proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included—

• Proposed changes to MS–DRG classifications based on our yearly review for FY 2019.

• Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2019 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.

• Proposed recalibration of the MS–DRG relative weights.

• A discussion of the proposed FY 2019 status of new technologies approved for add-on payments for FY 2018 and a presentation of our evaluation and analysis of the FY 2019 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to the proposed rule, we proposed to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

• The proposed FY 2019 wage index update using wage data from cost reporting periods beginning in FY 2015.

• Proposal regarding other wage-related costs in the wage index.

• Calculation of the proposed occupational mix adjustment for FY 2019 based on the 2016 Occupational Mix Survey.

• Analysis and implementation of the proposed FY 2019 occupational mix adjustment to the wage index for acute care hospitals.

• Proposed application of the rural floor and the frontier State floor and the proposed expiration of the imputed floor.

• Proposals to codify policies regarding multicampus hospitals.

• Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.

• The proposed adjustment to the wage index for acute care hospitals for FY 2019 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.

• Determination of the labor-related share for the proposed FY 2019 wage index.

• Public comment solicitation on wage index disparities.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section IV. of the preamble of the proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

• Proposed changes to MS–DRGs subject to the postacute care transfer policy and special payment policy and implementation of the statutory changes to the postacute care transfer policy.

• Proposed changes to the inpatient hospital update for FY 2019.

• Proposed changes related to the statutory changes to the low-volume hospital payment adjustment policy.

• Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.

• The statutorily required IME adjustment factor for FY 2019.

• Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.

• Proposed changes to the effective date of SCH and MDH classification status determinations.

• Proposed changes related to the extension of the MDH program.

• Proposed changes to the rules for payment adjustments under the

Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates for FY 2019.

- Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2019.
- Proposed changes to Medicare GME affiliation agreements for new urban teaching hospitals.
- Discussion of and proposals relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2019.
- Proposed revisions of the hospital inpatient admission orders documentation requirements.

4. Proposed FY 2019 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2019.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of the proposed rule, we discussed—

- Proposed changes to payments to certain excluded hospitals for FY 2019.
- Proposed changes to the regulations governing satellite facilities.
- Proposed changes to the regulations governing excluded units of hospitals.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of the proposed rule, we set forth—

- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2019.
- Proposed changes to the blended payment rate for site neutral payment rate cases.
- Proposed elimination of the 25-percent threshold policy.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of the proposed rule, we address—

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- Proposed changes to the requirements under the LTCH Quality Reporting Program (LTCH QRP).
- Proposed changes to requirements pertaining to the clinical quality measurement for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

8. Proposed Revision to the Supporting Documentation Requirements for an Acceptable Medicare Cost Report Submission

In section IX. of the preamble of the proposed rule, we set forth proposed revisions to the supporting documentation required for an acceptable Medicare cost report submission.

9. Requirements for Hospitals To Make Public List of Standard Charges

In section X. of the preamble of the proposed rule, we discussed our efforts to further improve the public accessibility of hospital standard charge information, effective January 1, 2019, in accordance with section 2718(e) of the Public Health Service Act.

10. Proposed Revisions Regarding Physician Certification and Recertification of Claims

In section XI. of the preamble of the proposed rule, we set forth proposed revisions to the requirements for supporting information used for physician certification and recertification of claims.

11. Request for Information

In section XII. of the preamble of the proposed rule, we included a request for information on the possible establishment of CMS patient health and safety requirements for hospitals and other Medicare- and Medicaid-participating providers and suppliers for interoperable electronic health records and systems for electronic health care information exchange.

12. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to the proposed rule, we set forth the proposed changes to the amounts and factors for determining the proposed FY 2019 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to the proposed rule, we addressed the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2019 for certain hospitals excluded from the IPPS.

13. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2019 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2019. We proposed to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

14. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, and PCHs.

15. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2019 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

16. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2018 recommendations concerning hospital inpatient payment

policies addressed the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2018 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at: *http://www.medpac.gov*.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS–DRG Reclassifications

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2018 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; and 82 FR 38010 through 38085, respectively).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. FY 2019 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90.

In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustment Made for FY 2018 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the

adjustment for FY 2018 from a 0.5 percentage point to a 0.4588 percentage point. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. This is a permanent adjustment to payment rates. While we did not address future adjustments required under section 414 of the MACRA and section 15005 of Public Law 114–255 at that time, we stated that we expected to propose positive 0.5 percentage point adjustments to the standardized amounts for FYs 2019 through 2023.

3. Adjustment for FY 2019

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20176 and 20177), consistent with the requirements of section 414 of the MACRA, we proposed to implement a positive 0.5 percentage point adjustment to the standardized amount for FY 2019. We indicated that this would be a permanent adjustment to payment rates. We stated in the proposed rule that we plan to propose future adjustments required under section 414 of the MACRA for FYs 2020 through 2023 in future rulemaking.

Comment: Several commenters stated that CMS has misinterpreted the Congressional directives regarding the level of positive adjustment required for FY 2018 and FY 2019. The commenters contended that, while the positive adjustments required under section 414 of the MACRA would only total 3.0 percentage points by FY 2023, the levels of these adjustments were determined using an estimated positive ''3.2 percent baseline'' adjustment that otherwise would have been made in FY 2018. The commenters believed that because CMS implemented an adjustment of −1.5 percentage points instead of the expected −0.8 percentage points in FY 2017, totaling −3.9 percentage points overall, CMS has imposed a permanent −0.7 percentage point negative adjustment beyond its statutory authority, contravening what the commenters asserted was Congress' clear instructions and intent. A majority of the commenters requested that CMS reverse its previous position and implement additional 0.7 percentage point adjustments for both FY 2018 and FY 2019. Some of the commenters requested that CMS use its statutory discretion to ensure that all 3.9 percentage points in negative adjustment be restored. In addition, some of the commenters, while acknowledging that CMS may be bound by law, expressed opposition to the permanent reductions and requested that CMS refrain from making any additional coding adjustments in the future.

Response: As we discussed in the FY 2019 IPPS/LTCH PPS proposed rule, we believe section 414 of the MACRA and section 15005 of the 21st Century Cures Act clearly set forth the levels of positive adjustments for FYs 2018 through 2023. We are not convinced that the adjustments prescribed by MACRA were predicated on a specific ''baseline'' adjustment level. While we had anticipated making a positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA, section 414 of the MACRA required that we implement a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023, and not the single positive adjustment we intended to make in FY 2018. As noted by the commenters, and discussed in the FY 2017 IPPS/LTCH PPS final rule, by phasing in a total positive adjustment of only 3.0 percentage points, section 414 of the MACRA would not fully restore even the 3.2 percentage points adjustment originally estimated by CMS in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515). Moreover, as discussed in the FY 2018 IPPS/LTCH PPS final rule, Public Law 114–255, which further reduced the positive adjustment required for FY 2018 from 0.5 percentage point to 0.4588 percentage point, was enacted on December 13, 2016, after CMS had proposed and finalized the final negative −1.5 percentage points adjustment required under section 631 of the ATRA. We see no evidence that Congress enacted these adjustments with the intent that CMS would make an additional +0.7 percentage point adjustment in FY 2018 to compensate for the higher than expected final ATRA adjustment made in FY 2017.

After consideration of the public comments we received, we are finalizing the +0.5 percentage point adjustment to the standardized amount for FY 2019, as required under section 414 of the MACRA.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785 through 56787) for a detailed discussion of the history of changes to the number of cost centers used in calculating the DRG relative weights. Since FY 2014, we have calculated the IPPS MS–DRG relative weights using 19 CCRs, which now include distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion of Policy for FY 2019

Consistent with our established policy, we calculated the final MS–DRG relative weights for FY 2019 using two data sources: the MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the 19 CCRs and the MS–DRG relative weights for FY 2019 is included in section II.G. of the preamble to this FY 2019 IPPS/LTCH PPS final rule. As we did with the FY 2018 IPPS/LTCH PPS final rule, for this FY 2019 final rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled ''FY 2019 IPPS Final Rule Home Page'' or ''Acute Inpatient Files for Download.''

Comment: One commenter requested that CMS use a single diagnostic radiology CCR to set weights, rather than using the separate CT and MRI cost centers. The commenter requested that if CMS maintains the separate CT and MRI cost centers, CMS not include cost reports from hospitals that use the ''square foot'' allocation methodology. The commenter provided an analysis to support its assertion that the CCRs for CT and MRI are incorrect and are inappropriately reducing payments under the IPPS. The commenter indicated that the charge compression hypothesis has been shown to be false with the use of the separate CT and MRI cost centers. The commenter discussed problems with cost allocation to the CT and MRI cost centers and referenced discussions in prior IPPS/LTCH PPS rules about this issue. The commenter acknowledged that CMS did not include a specific proposal in the FY 2019 proposed rule regarding this issue.

Response: As the commenter noted, we did not make any proposal for FY 2019 relating to the number of cost centers used to calculate the relative weights. As noted previously and discussed in detail in prior rulemakings, and as noted in response to a similar public comment received last year, we have calculated the IPPS MS–DRG relative weights using 19 CCRs, including distinct CCRs for MRIs and CT scans, since FY 2014. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785) for a detailed discussion of the basis for establishing these 19 CCRs. We further note that in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50518 through 50523), we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

We will continue to explore ways in which we can improve the accuracy of the cost report data and calculated CCRs used in the cost estimation process.

F. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2019 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for FY 2019 MS–DRG Updates

CMS has previously encouraged input from our stakeholders concerning the annual IPPS updates when that input was made available to us by December 7 of the year prior to the next annual proposed rule update. As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), as we work with the public to examine the ICD–10 claims data used for updates to the ICD–10 MS DRGs, we would like to examine areas where the MS–DRGs can be improved, which will require additional time for us to review requests from the public to make specific updates, analyze claims data, and consider any proposed updates. Given the need for more time to carefully evaluate requests and propose updates, we changed the deadline to request updates to the MS–DRGs to November 1 of each year. This will provide an additional 5 weeks for the data analysis and review process. Interested parties had to submit any comments and suggestions for FY 2019 by November 1, 2017, and are encouraged to submit any comments and suggestions for FY 2020 by November 1, 2018 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*. The comments that were submitted in a timely manner for FY 2019 are discussed in this section of the preamble of this final rule.

Following are the changes that we proposed to the MS–DRGs for FY 2019 in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20177 through 20257). We invited public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in the proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we proposed to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. For the FY 2019 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2017 update of the FY 2017 MedPAR file, which contains hospital bills received through September 30, 2017, for discharges occurring through September 30, 2017. In our discussion of the proposed MS–DRG reclassification changes, we referred to our analysis of claims data from the ''September 2017 update of the FY 2017 MedPAR file.''

In this FY 2019 IPPS/LTCH PPS final rule, we summarize the public comments we received on our proposals, present our responses, and state our final policies. For this FY 2019 final rule, we did not perform any further MS–DRG analysis of claims data. Therefore, all of the data analysis is based on claims data from the September 2017 update of the FY 2017 MedPAR file, which contains bills received through September 30, 2017, for discharges occurring through September 30, 2017.

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent;
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup;
- At least 500 cases are in the CC or MCC subgroup;
- There is at least a 20-percent difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

We are making the FY 2019 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 36, the ICD–10 MS–DRG Definitions Manual files Version 36 and the Definitions of Medicare Code Edits Manual Version 36 available to the public on our CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html.

2. Pre-MDC

a. Heart Transplant or Implant of Heart Assist System

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), we stated our intent to review the ICD–10 logic for Pre-MDC MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively), as well as MS–DRG 215 (Other Heart Assist System Implant) and MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively) where procedures involving heart assist devices are currently assigned. We also encouraged the public to submit any comments on restructuring the MS–DRGs for heart assist system procedures to the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2017.

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20178 through 20179), the logic for Pre-MDC MS–DRGs 001 and 002 is comprised of two lists. The first list includes procedure codes identifying a heart transplant procedure, and the second list includes procedure codes identifying the implantation of a heart assist system. The list of procedure codes identifying the implantation of a heart assist system includes the following three codes.

ICD–10–PCS code	Code description
02HA0QZ	Insertion of implantable heart assist system into heart, open approach.
02HA3QZ	Insertion of implantable heart assist system into heart, percutaneous approach.
02HA4QZ	Insertion of implantable heart assist system into heart, percutaneous endoscopic approach.

In addition to these three procedure codes, there are also 33 pairs of code combinations or procedure code ''clusters'' that, when reported together, satisfy the logic for assignment to MS–DRGs 001 and 002. The code combinations are represented by two procedure codes and include either one code for the insertion of the device with one code for removal of the device or one code for the revision of the device with one code for the removal of the device. The 33 pairs of code combinations are listed below.

Code	Code description		Code	Code description
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.

Code	Code description		Code	Code description
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA0QZ	Revision of implantable heart assist system in heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA0QZ	Revision of implantable heart assist system in heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA0QZ	Revision of implantable heart assist system in heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA0RZ	Revision of short-term external heart assist system in heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA0RZ	Revision of short-term external heart assist system in heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA0RZ	Revision of short-term external heart assist system in heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA3RZ	Revision of short-term external heart assist system in heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA3RZ	Revision of short-term external heart assist system in heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA3RZ	Revision of short-term external heart assist system in heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA4QZ	Revision of implantable heart assist system in heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA4QZ	Revision of implantable heart assist system in heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA4QZ	Revision of implantable heart assist system in heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA4RZ	Revision of short-term external heart assist system in heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA4RZ	Revision of short-term external heart assist system in heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA4RZ	Revision of short-term external heart assist system in heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.

In response to our solicitation for public comments on restructuring the MS–DRGs for heart assist system procedures, commenters recommended that CMS maintain the current logic under the Pre-MDC MS–DRGs 001 and 002. Similar to the discussion in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38011 through 38012) involving MS–DRG 215 (Other Heart Assist System Implant), the commenters provided examples of common clinical scenarios involving a left ventricular assist device (LVAD) and included the procedure codes that were reported under the ICD–9 based MS–DRGs in comparison to the procedure codes reported under the ICD–10 MS–DRGs, which are reflected in the following table.

Procedure	ICD–9–CM procedure code	ICD–9 MS–DRG	ICD–10–PCS codes	ICD–10 MS–DRG
New LVAD inserted	37.66 (Insertion of implantable heart assist system).	001 or 002	02WA0QZ (Insertion of implantable heart assist system into heart, open approach). 02WA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach). 02WA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach).	001 or 002

Procedure	ICD–9–CM procedure code	ICD–9 MS–DRG	ICD–10–PCS codes	ICD–10 MS–DRG
LVAD Exchange—existing LVAD is removed and replaced with either new LVAD system or new LVAD pump.	37.63 (Repair of heart assist system).	215	02PA0QZ (Removal of implantable heart assist system from heart, open approach). 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach). 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach) and. 02WA0QZ (Insertion of implantable heart assist system into heart, open approach). 02WA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach). 02WA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach).	001 or 002
LVAD revision and repair—existing LVAD is adjusted or repaired without removing the existing LVAD device.	37.63 (Repair of heart assist system).	215	02WA0QZ (Revision of implantable heart assist system in heart, open approach). 02WA3QZ (Revision of implantable heart assist system in heart, percutaneous approach). 02WA4QZ (Revision of implantable heart assist system in heart, percutaneous endoscopic approach).	215

The commenters noted that, for Pre-MDC MS–DRGs 001 and 002, the procedures involving the insertion of an implantable heart assist system, such as the insertion of a LVAD, and the procedures involving exchange of an LVAD (where an existing LVAD is removed and replaced with either a new LVAD or a new LVAD pump) demonstrate clinical similarities and utilize similar resources. Although the commenters recommended that CMS maintain the current logic under the Pre-MDC MS–DRGs 001 and 002, they also recommended that CMS continue to monitor the data in these MS–DRGs for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of patients undergoing procedures utilizing heart assist devices. The commenters also requested that coding guidance be issued for assignment of the correct ICD–10–PCS procedure codes describing LVAD exchanges to encourage accurate reporting of these procedures.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20180), we stated that we agree with the commenters that we should continue to monitor the data in Pre-MDC MS–DRGs 001 and 002 for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of patients undergoing procedures utilizing heart assist devices. In response to the request that coding guidance be issued for assignment of the correct ICD–10–PCS procedure codes describing LVAD exchanges to encourage accurate reporting of these procedures, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), coding advice is issued independently from payment policy. We also noted that, historically, we have not provided coding advice in rulemaking with respect to policy (82 FR 38045). We collaborate with the American Hospital Association (AHA) through the Coding Clinic for ICD–10–CM and ICD–10–PCS to promote proper coding. We recommended that the requestor and other interested parties submit any questions pertaining to correct coding for these technologies to the AHA.

In response to the public comments we received on this topic, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20180), we provided the results of our claims analysis from the September 2017 update of the FY 2017 MedPAR file for cases in Pre-MDC MS–DRGs 001 and 002. Our findings are shown in the following table.

MS–DRGs FOR HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 001—All cases	1,993	35.6	$185,660
MS–DRG 002—All cases	179	18.3	99,635

As shown in this table, for MS–DRG 001, there were a total of 1,993 cases with an average length of stay of 35.6 days and average costs of $185,660. For MS–DRG 002, there were a total of 179 cases with an average length of stay of 18.3 days and average costs of $99,635.

We then examined claims data in Pre-MDC MS–DRGs 001 and 002 for cases that reported one of the three procedure codes identifying the implantation of a heart assist system such as the LVAD. Our findings are shown in the following table.

MS–DRGs FOR HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 001—All cases	1,993	35.6	$185,660

MS–DRGs FOR HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 001—Cases with procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach)	1,260	35.5	206,663
MS–DRG 001—Cases with procedure code 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach)	1	8	33,889
MS–DRG 001—Cases with procedure code 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 002—All cases	179	18.3	99,635
MS–DRG 002—Cases with procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach)	82	19.9	131,957
MS–DRG 002—Cases with procedure code 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach)	0	0	0
MS–DRG 002—Cases with procedure code 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach)	0	0	0

As shown in this table, for MS–DRG 001, there were a total of 1,260 cases reporting procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach) with an average length of stay of 35.5 days and average costs of $206,663. There was one case that reported procedure code 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach) with an average length of stay of 8 days and average costs of $33,889. There were no cases reporting procedure code 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach). For MS–DRG 002, there were a total of 82 cases reporting procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach) with an average length of stay of 19.9 days and average costs of $131,957. There were no cases reporting procedure codes 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach) or 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach).

We also examined the cases in MS–DRGs 001 and 002 that reported one of the possible 33 pairs of code combinations or clusters. Our findings are shown in the following 8 tables. The first table provides the total number of cases reporting a procedure code combination (or cluster) compared to all of the cases in the respective MS–DRG, followed by additional detailed tables showing the number of cases, average length of stay, and average costs for each specific code combination that was reported in the claims data.

HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM

MS–DRGs 001 and 002	Number of cases	Average length of stay	Average costs
MS–DRG 001—All cases	1,993	35.6	$185,660
MS–DRG 001—Cases with a procedure code combination (cluster)	149	28.4	179,607
MS–DRG 002—All cases	179	18.3	99,635
MS–DRG 002—Cases with a procedure code combination (cluster)	6	3.8	57,343

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02HA0RS (Insertion of biventricular short-term external heart assist system into heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	3	20.3	$121,919
Cases with a procedure code combination of 02HA0RS (Insertion of biventricular short-term external heart assist system into heart, open approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	2	12	114,688
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	5	17	119,027

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

	Number of cases	Average length of stay	Average costs
MS–DRG 001			
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	30	55.6	$351,995
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	19	29.8	191,163

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM—Continued

	Number of cases	Average length of stay	Average costs
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	49	45.6	289,632
MS–DRG 002			
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	1	4	48,212
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	2	4.5	66,386
All cases reporting one or more of the above procedure code combinations in MS–DRG 002	3	4.3	60,328
All cases reporting one or more of the above procedure code combinations across both MS–DRGs 001 and 002	52	43.3	276,403

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

	Number of cases	Average length of stay	Average costs
MS–DRG 001			
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	3	43.3	$233,330
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	24	14.8	113,955
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	1	44	153,284
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	28	18.9	128,150
MS–DRG 002			
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	2	4	30,954
All cases reporting one of the above procedure code combinations in MS–DRG 002	2	4	30,954
All cases reporting one or more of the above procedure code combinations across both MS-DRGs 001 and 002	30	17.9	121,670

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	4	17.3	$154,885
Cases with a procedure code combination of 02HA4RZ (Insertion of short-term external heart assist system into heart, open approach *with* 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	2	15.5	80,852
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	6	16.7	130,207

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02WA0QZ (Revision of implantable heart assist system in heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	1	105	$516,557

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02WA0RZ (Revision of short-term external heart assist system in heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	2	40	$285,818
Cases with a procedure code combination of 02WA0RZ (Revision of short-term external heart assist system in heart, open approach) *with* 02PA03Z (Removal of short-term external heart assist system from heart, percutaneous approach)	1	43	372,673
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	3	41	314,770

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

	Number of cases	Average length of stay	Average costs
MS–DRG 001			
Cases with a procedure code combination of 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	2	24	$123,084
Cases with a procedure code combination of 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	55	14.7	104,963
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	57	15	105,599
MS–DRG 002			
Cases with a procedure code combination of 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	1	2	101,168
All cases reporting one or more of the above procedure code combinations across both MS–DRGs 001 and 002	58	14.8	105,522
MS–DRG 001			
Cases with a procedure code combination of 02WA4RZ (Revision of short-term external heart assist system in heart, percutaneous endoscopic approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	1	10	112,698

We did not find any cases reporting the following procedure code combinations (clusters) in the claims data.

02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.

The data show that there are differences in the average length of stay and average costs for cases in Pre-MDC MS–DRGs 001 and 002 according to the type of procedure (insertion, revision, or removal), the type of device (biventricular short-term external heart assist system, short-term external heart assist system or implantable heart assist system), and the approaches that were utilized (open, percutaneous, or percutaneous endoscopic). In the FY 2019 IPPS/LTCH PPS proposed rule, we agreed with the commenters' recommendation to maintain the structure of Pre-MDC MS–DRGs 001 and 002 for FY 2019 and stated that we would continue to analyze the claims data.

Comment: Commenters supported CMS' proposal to maintain the current structure of Pre-MDC MS–DRGs 001 and 002 for FY 2019, and to continue to analyze claims data for consideration of

future modifications. The commenters agreed with CMS that current claims data do not yet reflect recent advice published in *Coding Clinic* for ICD–10–CM/PCS regarding the coding of procedures involving external heart assist devices or recent changes to ICD–10–PCS codes for these procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are maintaining the current structure of Pre-MDC MS–DRGs 001 and 002 for FY 2019.

Commenters also suggested that CMS maintain the current logic for MS–DRG 215 (Other Heart Assist System Implant), but they recommended that CMS continue to monitor the data in MS–DRG 215 for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of procedures utilizing heart assist devices. As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20184), we also received a request to review claims data for procedures involving extracorporeal membrane oxygenation (ECMO) in combination with the insertion of a percutaneous short-term external heart assist device to determine if the current MS–DRG assignment is appropriate.

The logic for MS–DRG 215 is comprised of the procedure codes shown in the following table, for which we examined claims data in the September 2017 update of the FY 2017 MedPAR file in response to the commenters' requests. Our findings are shown in the following table.

MS–DRG 215

[Other Heart Assist System Implant]

	Number of cases	Average length of stay	Average costs
All cases	3,428	8.7	$68,965
Cases with procedure code 02HA0RJ (Insertion of short-term external heart assist system into heart, intraoperative, open approach)	0	0	0
Cases with procedure code 02HA0RS (Insertion of biventricular short-term external heart assist system into heart, open approach)	9	10	118,361
Cases with procedure code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach)	66	11.5	99,107
Cases with procedure code 02HA3RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach)	0	0	0
Cases with procedure code 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach)	117	7.2	64,302
Cases with procedure code 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach)	3,136	8.4	67,670
Cases with procedure code 02HA4RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach)	0	0	0
Cases with procedure code 02HA4RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach)	1	2	43,988
Cases with procedure code 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach)	31	5.3	57,042
Cases with procedure code 02WA0JZ (Revision of synthetic substitute in heart, open approach)	1	84	366,089
Cases with procedure code 02WA0QZ (Revision of implantable heart assist system in heart, open approach)	56	25.1	123,410
Cases with procedure code 02WA0RS (Revision of biventricular short-term external heart assist system in heart, open approach)	0	0	0
Cases with procedure code 02WA0RZ (Revision of short-term external heart assist system in heart, open approach)	8	13.5	99,378
Cases with procedure code 02WA3QZ (Revision of implantable heart assist system in heart, percutaneous approach)	0	0	0
Cases with procedure code 02WA3RS (Revision of biventricular short-term external heart assist system in heart, percutaneous approach)	0	0	0
Cases with procedure code 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach)	80	10	71,077
Cases with procedure code 02WA4QZ (Revision of implantable heart assist system in heart, percutaneous endoscopic approach)	0	0	0
Cases with procedure code 02WA4RS (Revision of biventricular short-term external heart assist system in heart, percutaneous endoscopic approach)	0	0	0
Cases with procedure code 02WA4RZ (Revision of short-term external heart assist system in heart, percutaneous endoscopic approach)	0	0	0

As shown in this table, for MS–DRG 215, we found a total of 3,428 cases with an average length of stay of 8.7 days and average costs of $68,965. For procedure codes describing the insertion of a biventricular short-term external heart assist system with open, percutaneous or percutaneous endoscopic approaches, we found a total of 127 cases with an average length of stay ranging from 2 to 10 days and average costs ranging from $43,988 to $118,361. For procedure codes describing the insertion of a short-term external heart assist system with open, percutaneous or percutaneous endoscopic approaches, we found a total of 3,233 cases with an average length of stay ranging from 5.3 days to 11.5 days and average costs ranging from $57,042 to $99,107. For procedure codes describing the revision of a short-term external heart assist system with open or percutaneous approaches, we found a total of 88 cases with an average length of stay ranging from 10 to 13.5 days and average costs ranging from $71,077 to $99,378. We found 1 case

reporting procedure code 02WA0JZ (Revision of synthetic substitute in heart, open approach), with an average length of stay of 84 days and average costs of $366,089. Lastly, we found 56 cases reporting procedure code 02WA0QZ (Revision of implantable heart assist system in heart, open approach) with an average length of stay of 25.1 days and average costs of $123,410.

As the data show, there is a wide range in the average length of stay and the average costs for cases reporting procedures that involve a biventricular short-term external heart assist system versus a short-term external heart assist system. There is an even greater range in the average length of stay and the average costs when comparing the revision of a short-term external heart assist system to the revision of a synthetic substitute in the heart or to the revision of an implantable heart assist system.

In the proposed rule, we stated that we agreed with the commenters that continued monitoring of the data and further analysis is necessary prior to proposing any modifications to MS–DRG 215. As stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), we are aware that the AHA published Coding Clinic advice that clarified coding and reporting for certain external heart assist devices due to the technology being approved for new indications. The current claims data do not yet reflect that updated guidance. We also noted that there have been recent updates to the descriptions of the codes for heart assist devices in the past year. For example, the qualifier ''intraoperative'' was added effective October 1, 2017 (FY 2018) to the procedure codes describing the insertion of short-term external heart assist system procedures to distinguish between procedures where the device was only used intraoperatively and was removed at the conclusion of the procedure versus procedures where the device was not removed at the conclusion of the procedure and for which that qualifier would not be reported. The current claims data do not yet reflect these new procedure codes, which are displayed in the following table and are assigned to MS–DRG 215.

ICD–10–PCS code	Code description
02HA0RJ	Insertion of short-term external heart assist system into heart, intraoperative, open approach.
02HA3RJ	Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach.
02HA4RJ	Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach.

In the proposed rule, we indicated that our clinical advisors also agreed that additional claims data are needed for analysis prior to proposing any changes to MS–DRG 215. Therefore, we did not propose to make any modifications to MS–DRG 215 for FY 2019.

Comment: Commenters supported CMS' proposal to not make any modifications to MS–DRG 215 for FY 2019 and supported continued analysis of claims data for consideration of modifications in future rulemaking. The commenters noted that the proposal was reasonable, given the data, the ICD–10–PCS procedure codes, and information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure of MS–DRG 215 for FY 2019.

As stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20185) and earlier in this section, we also received a request to review cases reporting the use of ECMO in combination with the insertion of a percutaneous short-term external heart assist device. Under ICD–10–PCS, ECMO is identified with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) and the insertion of a percutaneous short-term external heart assist device is identified with procedure code 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach). According to the commenter, when ECMO procedures are performed percutaneously, they are less invasive and less expensive than traditional ECMO. The commenter also noted that, currently under ICD–10–PCS, there is not a specific procedure code to identify percutaneous ECMO, and providers are only able to report ICD–10–PCS procedure code 5A15223, which may be inappropriately resulting in a higher paying MS–DRG. Therefore, the commenter submitted a separate request to create a new ICD–10–PCS procedure code specifically for percutaneous ECMO which was discussed at the March 6–7, 2018 ICD–10 Coordination and Maintenance Committee Meeting. We refer readers to section II.F.18. of the preamble of this final rule for further information regarding this meeting and the discussion for a new procedure code.

The requestor suggested that cases reporting a procedure code for ECMO in combination with the insertion of a percutaneous short-term external heart assist device could be reassigned from Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure) to MS–DRG 215. Our analysis involved examining cases in Pre-MDC MS–DRG 003 in the September 2017 update of the FY 2017 MedPAR file for cases reporting ECMO with and without the insertion of a percutaneous short-term external heart assist device. Our findings are shown in the following table.

ECMO AND PERCUTANEOUS SHORT-TERM EXTERNAL HEART ASSIST DEVICE

Pre-MDC MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 003—All cases	14,383	29.5	$118,218
MS–DRG 003—Cases with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous)	1,786	19	119,340
MS–DRG 003—Cases with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) and 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach)	94	11.4	110,874

ECMO AND PERCUTANEOUS SHORT-TERM EXTERNAL HEART ASSIST DEVICE—Continued

Pre-MDC MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 003—Cases with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) and 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach)	1	1	64,319

As shown in this table, we found a total of 14,383 cases with an average length of stay of 29.5 days and average costs of $118,218 in Pre-MDC MS–DRG 003. We found 1,786 cases reporting procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) with an average length of stay of 19 days and average costs of $119,340. We found 94 cases reporting procedure code 5A15223 and 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach) with an average length of stay of 11.4 days and average costs of $110,874. Lastly, we found 1 case reporting procedure code 5A15223 and 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach) with an average length of stay of 1 day and average costs of $64,319.

We also reviewed the cases in MS–DRG 215 for procedure codes 02HA3RZ and 02HA4RZ. Our findings are shown in the following table.

PERCUTANEOUS SHORT-TERM EXTERNAL HEART ASSIST DEVICE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 215—All cases	3,428	8.7	$68,965
MS–DRG 215—Cases with procedure code 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach)	3,136	8.4	67,670
MS–DRG 215—Cases with procedure code 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach)	31	5.3	57,042

As shown in this table, we found a total of 3,428 cases with an average length of stay of 8.7 days and average costs of $68,965. We found a total of 3,136 cases reporting procedure code 02HA3RZ with an average length of stay of 8.4 days and average costs of $67,670. We found a total of 31 cases reporting procedure code 02HA4RZ with an average length of stay of 5.3 days and average costs of $57,042.

We stated in the proposed rule that, for Pre-MDC MS–DRG 003, while the average length of stay and average costs for cases where procedure code 5A15223 was reported with procedure code 02HA3RZ or procedure code 02HA4RZ are lower than the average length of stay and average costs for cases where procedure code 5A15223 was reported alone, we are unable to determine from the data if those ECMO procedures were performed percutaneously in the absence of a unique code. In addition, the one case reporting procedure code 5A15223 with 02HA4RZ only had a 1 day length of stay and it is unclear from the data what the circumstances of that case may have involved. For example, the patient may have been transferred or may have expired. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20186), we proposed to not reassign cases reporting procedure code 5A15223 when reported with procedure code 02HA3RZ or procedure code 02HA4RZ for FY 2019. We stated in the proposed rule that our clinical advisors agreed that until there is a way to specifically identify percutaneous ECMO in the claims data to enable further analysis, a proposal at this time is not warranted.

Comment: Commenters supported CMS' proposal to not reassign cases reporting the use of ECMO (procedure code 5A15223) in combination with the insertion of a percutaneous short-term external heart assist device (procedure code 02HA3RZ or procedure code 02HA4RZ) for FY 2019.

Response: We appreciate the commenters' support.

Comment: Other commenters acknowledged that new ICD–10–PCS procedure codes that identify percutaneous ECMO procedures were made publicly available in May 2018. The commenters suggested that the new procedure codes be assigned to MS–DRGs that reflect cases representing patients with similar clinical characteristics and whose treatment requires similar resource utilization, such as MS–DRG 215. Some commenters specifically requested that the new procedure code describing a percutaneous veno-arterial (VA) ECMO procedure be considered for assignment to MS–DRG 215 versus Pre-MDC MS–DRG 003 because MS–DRG 215 is the primary MS–DRG for procedures involving the implantation of peripheral heart assist pumps, with similar cases representing patient conditions and clinical coherence. The commenters noted that the percutaneous ECMO procedure is less invasive and less expensive than the traditional ECMO procedure, and has the clinical similarities and requires similar resource utilization as procedures currently assigned to MS–DRG 215, such as the percutaneous ventricular assist devices procedure.

Another commenter suggested that CMS should assign cases representing patients receiving treatment involving the peripheral VA ECMO procedure to MS–DRG 215 or another MS–DRG within MDC 5. The commenter stated that cases representing patients currently assigned to MS–DRG 215 are clinically coherent to the characteristics of the patients who undergo a peripheral VA ECMO procedure. Another commenter recommended that the new procedure code describing a percutaneous veno-venous (VV) ECMO procedure be considered for assignment to MS–DRG 004 or another MS–DRG within MDC 4 because the indication is to provide respiratory support.

Response: The commenters are correct that the FY 2019 ICD–10–PCS procedure code files (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/2019-ICD-10-PCS.html*) include new ICD–10–PCS procedure codes that identify percutaneous ECMO procedures. In addition, the files also show that the current code for ECMO

procedures (ICD–10–PCS code 5A15223) has been revised. These new procedure codes, and the revised ECMO procedure code and description, effective October 1, 2018, are shown in the following table.

ICD–10–PCS code	Code description
5A1522F	Extracorporeal Oxygenation, Membrane, Central.
5A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial.
5A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous.

In response to the commenters' suggestions to assign the new procedure codes for percutaneous ECMO procedures to MS–DRG 215, we note that the new procedure codes created to describe percutaneous ECMO procedures were not finalized at the time of the proposed rule. In addition, the deletion of the current procedure code for ECMO (ICD–10–PCS code 5A15223) and the creation of the new procedure code for central ECMO were not finalized at the time of the proposed rule. As these codes were not finalized at the time of the proposed rule, they were not reflected in Table 6B.—New Procedure Codes (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) associated with the FY 2019 IPPS/LTCH PPS proposed rule. Therefore, because these procedure codes were not yet approved, there were no proposed MDC, MS–DRG, or O.R. and non-O.R. designations for these new procedure codes.

Consistent with our annual process of assigning new procedure codes to MDCs and MS–DRGs, and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignments. The predecessor procedure code (ICD–10–PCS code 5A15223) for the new percutaneous ECMO procedure codes describes an open approach which requires an incision along the sternum (sternotomy) and is performed for open heart surgery. It is considered extremely invasive and carries significant risks for complications, including bleeding, infection, and vessel injury. For central ECMO, arterial cannulation typically occurs directly into the ascending aorta and venous cannulation occurs directly into the right atrium. Conversely, percutaneous (peripheral) ECMO does not require a sternotomy and can be performed in the intensive care unit or at the bedside. The cannulae are placed percutaneously and can utilize a variety of configurations, according to the indication (VA or VV) and patient age (adult vs. pediatric). While percutaneous ECMO also carries risks, they differ from those of central ECMO. For example, our clinical advisor note that patients receiving percutaneous ECMO are at a greater risk of suffering vascular complications.

Upon review, our clinical advisors do not support assigning the new procedure codes for peripheral ECMO procedures to the same MS–DRG as the predecessor code for open (central) ECMO in Pre-MDC MS–DRG 003. Our clinical advisors also do not agree with designating percutaneous ECMO procedures as O.R. procedures because they are less resource intensive compared to open ECMO procedures. As shown in Table 6B.—New Procedure Codes associated with this final rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*), the new procedure codes for percutaneous ECMO procedures have been designated as non-O.R. procedures that will affect the MS–DRG assignment for specific medical MS–DRGs. Effective October 1, 2018, the MS–DRGs for which the percutaneous ECMO procedures will affect MS–DRG assignment are shown in the following table, along with the revised MS–DRG titles.

MDC	MS–DRG	MS–DRG title
4	207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
5	291	Heart Failure and Shock with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
5	296	Cardiac Arrest, Unexplained with MCC or Peripheral Extracorporeal Membrane Oxygenation (ECMO).
18	870	Septicemia or Severe Sepsis with MV >96 Hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO).

Our clinical advisors support the designation of the peripheral ECMO procedures as a non-O.R. procedure affecting the MS–DRG assignment of MS–DRG 207 because they consider the procedure to be similar to providing mechanical ventilation greater than 96 hours in terms of both clinical severity and resource use. Because any respiratory diagnosis classified under MDC 4 with mechanical ventilation greater than 96 hours is assigned to MS–DRG 207, it is reasonable to expect that any patient with a respiratory diagnosis who requires treatment involving a peripheral ECMO procedure should also be assigned to MS–DRG 207. The same rationale was applied for MS–DRG 870, which also includes mechanical ventilation greater than 96 hours. In addition, based on the common clinical indications for which a percutaneous ECMO procedure is utilized, such as cardiogenic shock and cardiac arrest, our clinical advisors determined that MS–DRGs 291 (Heart Failure and Shock with MCC) and 296 (Cardiac Arrest, Unexplained with MCC) also are appropriate for a percutaneous ECMO procedure to affect the MS–DRG assignment. The MS–DRG assignment for a central ECMO procedure will remain in Pre-MDC MS–DRG 003.

In cases where a percutaneous external heart assist device is utilized, in combination with a percutaneous ECMO procedure, effective October 1, 2018, the ICD–10 MS–DRG Version 36 GROUPER logic results in a case assignment to MS–DRG 215 because the percutaneous external heart assist device procedure is designated as an O.R. procedure and assigned to MS–DRG 215.

Because the procedure codes describing percutaneous ECMO procedures are new, becoming effective October 1, 2018, we do not yet have any claims data to analyze. Once claims data becomes available, we can examine the

volume, and length of stay and cost data to determine if modifications to the assignment of these procedure codes are warranted.

After consideration of the public comments we received, we are finalizing our proposal to not reassign cases reporting ICD–10–PCS procedure code 5A15223 when reported with ICD–10–PCS procedure code 02HA3RZ or ICD–10–PCS procedure code 02HA4RZ for FY 2019. Consistent with our policy for determining MS–DRG assignment for new codes and for the reasons discussed, the two new procedure codes describing percutaneous ECMO procedures discussed and displayed in the table above, under the ICD–10 MS–DRGs Version 36 GROUPER logic, effective October 1, 2018, are designated as non-O.R. procedures impacting the MS–DRG assignment of MS–DRGs 207, 291, 296, and 870. The MS–DRG assignment for the central ECMO procedure remains in Pre-MDC MS–DRG 003.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20186), we also discussed that a commenter also suggested that CMS maintain the current logic for MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively), but recommended that CMS continue to monitor the data in these MS–DRGs for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of procedures involving heart assist devices.

The logic for heart assist system devices in MS–DRGs 268 and 269 is comprised of the procedure codes shown in the following table, for which we examined claims data in the September 2017 update of the FY 2017 MedPAR file in response to the commenter's request. Our findings are shown in the following table.

MS–DRGs for Aortic and Heart Assist Procedures Except Pulsation Balloon

	Number of cases	Average length of stay	Average costs
MS–DRG 268—All cases	3,798	9.6	$49,122
MS–DRG 268—Cases with procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach)	16	23.4	79,850
MS–DRG 268—Cases with procedure code 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach)	28	10.5	31,797
MS–DRG 268—Cases with procedure code 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	96	12.4	51,469
MS–DRG 268—Cases with procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach)	5	7.8	37,592
MS–DRG 268—Cases with procedure code 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 269—All cases	16,900	2.4	30,793
MS–DRG 269—Cases with procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach)	10	8	23,741
MS–DRG 269—Cases with procedure code 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach)	6	5	19,421
MS–DRG 269—Cases with procedure code 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	11	4	25,719
MS–DRG 269—Cases with procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach)	1	3	14,415
MS–DRG 269—Cases with procedure code 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0

As shown in this table, for MS–DRG 268, there were a total of 3,798 cases, with an average length of stay of 9.6 days and average costs of $49,122. There were 16 cases reporting procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach), with an average length of stay of 23.4 days and average costs of $79,850. There were no cases that reported procedure codes 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach), 02PA0RZ (Removal of short-term external heart assist system from heart, open approach), 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach), 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach) or 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach). There were 28 cases reporting procedure code 02PA3QZ (Removal of implantable

heart assist system from heart, percutaneous approach), with an average length of stay of 10.5 days and average costs of $31,797. There were 96 cases reporting procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach), with an average length of stay of 12.4 days and average costs of $51,469. There were 5 cases reporting procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach), with an average length of stay of 7.8 days and average costs of $37,592. For MS–DRG 269, there were a total of 16,900 cases, with an average length of stay of 2.4 days and average costs of $30,793. There were 10 cases reporting procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach), with an average length of stay of 8 days and average costs of $23,741. There were no cases reporting procedure codes 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach), 02PA0RZ (Removal of short-term external heart assist system from heart, open approach), 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach), 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach) or 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach). There were 6 cases reporting procedure code 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach), with an average length of stay of 5 days and average costs of $19,421. There were 11 cases reporting procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach), with an average length of stay of 4 days and average costs of $25,719. There was 1 case reporting procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach), with an average length of stay of 3 days and average costs of $14,415.

The data show that there are differences in the average length of stay and average costs for cases in MS–DRGs 268 and 269 according to the type of device (short-term external heart assist system or implantable heart assist system), and the approaches that were utilized (open, percutaneous, or percutaneous endoscopic). In the proposed rule, we stated that we agreed with the recommendation to maintain the structure of MS–DRGs 268 and 269 for FY 2019 and will continue to analyze the claims data for possible future updates. As such, we proposed to not make any changes to the structure of MS–DRGs 268 and 269 for FY 2019.

Comment: Commenters supported CMS' proposal to not make any changes to the structure of MS–DRGs 268 and 269 for FY 2019.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the structure of MS–DRGs 268 and 269 for FY 2019.

b. Brachytherapy

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20188), we received a request to create a new Pre-MDC MS–DRG for all procedures involving the CivaSheet® technology, an implantable, planar brachytherapy source designed to enable delivery of radiation to the site of the cancer tumor excision or debulking, while protecting neighboring tissue. The requestor stated that physicians have used the CivaSheet® technology for a number of indications, such as colorectal, gynecological, head and neck, soft tissue sarcomas and pancreatic cancer. The requestor noted that potential uses also include nonsmall-cell lung cancer, ocular melanoma, and atypical meningioma. Currently, procedures involving the CivaSheet® technology are reported using ICD–10–PCS Section D—Radiation Therapy codes, with the root operation ''Brachytherapy.'' These codes are non-O.R. codes and group to the MS–DRG to which the principal diagnosis is assigned.

In response to this request, we analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for cases representing patients who received treatment that reported low dose rate (LDR) brachytherapy procedure codes across all MS–DRGs. We referred readers to Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes associated with the proposed rule, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* A detailed list of these procedure codes was shown in Table 6P.1.associated with the proposed rule. Our findings are reflected in the following table. As we note below in response to comments, there were errors in the table included in the proposed rule (83 FR 20188) with regard to an identified MS–DRG and procedure code. However, there were no errors in the data findings reported. In the proposed rule, we identified claims data for MS–DRG 129 with procedure code D710BBZ (Low dose rate (LDR) brachytherapy of bone marrow using Palladium-103 (Pd-103)). That entry was an inadventent error. The correct MS–DRG, that is, MS–DRG 054, and procedure code, that is, D010BBZ, are reflected in the table that follows. In addition, in the proposed rule we inadvertently identified MS–DRG 724 with procedure code DV10BBZ (Low dose rate (LDR) brachytherapy of prostate using Palladium 103 (Pd-103)). Upon review, this case was actually reported with MS–DRG 189. The data findings identified for each of these 4 cases are correctly reflected in the table that follows.

CASES REPORTING LOW DOSE RATE (LDR) BRACHYTHERAPY PROCEDURE CODES ACROSS ALL MS–DRGS

ICD–10–PCS procedures	Number of cases	Average length of stay	Average costs
MS–DRG 054 (Nervous System Neoplasms with CC)—Cases with procedure code D010BBZ (Low dose rate (LDR) brachytherapy of brain using Palladium-103 (Pd-103))	1	7	$10,357
MS–DRG 189 (Pulmonary Edema and Respiratory Failure)—Cases with procedure code DV10BBZ (Low dose rate (LDR) brachytherapy of prostate using Palladium-103 (Pd-103))	1	7	32,298
MS–DRG 129 (Major Head and Neck Procedures with CC/MCC or Major Device)—Cases with procedure code DW11BBZ (Low dose rate (LDR) brachytherapy of head and neck using Palladium-103 (Pd-103))	1	3	42,565
MS–DRG 330 (Major Small and Large Bowel Procedures with CC)—Cases with procedure code DW16BBZ (Low dose rate (LDR) brachytherapy of pelvic region using Palladium-103 (Pd-103))	1	8	74,190

As shown in the immediately preceding table, we identified 4 cases reporting one of these LDR brachytherapy procedure codes across all MS–DRGs, with an average length of stay of 6.3 days and average costs of $39,853. In the proposed rule, we stated that we believe that creating a new Pre-MDC MS–DRG based on such a small number of cases could lead to distortion in the relative payment weights for the Pre-MDC MS–DRG. Having a larger number of clinically cohesive cases within the Pre-MDC MS–DRG provides greater stability for annual updates to the relative payment weights. Therefore, we did not propose to create a new Pre-MDC MS–DRG for procedures involving the CivaSheet® technology for FY 2019.

Comment: Some commenters supported CMS' proposal not to create a new MS–DRG for assignment of procedures involving the CivaSheet® technology. Several commenters, including the manufacturer of the CivaSheet® technology, disagreed with CMS' proposal, and stated that the current payment for cases involving the CivaSheet® technology is inadequate and does not currently allow widespread adoption and use of the technology. One commenter noted that its contractor also identified four cases in the proposed rule, but raised some concerns regarding the procedure codes and costs associated with the cases identified in the proposed rule. Other commenters described the clinical benefits and potential cost-savings associated with the CivaSheet® technology, and requested that CMS reconsider its proposal to not create a new Pre- MDC MS–DRG for the assignment of cases involving the use of this technology. The commenters stated that they understood CMS' concern about the lack of volume, but indicated that the lack of adequate payment for procedures involving the CivaSheet® technology does not allow more widespread use. The manufacturer requested that, if CMS finalizes its proposal not to create a new MS–DRG for assignment of cases involving the CivaSheet® technology, CMS consider other payment mechanisms by which to ensure adequate payment for hospitals providing this service.

Response: We appreciate the commenters' support and input. With respect to the commenters who disagreed with our proposal, we reiterate that our analysis of the claims data and our clinical advisors did not support the creation of a new MS–DRG based on the very small number of cases identified. As we noted in the proposed rule, only four cases were identified. The MS–DRGs are a classification system intended to group together those diagnoses and procedures with similar clinical characteristics and utilization of resources. As we discussed in the proposed rule, basing a new MS–DRG on such a small number of cases could lead to distortions in the relative payment weights for the MS–DRG because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights.

We agree with the commenter that there were some inadvertent errors in the table included in the proposed rule in reference to certain procedure codes and MS–DRGs; the table in this final rule above now correctly reflects the procedure codes and MS–DRGs reflected in the FY 2017 MedPAR file (as of the September 2017 update). We note that because our proposal was based on the small number of cases, and not the nature of those cases, these errors had no bearing on our proposal or our decision to finalize this proposal. We acknowledge the commenters' concerns about the adequacy of payment for these low volume services. Therefore, as part of our ongoing, comprehensive analysis of the MS–DRGs under ICD–10, we will continue to explore mechanisms through which to address rare diseases and low volume DRGs.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG structure for procedures involving the CivaSheet® technology for FY 2019.

c. Laryngectomy

The logic for case assignment to Pre-MDC MS–DRGs 11, 12, and 13 (Tracheostomy for Face, Mouth and Neck Diagnoses with MCC, with CC, and without CC/MCC, respectively) as displayed in the ICD–10 MS–DRG Version 35 Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending,* is comprised of a list of procedure codes for laryngectomies, a list of procedure codes for tracheostomies, and a list of diagnosis codes for conditions involving the face, mouth, and neck. The procedure codes for laryngectomies are listed separately and are reported differently from the procedure codes listed for tracheostomies. The procedure codes listed for tracheostomies must be reported with a diagnosis code involving the face, mouth, or neck as a principal diagnosis to satisfy the logic for assignment to Pre-MDC MS–DRG 11, 12, or 13. Alternatively, any principal diagnosis code reported with a procedure code from the list of procedure codes for laryngectomies will satisfy the logic for assignment to Pre-MDC MS–DRG 11, 12, or 13.

To improve the manner in which the logic for assignment is displayed in the ICD–10 MS–DRG Definitions Manual and to clarify how it is applied for grouping purposes, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20188), we proposed to reorder the lists of the diagnosis and procedure codes. The list of principal diagnosis codes for face, mouth, and neck would be sequenced first, followed by the list of the tracheostomy procedure codes and, lastly, the list of laryngectomy procedure codes.

We also proposed to revise the titles of Pre-MDC MS–DRGs 11, 12, and 13 from ''Tracheostomy for Face, Mouth and Neck Diagnoses with MCC, with CC and without CC/MCC, respectively'' to ''Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with MCC'', ''Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with CC'', and ''Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy without CC/MCC'', respectively, to reflect that laryngectomy procedures may also be assigned to these MS–DRGs.

Comment: Commenters supported CMS' proposal to reorder the lists of diagnoses and procedure codes for Pre-MDC MS–DRGs 11, 12 and 13 in the ICD–10 MS–DRG Definitions Manual to clarify the GROUPER logic. The commenters stated that the proposal was reasonable given the ICD–10–CM diagnosis codes, the ICD–10–PCS procedure codes, and the information provided. Commenters also supported the proposal to revise the titles for Pre-MDC MS–DRGs 11, 12 and 13.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to reorder the lists of diagnoses and procedure codes for Pre-MDC MS–DRGs 11, 12, and 13 in the ICD–10 MS–DRG Definitions Manual Version 36. We also are finalizing our proposal to revise the titles for Pre-MDC MS–DRGs 11, 12, and 13 as follows for the ICD–10 MS–DRGs Version 36, effective October 1, 2018:

- MS–DRG 11 (Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with MCC);

- MS–DRG 12 (Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with CC); and
- MS–DRG 13 (Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy without CC/MCC).

d. Chimeric Antigen Receptor (CAR) T-Cell Therapy

Chimeric Antigen Receptor (CAR) T-cell therapy is a cell-based gene therapy in which T-cells are genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side effects that would require medical intervention.

Two CAR T-cell therapies received FDA approval in 2017. KYMRIAH® (manufactured by Novartis Pharmaceuticals Corporation) was approved for the use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. In May 2018, KYMRIAH received FDA approval for a second indication, treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. YESCARTA® (manufactured by Kite Pharma, Inc.) was approved for use in the treatment of adult patients with relapsed or refractory large B-cell lymphoma and who have not responded to or who have relapsed after at least two other kinds of treatment.

Procedures involving the CAR T-cell therapies are currently identified with ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3), which both became effective October 1, 2017. Procedures described by these two ICD–10–PCS procedure codes are designated as non-O.R. procedures that have no impact on MS–DRG assignment.

As we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20189), we have received many inquiries from the public regarding payment of CAR T-cell therapy under the IPPS. Suggestions for the MS–DRG assignment for FY 2019 ranged from assigning ICD–10–PCS procedure codes XW033C3 and XW043C3 to an existing MS–DRG to the creation of a new MS–DRG for CAR T-cell therapy. In the context of the recommendation to create a new MS–DRG for FY 2019, we also received suggestions that payment should be established in a way that promotes comparability between the inpatient setting and outpatient setting.

As part of our review of these suggestions, we examined the existing MS–DRGs to identify the MS–DRGs that represent cases most clinically similar to those cases in which the CAR T-cell therapy procedures would be reported. The CAR T-cell procedures involve a type of autologous immunotherapy in which the patient's cells are genetically transformed and then returned to that patient after the patient undergoes cell depleting chemotherapy. Our clinical advisors believe that patients receiving treatment utilizing CAR T-cell therapy procedures would have similar clinical characteristics and comorbidities to those seen in cases representing patients receiving treatment for other hematologic cancers who are treated with autologous bone marrow transplant therapy that are currently assigned to MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC). Therefore, after consideration of the inquiries received as to how the IPPS can appropriately group cases reporting the use of CAR T-cell therapy, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20189), we proposed to assign ICD–10–PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS–DRG 016 for FY 2019. In addition, we proposed to revise the title of MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC'' to ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy.''

However, we noted in the proposed rule that, as discussed in greater detail in section II.H.5.a. of the preamble of the proposed rule and this final rule, the manufacturer of KYMRIAH and the manufacturer of YESCARTA submitted applications for new technology add-on payments for FY 2019. We stated that we also recognize that many members of the public have noted that the combination of the new technology add-on payment applications, the extremely high-cost of these CAR T-cell therapies, and the potential for volume increases over time present unique challenges with respect to the MS–DRG assignment for procedures involving the utilization of CAR T-cell therapies and cases representing patients receiving treatment involving CAR T-cell therapies. We stated in the proposed rule that we believed that, in the context of these pending new technology add-on payment applications, there may also be merit in the alternative suggestion we received to create a new MS–DRG for procedures involving the utilization of CAR T-cell therapies and cases representing patients receiving treatment involving CAR T-cell therapy to which we could assign ICD–10–PCS procedure codes XW033C3 and XW043C3, effective for discharges occurring in FY 2019. We stated that, as noted in section II.H.5.a. of the preamble of the proposed rule, if a new MS–DRG were to be created then consistent with section 1886(d)(5)(K)(ix) of the Act there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

We invited public comments on our proposed approach of assigning ICD–10–PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS–DRG 016 for FY 2019. We also invited public comments on alternative approaches, including in the context of the pending KYMRIAH and YESCARTA new technology add-on payment applications, and the most appropriate way to establish payment for FY 2019 under any alternative approaches. We indicated that such payment alternatives may include using a CCR of 1.0 for charges associated with ICD–10–PCS procedure codes XW033C3 and XW043C3, given that many public inquirers believed that hospitals would be unlikely to set charges different from the costs for KYMRIAH and YESCARTA CAR T-cell therapies, as discussed further in section II.A.4.g.2. of the Addendum of the proposed rule and this final rule. We further stated that these payment alternatives, including payment under any potential new MS–DRG, also could take into account an appropriate portion of the average sales price (ASP) for these drugs, including in the context of the pending new technology add-on payment applications.

We invited comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices, which is a high priority for this Administration. In addition, we stated that we are considering approaches and authorities to encourage value-based care and lower drug prices. We solicited comments on how the payment methodology alternatives may intersect and affect future participation in any such alternative approaches.

We noted that, as stated in section II.F.1.b. of the preamble of the proposed rule, we described the criteria used to establish new MS–DRGs. In particular,

we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider whether observed average differences are consistent across patients or attributable to cases that were extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases. Based on the principles typically used to establish a new MS–DRG, we solicited comments on how the administration of the CAR T-cell therapies and associated services meet the criteria for the creation of a new MS–DRG. Also, section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Given that a new MS–DRG must be established in a budget neutral manner, we stated that we are concerned with the redistributive effects away from core hospital services over time toward specialized hospitals and how that may affect payment for these core services. Therefore, we solicited public comments on our concerns with the payment alternatives that we were considering for CAR T-cell therapies.

Comment: Many commenters stated that the existing payment mechanisms under the IPPS do not allow for accurate payment of CAR T-cell therapy due its unprecedented high cost. Commenters also asserted structural insufficiencies in the new technology add-on payments for the drug therapy, such as the maximum add-on payment of 50 percent; the inapplicability of the usual cost to charge ratios used in ratesetting and payment, including those used in determining new technology add-on payments, outlier payments, and payments to IPPS-excluded cancer hospitals; and a lack of sufficient historical data and experience related to a therapy with a cost of this magnitude. In addition, commenters stated that payment for CAR T-cell therapy should avoid inappropriate financial incentives for care to be provided in an outpatient instead of an inpatient setting. Many commenters requested a permanent and long-term solution to ensure accurate payment for CAR T-cell therapy while concurrently ensuring any redistributive payment effects within the IPPS are limited.

Some commenters recommended that, until a more permanent solution is developed, CMS finalize the proposed assignment of CAR T-cell therapy to MS–DRG 016, approve the NTAP application for CAR T-cell therapy, and/or allow for a CCR of 1.0 for CAR T-cell therapy. However, some commenters disagreed with CMS' proposed assignment of CAR T-cell therapy to MS–DRG 016 and requested a new separate MS–DRG. These commenters disagreed that patients receiving CAR T-cell therapy are sufficiently clinically similar to patients receiving autologous bone marrow transplants. Reasons cited by these commenters included differences in lengths of stay, the level and predictability of associated toxicity, and the overall disease burden. Some of these commenters suggested creating a new separate MS–DRG for CAR T-cell therapy and developing the FY 2019 weight for this MS–DRG not based only on historical claims data but also including alternative data on the cost of CAR T-cell therapy drugs, such as average sales price (ASP) data. Some commenters pointed to the establishment of a separate DRG for drug eluting stents under the IPPS as a possible payment model for CAR T-cell therapy.

Other commenters did not support the creation of a new separate MS–DRG for CAR T-cell therapy. Reasons cited by these commenters included the relative newness of the therapy, the limited number of providers delivering these treatments, the low volume of patients, redistributive effects, and the lack of long term data surrounding length of stay, treatment complexities, and costs. These commenters urged CMS to collect more comprehensive clinical and cost data before considering assignment of a new MS–DRG to these therapies.

Some commenters requested that CMS carve out the cost of CAR T-cell therapy from the IPPS and pay for it on a pass-through basis reflecting the cost of the therapy to the hospital and indicated that this was the approach taken by some state Medicaid programs. These commenters believed that payment on a pass-through basis, for inpatient and/or outpatient care, provides the most accurate payment while minimizing inappropriate payment incentives across the inpatient and outpatient setting.

Commenters also made technical and operational suggestions to CMS if we were to adopt changes to our existing payment mechanisms in the final rule as they apply to CAR T-cell therapy, including how a CCR of 1.0 would be operationalized, or how CMS would collect data on the cost of CAR T-cell therapy for pass-through and other purposes.

Response: Building on President Trump's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,* the CMS Center for Medicare and Medicaid Innovation (Innovation Center) is soliciting public comment in the CY 2019 OPPS/ASC proposed rule on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out of pocket spending. CMS sought similar feedback in a previous solicitation of comments,[4] and, most recently, in the President's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.*[5]

Given the relative newness of CAR T-cell therapy, the potential model, including the reasons underlying our consideration of a potential model described in greater detail in the CY 2019 OPPS/ASC proposed rule, and our request for feedback on this model approach, we believe it would be premature to adopt changes to our existing payment mechanisms, either under the IPPS or for IPPS-excluded cancer hospitals, specifically for CAR T-cell therapy. Therefore, we disagree with commenters who have requested such changes under the IPPS for FY

[4] CMS included a solicitation of comments on the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals (81 FR 13247) in a proposed rule, on March 11, 2016, entitled ''Medicare Program; Part B Drug Payment Model'' (81 FR 13230). The solicitation of comments sought to help CMS determine if there was sufficient interest in the CAP program, and to gather public input if we were to consider developing and testing a future model that would be at least partly based on the authority for the CAP under section 1847B of the Act. The March 11, 2016 proposed rule was withdrawn on October 4, 2017 (82 FR 46182) to ensure agency flexibility in reexamining important issues related to the proposed payment model and exploring new options and alternatives with stakeholders as CMS develops potential payment models that support innovative approaches to improve quality, accessibility, and affordability, reduce Medicare program expenditures, and empower patients and doctors to make decisions about their health care.

[5] President Donald J. Trump's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, May 11, 2018. Available at: *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.*

2019, including, but not limited to, the creation of a pass-through payment; structural changes in new technology add-on payments for the drug therapy; changes in the usual cost-to-charge ratios (CCRs) used in ratesetting and payment, including those used in determining new technology add-on payments, outlier payments, and payments to IPPS excluded cancer hospitals; and the creation of a new MS–DRG specifically for CAR T-cell therapy prior to gaining more experience with the therapy.

We agree with commenters who recommended that we finalize the proposed assignment of CAR–T therapy to MS–DRG 016 rather than consider the creation of a new MS–DRG for these therapies, given the relative newness of the therapy, the limited number of providers delivering these treatments, the low volume of patients, redistributive effects, and the lack of long-term data surrounding length of stay, treatment complexities, and costs. In addition to the potential model, we agree we should collect more comprehensive clinical and cost data before considering assignment of a new MS–DRG to these therapies.

In response to the commenters who indicated that MS–DRG 016 is a poor clinical match for CAR T-cell therapy patients and would prefer that we create a new MS–DRG for CAR–T cell therapy, we acknowledge that there are differences between the treatment approaches, but we continue to believe that MS–DRG 016 is the most appropriate match of the existing MS–DRGs, given similarities between CAR–T cell therapy and autologous bone marrow transplant in harvesting and infusion of patient cells as well as post-infusion monitoring for and management of potentially severe adverse effects. We reiterate that, in light of the potential model and our request for feedback on this approach, it would be premature to create a new MS–DRG specifically for CAR T-cell therapy. We will consider requests for alternative MS–DRG assignments and/or the creation of a new MS–DRG for CAR T-cell therapy after we review the public feedback on a potential model and as we gain further experience with CAR T-cell therapy and can better evaluate the commenters' concerns.

As described in more detail in section II.H. of the preamble of this final rule, we are approving new technology add-on payments for CAR T-cell therapy for FY 2019.

In response to commenters who made technical and operational suggestions if CMS were to adopt changes to its existing payment mechanisms in the final rule as they apply to CAR T-cell therapy, because we are not adopting such changes, we are not addressing those technical and operational comments at the current time but will consider them for future rulemaking as appropriate.

After consideration of the public comments we received, we are finalizing our proposed approach of assigning ICD–10–PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS–DRG 016 for FY 2019 and to revise the title of MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC'' to ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy.''

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Epilepsy With Neurostimulator

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019), based on a request we received and our review of the claims data, the advice of our clinical advisors, and consideration of public comments, we finalized our proposal to reassign all cases reporting a principal diagnosis of epilepsy and one of the following ICD–10–PCS code combinations, which capture cases involving neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator), to retitled MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), even if there is no MCC reported:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach); and
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

The finalized listing of epilepsy diagnosis codes (82 FR 38018 through 38019) contained codes provided by the requestor (82 FR 38016), in addition to diagnosis codes organized in subcategories G40.A- and G40.B- as recommended by a commenter in response to the proposed rule (82 FR 38018) because the diagnosis codes organized in these subcategories also are representative of diagnoses of epilepsy.

For FY 2019, we received a request to include two additional diagnosis codes organized in subcategory G40.1- in the listing of epilepsy diagnosis codes for cases assigned to MS–DRG 023 because these diagnosis codes also represent diagnoses of epilepsy. The two additional codes identified by the requestor are:

- G40.109 (Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus); and
- G40.111 (Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20190), we stated that we agreed with the requestor that diagnosis codes G40.109 and G40.111 also are representative of epilepsy diagnoses and should be added to the listing of epilepsy diagnosis codes for cases assigned to MS–DRG 023 because they also capture a type of epilepsy. Our clinical advisors reviewed this issue and agreed that adding the two additional epilepsy diagnosis codes is appropriate. Therefore, we proposed to add ICD–10–CM diagnosis codes G40.109 and G40.111 to the listing of epilepsy diagnosis codes for cases assigned to MS–DRG 023, effective October 1, 2018.

Comment: Commenters agreed with CMS' proposal to add ICD–10–CM diagnosis codes G40.109 and G40.111 to the list of epilepsy diagnosis codes for assignment to MS–DRG 023. The commenters stated that the proposal was reasonable, given the ICD–10–CM diagnosis codes and the information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–CM diagnosis codes G40.109 and G40.111 to the list of epilepsy diagnosis codes for assignment to MS–DRG 023 in the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

b. Neurological Conditions With Mechanical Ventilation

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20190), we received two separate, but related requests to create new MS–DRGs for cases that identify patients who have been diagnosed with neurological conditions classified under MDC 1 (Diseases and Disorders of the Nervous

System) and who require mechanical ventilation with and without a thrombolytic and in the absence of an O.R. procedure. The requestors suggested that CMS consider when mechanical ventilation is reported with a neurological condition for the ICD–10 MS–DRG GROUPER assignment logic, similar to the current logic for MS–DRGs 207 and 208 (Respiratory System Diagnosis with Ventilator Support >96 Hours and <=96 Hours, respectively) under MDC 4 (Diseases and Disorders of the Respiratory System), which consider respiratory conditions that require mechanical ventilation and are assigned a higher relative weight.

The requestors stated that patients with a principal diagnosis of respiratory failure requiring mechanical ventilation are currently assigned to MS–DRG 207 (Respiratory System Diagnoses with Ventilator Support >96 Hours), which has a relative weight of 5.4845, and to MS–DRG 208 (Respiratory System Diagnoses with Ventilator Support <=96 Hours), which has a relative weight of 2.3678. The requestors also stated that patients with a principal diagnosis of ischemic cerebral infarction who received a thrombolytic agent during the hospital stay and did not undergo an O.R. procedure are assigned to MS–DRGs 061, 062, and 063 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively) under MDC 1, while patients with a principal diagnosis of intracranial hemorrhage or ischemic cerebral infarction who did not receive a thrombolytic agent during the hospital stay and did not undergo an O.R. procedure are assigned to MS–DRGs 064, 065 and 66 (Intracranial Hemorrhage or Cerebral Infarction with MCC, with CC or TPA in 24 Hours, and without CC/MCC, respectively) under MDC 1.

The requestors provided the current FY 2018 relative weights for these MS–DRGs as shown in the following table.

MS–DRG	MS–DRG title	Relative weight
MS–DRG 061	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC	2.7979
MS–DRG 062	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with CC	l.9321
MS–DRG 063	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent without CC/MCC	l.6169
MS–DRG 064	Intracranial Hemorrhage or Cerebral Infarction with MCC	l.7685
MS–DRG 065	Intracranial Hemorrhage or Cerebral Infarction with CC or TPA in 24 hours	1.0311
MS–DRG 066	Intracranial Hemorrhage or Cerebral Infarction with MCC	.7466

The requestors stated that although the ICD–10–CM Official Guidelines for Coding and Reporting allow sequencing of acute respiratory failure as the principal diagnosis when it is jointly responsible (with an acute neurologic event) for admission, which would result in assignment to MS–DRGs 207 or 208 when the patient requires mechanical ventilation, it would not be appropriate to sequence acute respiratory failure as the principal diagnosis when it is secondary to intracranial hemorrhage or ischemic cerebral infarction.

The requestors also stated that reporting for other purposes, such as quality measures, clinical trials, and Joint Commission and State certification or survey cases, is based on the principal diagnosis, and it is important, from a quality of care perspective, that the intracranial hemorrhage or cerebral infarction codes continue to be sequenced as principal diagnosis. The requestors believed that cases of patients who present with cerebral infarction or cerebral hemorrhage and acute respiratory failure are currently in conflict for principal diagnosis sequencing because the cerebral infarction or cerebral hemorrhage code is needed as the principal diagnosis for quality reporting and other purposes. However, acute respiratory failure is needed as the principal diagnosis for purposes of appropriate payment under the MS–DRGs.

The requestors stated that by creating new MS–DRGs for neurological conditions with mechanical ventilation, those patients who require mechanical ventilation for airway protection on admission and those patients who develop acute respiratory failure requiring mechanical ventilation after admission can be grouped to MS–DRGs that provide appropriate payment for the mechanical ventilation resources. The requestors suggested two new MS–DRGs, citing as support that new MS–DRGs were created for patients with sepsis requiring mechanical ventilation greater than and less than 96 hours.

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20191) and earlier in this section, the requests we received were separate, but related requests. The first request was to specifically identify patients presenting with intracranial hemorrhage or cerebral infarction with mechanical ventilation and create two new MS–DRGs as follows:

- Suggested new MS–DRG XXX (Intracranial Hemorrhage or Cerebral Infarction with Mechanical Ventilation >96 Hours); and
- Suggested new MS–DRG XXX (Intracranial Hemorrhage or Cerebral Infarction with Mechanical Ventilation <=96 Hours).

The second request was to consider *any* principal diagnosis under the current GROUPER logic for MDC 1 with mechanical ventilation and create two new MS–DRGs as follows:

- Suggested New MS–DRG XXX (Neurological System Diagnosis with Mechanical Ventilation 96+ Hours); and
- Suggested New MS–DRG XXX (Neurological System Diagnosis with Mechanical Ventilation <96 Hours).

Both requesters suggested that CMS use the three ICD–10–PCS codes identifying mechanical ventilation to assign cases to the respective suggested new MS–DRGs. The three ICD–10–PCS codes are shown in the following table.

ICD–10–PCS code	Code description
5A1935Z	Respiratory ventilation, less than 96 consecutive hours.
5A1945Z	Respiratory ventilation, 24–96 consecutive hours.
5A1955Z	Respiratory ventilation, greater than 96 consecutive hours.

Below we discuss the different aspects of each request in more detail.

The first request involved two aspects: (1) Analyzing patients diagnosed with cerebral infarction and required mechanical ventilation who received a thrombolytic (for example, TPA) and did not undergo an O.R. procedure; and (2) analyzing patients diagnosed with intracranial hemorrhage or ischemic cerebral infarction and required mechanical ventilation who did not receive a thrombolytic (for example, TPA) during the current episode of care and did not undergo an O.R. procedure.

For the first subset of patients, we analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 061, 062, and 063 because cases that are assigned to these MS–DRGs specifically identify patients who were diagnosed with a cerebral infarction and received a thrombolytic. The 90 ICD–10–CM diagnosis codes that specify a cerebral infarction and were included in our analysis are listed in Table 6P.1a associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

The ICD–10–PCS procedure codes displayed in the following table describe use of a thrombolytic agent.

ICD–10–PCS code	Code description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach.
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach.
3E04017	Introduction of other thrombolytic into central vein, open approach.
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach.
3E05017	Introduction of other thrombolytic into peripheral artery, open approach.
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach.
3E06017	Introduction of other thrombolytic into central artery, open approach.
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach.
3E08017	Introduction of other thrombolytic into heart, open approach.
3E08317	Introduction of other thrombolytic into heart, percutaneous approach.

We examined claims data in MS–DRGs 061, 062, and 063 and identified cases that reported mechanical ventilation of any duration with a principal diagnosis of cerebral infarction where a thrombolytic agent was administered and the patient did not undergo an O.R. procedure. Our findings are shown in the following table.

CEREBRAL INFARCTION WITH THROMBOLYTIC AND MV

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 061—All cases	5,192	6.4	$20,097
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	166	12.8	41,691
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation = 24–96 hours	378	7.5	26,368
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <24 hours	214	4.9	19,795
MS–DRG 062—All cases	9,730	3.9	13,865
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	0
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation = 24–96 hours	10	5.3	19,817
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <24 hours	23	3.8	14,026
MS–DRG 063—All cases	1,984	2.7	11,771
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	0
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation = 24–96 hours	3	2.7	14,588
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <24 hours	5	2.0	11,195

As shown in this table, there were a total of 5,192 cases in MS–DRG 061 with an average length of stay of 6.4 days and average costs of $20,097. There were a total of 758 cases reporting the use of mechanical ventilation in MS–DRG 061 with an average length of stay ranging from 4.9 days to 12.8 days and average costs ranging from $19,795 to $41,691. For MS–DRG 062, there were a total of 9,730 cases with an average length of stay of 3.9 days and average costs of $13,865. There were a total of 33 cases reporting the use of mechanical ventilation in MS–DRG 062 with an average length of stay ranging from 3.8 days to 5.3 days and average costs ranging from $14,026 to $19,817. For MS–DRG 063, there were a total of 1,984 cases with an average length of stay of 2.7 days and average costs of $11,771. There were a total of 8 cases reporting the use of mechanical ventilation in MS–DRG 063 with an average length of stay ranging from 2.0 days to 2.7 days and average costs ranging from $11,195 to $14,588.

We then compared the total number of cases in MS–DRGs 061, 062, and 063 specifically reporting mechanical

ventilation >96 hours with a principal diagnosis of cerebral infarction where a thrombolytic agent was administered and the patient did not undergo an O.R. procedure against the total number of cases reporting mechanical ventilation <=96 hours with a principal diagnosis of cerebral infarction where a thrombolytic agent was administered and the patient did not undergo an O.R. procedure. Our findings are shown in the following table.

CEREBRAL INFARCTION WITH THROMBOLYTIC AND MV

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 061—All cases	5,192	6.4	$20,097
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	166	12.8	41,691
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <=96 hours	594	6.5	23,780
MS–DRG 062—All cases	9,730	3.9	13,865
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	0
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <=96 hours	34	4.2	15,558
MS–DRG 063—All cases	1,984	2.7	11,771
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	0
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <=96 hours	8	2.3	12,467

As shown in this table, the total number of cases reported in MS–DRG 061 was 5,192, with an average length of stay of 6.4 days and average costs of $20,097. There were 166 cases that reported mechanical ventilation >96 hours, with an average length of stay of 12.8 days and average costs of $41,691. There were 594 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 6.5 days and average costs of $23,780.

The total number of cases reported in MS–DRG 062 was 9,730, with an average length of stay of 3.9 days and average costs of $13,865. There were no cases identified in MS–DRG 062 where mechanical ventilation >96 hours was reported. However, there were 34 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 4.2 days and average costs of $15,558.

The total number of cases reported in MS–DRG 63 was 1,984 with an average length of stay of 2.7 days and average costs of $11,771. There were no cases identified in MS–DRG 063 where mechanical ventilation >96 hours was reported. However, there were 8 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 2.3 days and average costs of $12,467.

For the second subset of patients, we examined claims data for MS–DRGs 064, 065, and 066. We identified cases reporting mechanical ventilation of any duration with a principal diagnosis of cerebral infarction or intracranial hemorrhage where a thrombolytic agent was not administered during the current hospital stay and the patient did not undergo an O.R. procedure. The 33 ICD–10–CM diagnosis codes that specify an intracranial hemorrhage and were included in our analysis are listed in Table 6P.1b associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

We also used the list of 90 ICD–10–CM diagnosis codes that specify a cerebral infarction listed in Table 6P.1a associated with the proposed rule for our analysis. We noted that the GROUPER logic for case assignment to MS–DRG 065 includes that a thrombolytic agent (for example, TPA) was administered within 24 hours of the current hospital stay. The ICD–10–CM diagnosis code that describes this scenario is Z92.82 (Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility). We did not review the cases reporting that diagnosis code for our analysis. Our findings are shown in the following table.

CEREBRAL INFARCTION OR INTRACRANIAL HEMORRHAGE WITH MV AND WITHOUT THROMBOLYTIC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 064—All cases	76,513	6.0	$12,574
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	2,153	13.4	38,262
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation = 24–96 hours	4,843	6.6	18,119
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <24 hours	4,001	3.1	8,675
MS–DRG 065—All cases	106,554	3.7	7,236
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	22	10.2	20,759
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation = 24–96 hours	127	4.2	12,688
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <24 hours	301	2.1	6,145

CEREBRAL INFARCTION OR INTRACRANIAL HEMORRHAGE WITH MV AND WITHOUT THROMBOLYTIC—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 066—All cases	34,689	2.5	5,321
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	1	4.0	3,426
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation = 24–96 hours	31	3.7	10,364
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <24 hours	163	1.4	4,148

The total number of cases reported in MS–DRG 064 was 76,513, with an average length of stay of 6.0 days and average costs of $12,574. There were a total of 10,997 cases reporting the use of mechanical ventilation in MS–DRG 064 with an average length of stay ranging from 3.1 days to 13.4 days and average costs ranging from $8,675 to $38,262. For MS–DRG 065, there were a total of 106,554 cases with an average length of stay of 3.7 days and average costs of $7,236. There were a total of 450 cases reporting the use of mechanical ventilation in MS–DRG 065 with an average length of stay ranging from 2.1 days to 10.2 days and average costs ranging from $6,145 to $20,759. For MS–DRG 066, there were a total of 34,689 cases with an average length of stay of 2.5 days and average costs of $5,321. There were a total of 195 cases reporting the use of mechanical ventilation in MS–DRG 066 with an average length of stay ranging from 1.4 days to 4.0 days and average costs ranging from $3,426 to $10,364.

We then compared the total number of cases in MS–DRGs 064, 065, and 066 specifically reporting mechanical ventilation >96 hours with a principal diagnosis of cerebral infarction or intracranial hemorrhage where a thrombolytic agent was not administered and the patient did not undergo an O.R. procedure against the total number of cases reporting mechanical ventilation <=96 hours with a principal diagnosis of cerebral infarction or intracranial hemorrhage where a thrombolytic agent was not administered and the patient did not undergo an O.R. procedure. Our findings are shown in the following table.

CEREBRAL INFARCTION OR INTRACRANIAL HEMORRHAGE WITH MV AND WITHOUT THROMBOLYTIC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 064—All cases	76,513	6.0	$12,574
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	2,153	13.4	38,262
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <=96 hours	8,794	4.9	13,704
MS–DRG 065—All cases	106,554	3.7	7,236
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	22	10.2	20,759
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <=96 hours	428	2.7	8,086
MS–DRG 066—All cases	34,689	2.5	5,321
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	1	4.0	3,426
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <=96 hours	194	1.8	5,141

The total number of cases reported in MS–DRG 064 was 76,513, with an average length of stay of 6.0 days and average costs of $12,574. There were 2,153 cases that reported mechanical ventilation >96 hours, with an average length of stay of 13.4 days and average costs of $38,262, and there were 8,794 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 4.9 days and average costs of $13,704.

The total number of cases reported in MS–DRG 65 was 106,554, with an average length of stay of 3.7 days and average costs of $7,236. There were 22 cases that reported mechanical ventilation >96 hours, with an average length of stay of 10.2 days and average costs of $20,759, and there were 428 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 2.7 days and average costs of $8,086.

The total number of cases reported in MS–DRG 66 was 34,689, with an average length of stay of 2.5 days and average costs of $5,321. There was one case that reported mechanical ventilation >96 hours, with an average length of stay of 4.0 days and average costs of $3,426, and there were 194 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 1.8 days and average costs of $5,141.

We also analyzed claims data for MS–DRGs 207 and 208. As shown in the following table, there were a total of 19,471 cases found in MS–DRG 207 with an average length of stay of 13.8 days and average costs of $38,124. For MS–DRG 208, there were a total of 55,802 cases found with an average length of stay of 6.7 days and average costs of $17,439.

RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 207—All cases	19,471	13.8	$38,124
MS–DRG 208—All cases	55,802	6.7	17,439

We stated in the proposed rule that our analysis of claims data relating to the first request for MS–DRGs 061, 062, 063, 064, 065, and 066 and consultation with our clinical advisors do not support creating new MS–DRGs for cases that identify patients diagnosed with cerebral infarction or intracranial hemorrhage who require mechanical ventilation with or without a thrombolytic and in the absence of an O.R. procedure.

For the first subset of patients (in MS–DRGs 061, 062 and 063), our data findings for MS–DRG 061 demonstrate the 166 cases that reported mechanical ventilation >96 hours had a longer average length of stay (12.8 days versus 6.4 days) and higher average costs ($41,691 versus $20,097) compared to all the cases in MS–DRG 061. However, there were no cases that reported mechanical ventilation >96 hours for MS–DRG 062 or MS–DRG 063. For the 594 cases that reported mechanical ventilation <=96 hours in MS–DRG 061, the data show that the average length of stay was consistent with the average length of stay of all of the cases in MS–DRG 061 (6.5 days versus 6.4 days) and the average costs were also consistent with the average costs of all of the cases in MS–DRG 061 ($23,780 versus $20,097). For the 34 cases that reported mechanical ventilation <=996 hours in MS–DRG 062, the data show that the average length of stay was consistent with the average length of stay of all of the cases in MS–DRG 062 (4.2 days versus 3.9 days) and the average costs were also consistent with the average costs of all of the cases in MS DRG 062 ($15,558 versus $13,865). Lastly, for the 8 cases that reported mechanical ventilation <=96 hours in MS–DRG 063, the data show that the average length of stay was consistent with the average length of stay of all of the cases in MS–DRG 063 (2.3 days versus 2.7 days) and the average costs were also consistent with the average costs of all of the cases in MS DRG 063 ($12,467 versus $11,771).

For the second subset of patients (in MS–DRGs 064, 065 and 066), the data findings for the 2,153 cases that reported mechanical ventilation >96 hours in MS–DRG 064 showed a longer average length of stay (13.4 days versus 6.0 days) and higher average costs ($38,262 versus $12,574) compared to all of the cases in MS–DRG 064. However, the 2,153 cases represent only 2.8 percent of all the cases in MS–DRG 064. For the 22 cases that reported mechanical ventilation >96 hours in MS–DRG 065, the data showed a longer average length of stay (10.2 days versus 3.7 days) and higher average costs ($20,759 versus $7,236) compared to all of the cases in MS–DRG 065. However, the 22 cases represent only 0.02 percent of all the cases in MS–DRG 065. For the one case that reported mechanical ventilation >96 hours in MS–DRG 066, the data showed a longer average length of stay (4.0 days versus 2.5 days) and lower average costs ($3,426 versus $5,321) compared to all of the cases in MS–DRG 066. For the 8,794 cases that reported mechanical ventilation <=96 hours in MS–DRG 064, the data showed that the average length of stay was shorter than the average length of stay for all of the cases in MS–DRG 064 (4.9 days versus 6.0 days) and the average costs were consistent with the average costs of all of the cases in MS–DRG 064 ($13,704 versus $12,574). For the 428 cases that reported mechanical ventilation <=96 hours in MS–DRG 065, the data showed that the average length of stay was shorter than the average length of stay for all of the cases in MS–DRG 065 (2.7 days versus 3.7 days) and the average costs were consistent with the average costs of all the cases in MS–DRG 065 ($8,086 versus $7,236). For the 194 cases that reported mechanical ventilation <=96 hours in MS–DRG 066, the data showed that the average length of stay was shorter than the average length of stay for all of the cases in MS–DRG 066 (1.8 days versus 2.5 days) and the average costs were less than the average costs of all of the cases in MS–DRG 066 ($5,141 versus $5,321).

We stated in the proposed rule that, based on the analysis described above, the current MS–DRG assignment for the cases in MS–DRGs 061, 062, 063, 064, 065 and 066 that identify patients diagnosed with cerebral infarction or intracranial hemorrhage who require mechanical ventilation with or without a thrombolytic and in the absence of an O.R. procedure appears appropriate.

Our clinical advisors also noted that patients requiring mechanical ventilation (in the absence of an O.R. procedure) are known to be more resource intensive and it would not be practical to create new MS–DRGs specifically for this subset of patients diagnosed with an acute neurologic event, given the various indications for which mechanical ventilation may be utilized. We stated in the proposed rule that, if we were to create new MS–DRGs for patients diagnosed with an intracranial hemorrhage or cerebral infarction who require mechanical ventilation, it would not address all of the other patients who also utilize mechanical ventilation resources. It would also necessitate further extensive analysis and evaluation for several other conditions that require mechanical ventilation across each of the 25 MDCs under the ICD–10 MS–DRGs.

To evaluate the frequency in which the use of mechanical ventilation is reported for different clinical scenarios, we examined claims data across each of the 25 MDCs to determine the number of cases reporting the use of mechanical ventilation >96 hours. Our findings are shown in the table below.

MECHANICAL VENTILATION >96 HOURS ACROSS ALL MDCS

MDC	Number of cases	Average length of stay	Average costs
All cases with mechanical ventilation >96 hours	127,626	18.4	$61,056
MDC 1 (Diseases and Disorders of the Nervous System)—Cases with mechanical ventilation >96 hours	13,668	18.3	61,234
MDC 2 (Disease and Disorders of the Eye)—Cases with mechanical ventilation >96 hours	33	22.7	79,080

MECHANICAL VENTILATION >96 HOURS ACROSS ALL MDCS—Continued

MDC	Number of cases	Average length of stay	Average costs
MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)—Cases with mechanical ventilation >96 hours	602	20.3	62,625
MDC 4 (Diseases and Disorders of the Respiratory System)—Cases with mechanical ventilation >96 hours	27,793	16.6	48,869
MDC 5 (Diseases and Disorders of the Circulatory System)—Cases with mechanical ventilation >96 hours	16,923	20.7	84,565
MDC 6 (Diseases and Disorders of the Digestive System)—Cases with mechanical ventilation >96 hours	6,401	22.4	73,759
MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas)—Cases with mechanical ventilation >96 hours	1,803	24.5	80,477
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)—Cases with mechanical ventilation >96 hours	2,780	22.3	83,271
MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)—Cases with mechanical ventilation >96 hours	390	22.2	68,288
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)—Cases with mechanical ventilation >96 hours	1,168	20.9	60,682
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)—Cases with mechanical ventilation >96 hours	2,325	19.6	57,893
MDC 12 (Diseases and Disorders of the Male Reproductive System)—Cases with mechanical ventilation >96 hours	54	26.8	95,204
MDC 13 (Diseases and Disorders of the Female Reproductive System)—Cases with mechanical ventilation >96 hours	89	24.6	83,319
MDC 14 (Pregnancy, Childbirth and the Puerperium)—Cases with mechanical ventilation >96 hours	22	17.4	56,981
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)—Cases with mechanical ventilation >96 hours	468	20.1	68,658
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)—Cases with mechanical ventilation >96 hours	538	29.7	99,968
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)—Cases with mechanical ventilation >96 hours	48,176	17.3	55,022
MDC 19 (Mental Diseases and Disorders)—Cases with mechanical ventilation >96 hours	54	29.3	52,749
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)—Cases with mechanical ventilation >96 hours	312	20.5	47,637
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)—Cases with mechanical ventilation >96 hours	2,436	18.2	57,712
MDC 22 (Burns)—Cases with mechanical ventilation >96 hours	242	34.8	188,704
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)—Cases with mechanical ventilation >96 hours	64	17.7	50,821
MDC 24 (Multiple Significant Trauma)—Cases with mechanical ventilation >96 hours	922	17.6	72,358
MDC 25 (Human Immunodeficiency Virus Infections)—Cases with mechanical ventilation >96 hours	363	19.1	56,688

As shown in the table, the top 5 MDCs with the largest number of cases reporting mechanical ventilation >96 hours are MDC 18, with 48,176 cases; MDC 4, with 27,793 cases; MDC 5, with 16,923 cases; MDC 1, with 13,668 cases; and MDC 6, with 6,401 cases. We noted that the claims data demonstrate that the average length of stay is consistent with what we would expect for cases reporting the use of mechanical ventilation >96 hours across each of the 25 MDCs. The top 5 MDCs with the highest average costs for cases reporting mechanical ventilation >96 hours were MDC 22, with average costs of $188,704; MDC 17, with average costs of $99,968; MDC 12, with average costs of $95,204; MDC 5, with average costs of $84,565; and MDC 13, with average costs of $83,319. We noted that the data for MDC 8 demonstrated similar results compared to MDC 13 with average costs of $83,271 for cases reporting mechanical ventilation >96 hours. In summary, the claims data reflect a wide variance with regard to the frequency and average costs for cases reporting the use of mechanical ventilation >96 hours.

We also examined claims data across each of the 25 MDCs for the number of cases reporting the use of mechanical ventilation <=96 hours. Our findings are shown in the table below.

MECHANICAL VENTILATION <=96 HOURS ACROSS ALL MDCS

MDC	Number of cases	Average length of stay	Average costs
All cases with mechanical ventilation <=96 hours	266,583	8.5	$26,668
MDC 1 (Diseases and Disorders of the Nervous System)—Cases with mechanical ventilation <=96 hours	29,896	7.4	22,838
MDC 2 (Disease and Disorders of the Eye)—Cases with mechanical ventilation <=96 hours	60	8.4	29,708
MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)—Cases with mechanical ventilation <=96 hours	1,397	9.8	29,479
MDC 4 (Diseases and Disorders of the Respiratory System)—Cases with mechanical ventilation <=96 hours	64,861	7.8	20,929

MECHANICAL VENTILATION <=96 HOURS ACROSS ALL MDCS—Continued

MDC	Number of cases	Average length of stay	Average costs
MDC 5 (Diseases and Disorders of the Circulatory System)—Cases with mechanical ventilation <=96 hours	45,147	8.8	35,818
MDC 6 (Diseases and Disorders of the Digestive System)—Cases with mechanical ventilation <=96 hours	15,629	11.3	33,660
MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas)—Cases with mechanical ventilation <=96 hours	4,678	10.5	31,565
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)—Cases with mechanical ventilation <=96 hours	7,140	10.4	40,183
MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)—Cases with mechanical ventilation <=96 hours	1,036	10.7	26,809
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)—Cases with mechanical ventilation <=96 hours	3,591	9.0	23,863
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)—Cases with mechanical ventilation <=96 hours	5,506	10.2	27,951
MDC 12 (Diseases and Disorders of the Male Reproductive System)—Cases with mechanical ventilation <=96 hours	168	11.5	35,009
MDC 13 (Diseases and Disorders of the Female Reproductive System)—Cases with mechanical ventilation <=96 hours	310	10.8	32,382
MDC 14 (Pregnancy, Childbirth and the Puerperium)—Cases with mechanical ventilation <=96 hours	55	7.6	21,785
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)—Cases with mechanical ventilation <=96 hours	1,171	8.7	26,138
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)—Cases with mechanical ventilation <=96 hours	1,178	15.3	46,335
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)—Cases with mechanical ventilation <=96 hours	69,826	8.5	25,253
MDC 19 (Mental Diseases and Disorders)—Cases with mechanical ventilation <=96 hours	264	10.4	18,805
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)—Cases with mechanical ventilation <=96 hours	918	8.3	19,376
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)—Cases with mechanical ventilation <=96 hours	10,842	6.5	17,843
MDC 22 (Burns)—Cases with mechanical ventilation <=96 hours	353	9.7	45,557
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)—Cases with mechanical ventilation <=96 hours	307	6.6	16,159
MDC 24 (Multiple Significant Trauma)—Cases with mechanical ventilation <=96 hours	1,709	8.8	36,475
MDC 25 (Human Immunodeficiency Virus Infections)—Cases with mechanical ventilation <=96 hours	541	10.4	29,255

As shown in the table, the top 5 MDCs with the largest number of cases reporting mechanical ventilation <=96 hours are MDC 18, with 69,826 cases; MDC 4, with 64,861 cases; MDC 5, with 45,147 cases; MDC 1, with 29,896 cases; and MDC 6, with 15,629 cases. We noted that the claims data demonstrate that the average length of stay is consistent with what we would expect for cases reporting the use of mechanical ventilation <=96 hours across each of the 25 MDCs. The top 5 MDCs with the highest average costs for cases reporting mechanical ventilation <=96 hours are MDC 17, with average costs of $46,335; MDC 22, with average costs of $45,557; MDC 8, with average costs of $40,183; MDC 24, with average costs of $36,475; and MDC 5, with average costs of $35,818. Similar to the cases reporting mechanical ventilation >96 hours, the claims data for cases reporting the use of mechanical ventilation <=96 hours also reflect a wide variance with regard to the frequency and average costs. Depending on the number of cases in each MS–DRG, it may be difficult to detect patterns of complexity and resource intensity.

With respect to the requestor's statement that reporting for other purposes, such as quality measures, clinical trials, and Joint Commission and State certification or survey cases, is based on the principal diagnosis, and their belief that patients who present with cerebral infarction or cerebral hemorrhage and acute respiratory failure are currently in conflict for principal diagnosis sequencing because the cerebral infarction or cerebral hemorrhage code is needed as the principal diagnosis for quality reporting and other purposes (however, acute respiratory failure is needed as the principal diagnosis for purposes of appropriate payment under the MS–DRGs), we noted that providers are required to assign the principal diagnosis according to the ICD–10–CM Official Guidelines for Coding and Reporting and these assignments are not based on factors such as quality measures or clinical trials indications. Furthermore, we do not base MS–DRG reclassification decisions on those factors. If the cerebral hemorrhage or ischemic cerebral infarction is the reason for admission to the hospital, the cerebral hemorrhage or ischemic cerebral infarction diagnosis code should be assigned as the principal diagnosis.

We acknowledged in the proposed rule that new MS–DRGs were created for cases of patients with sepsis requiring mechanical ventilation greater than and less than 96 hours. However, those MS–DRGs (MS–DRG 575 (Septicemia with Mechanical Ventilation 96+ Hours Age >17) and MS–DRG 576 (Septicemia without Mechanical Ventilation 96+ Hours Age >17)) were created several years ago, in FY 2007 (71 FR 47938 through 47939) in response to public comments suggesting alternatives for the need to recognize the treatment for that subset of patients with severe sepsis who exhibit a greater degree of severity and resource consumption as septicemia is a systemic condition, and also as a

preliminary step in the transition from the CMS DRGs to MS–DRGs.

We stated in the proposed rule that we believe that additional analysis and efforts toward a broader approach to refining the MS–DRGs for cases of patients requiring mechanical ventilation across the MDCs involves carefully examining the potential for instability in the relative weights and disrupting the integrity of the MS–DRG system based on the creation of separate MS–DRGs involving small numbers of cases for various indications in which mechanical ventilation may be required.

The second request focused on patients diagnosed with *any* neurological condition classified under MDC 1 requiring mechanical ventilation in the absence of an O.R. procedure and without having received a thrombolytic agent. Because the first request specifically involved analysis for the acute neurological conditions of cerebral infarction and intracranial hemorrhage under MDC 1 and our findings did not support creating new MS–DRGs for those specific conditions, we did not perform separate claims analysis for other conditions classified under MDC 1.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule, we did not propose to create new MS–DRGs for cases that identify patients diagnosed with neurological conditions classified under MDC 1 who require mechanical ventilation with or without a thrombolytic and in the absence of an O.R. procedure.

Comment: Commenters supported CMS' proposal to not create new MS–DRGs, classified under MDC 1, for cases representing patients diagnosed with a neurological condition who require mechanical ventilation with or without a thrombolytic, and in the absence of an O.R. procedure. The commenters stated that the proposal was reasonable, given the data, the ICD–10–CM diagnosis codes, the ICD–10–PCS procedure codes, and the information provided. However, the commenters also recommended that CMS continue to conduct further analyses across all the MDCs for the subset of patients who require mechanical ventilation in an effort to better address the reporting and payment issues.

Response: We appreciate the commenters' support and agree that further analyses are necessary to evaluate the development of potential proposals for the subset of patients requiring mechanical ventilation across all the MDCs.

Comment: One commenter disagreed with CMS' proposal to not create new MS–DRGs for patients admitted with strokes and treated with mechanical ventilation. The commenter expressed appreciation for CMS' efforts in analyzing the cost and length of stay data for this subset of patients. However, the commenter believed that the results of the analysis identifying patients who receive mechanical ventilation >96 hours and also have an MCC demonstrate that these cases require twice the cost of all cases in MS–DRG 61 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC) and MS–DRG 64 (Intracranial Hemorrhage or Cerebral Infarction with MCC). The commenter requested that CMS reconsider alternative options for this subset of patients due to the cost and length of stay disparities.

Response: We acknowledge the commenters' concern that the average length of stay and average costs for cases where mechanical ventilation >96 hours was reported with an MCC for MS–DRG 61 and MS–DRG 64 are greater when compared to the average length of stay and average costs for all cases in those MS–DRGs. However, as stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20195), our clinical advisors noted that patients requiring mechanical ventilation are known to be more resource intensive and it would not be practical to create new MS–DRGs for this subset of patients given the various other indications in which mechanical ventilation may be utilized for other patients. We will consider additional analysis in the future in our efforts toward a broader approach to refining the MS–DRGs for cases of patients requiring mechanical ventilation across the MDCs.

Comment: One commenter suggested that, although CMS' analysis of the cases reporting a neurological condition with mechanical ventilation was acceptable, CMS consider creating a new MS–DRG for poisoning with mechanical ventilation in future rulemaking. The commenter believed that a patient who is in critical condition as a result of a poisoning and requires prolonged mechanical ventilation is not being recognized appropriately under the current MS–DRG relative payment weights.

Response: We appreciate the commenter's input and suggestion. As noted earlier, we will consider additional analysis in our efforts toward a broader approach to refining the MS–DRGs for cases of patients requiring mechanical ventilation across the MDCs.

After consideration of the public comments we received, we are finalizing our proposal to not create new MS–DRGs, classified under MDC 1, for cases that identify patients requiring mechanical ventilation and are diagnosed with stroke or any other neurological condition with or without a thrombolytic, and in the absence of an O.R. procedure for FY 2019.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Pacemaker Insertions

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56804 through 56809), we discussed a request to examine the ICD–10–PCS procedure code combinations that describe procedures involving pacemaker insertions to determine if some procedure code combinations were excluded from the Version 33 ICD–10 MS–DRG assignments for MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively) under MDC 5. We finalized our proposal to modify the Version 34 ICD–10 MS–DRG GROUPER logic so the specified procedure code combinations were no longer required for assignment into those MS–DRGs. As a result, the logic for pacemaker insertion procedures was simplified by separating the procedure codes describing cardiac pacemaker device insertions into one list and separating the procedure codes describing cardiac pacemaker lead insertions into another list. Therefore, when any ICD–10–PCS procedure code describing the insertion of a pacemaker device is reported from that specific logic list with any ICD–10–PCS procedure code describing the insertion of a pacemaker lead from that specific logic list (81 FR 56804 through 56806), the case is assigned to MS–DRGs 242, 243, and 244 under MDC 5.

We then discussed our examination of the Version 33 GROUPER logic for MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively) because assignment of cases to these MS–DRGs also included qualifying ICD–10–PCS procedure code combinations involving pacemaker insertions (81 FR 56806 through 56808). Specifically, the logic for Version 33 ICD–10 MS–DRGs 258 and 259 included ICD–10–PCS procedure code combinations describing the removal of pacemaker devices and the insertion of new pacemaker devices. We finalized our proposal to modify the Version 34 ICD–10 MS–DRG GROUPER logic for MS–DRGs 258 and 259 to establish that a case reporting any procedure code from the list of ICD–10–PCS procedure codes describing procedures involving pacemaker device insertions without any other procedure

codes describing procedures involving pacemaker leads reported would be assigned to MS–DRGs 258 and 259 (81 FR 56806 through 56807) under MDC 5. In addition, we pointed out that a limited number of ICD–10–PCS procedure codes describing pacemaker insertion are classified as non-operating room (non-O.R.) codes within the MS–DRGs and that the Version 34 ICD–10 MS–DRG GROUPER logic would continue to classify these procedure codes as non-O.R. codes. We noted that a case reporting any one of these non-O.R. procedure codes describing a pacemaker device insertion without any other procedure code involving a pacemaker lead would be assigned to MS–DRGs 258 and 259. Therefore, the listed procedure codes describing a pacemaker device insertion under MS–DRGs 258 and 259 are designated as non-O.R. affecting the MS–DRG.

Lastly, we discussed our examination of the Version 33 GROUPER logic for MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively), and noted that cases assigned to these MS–DRGs also included lists of procedure code combinations describing procedures involving the removal of pacemaker leads and the insertion of new leads, in addition to lists of single procedure codes describing procedures involving the insertion of pacemaker leads, removal of cardiac devices, and revision of cardiac devices (81 FR 56808). We finalized our proposal to modify the ICD–10 MS–DRG GROUPER logic for MS–DRGs 260, 261, and 262 so that cases reporting any one of the listed ICD–10–PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices are assigned to MS DRGs 260, 261, and 262 under MDC 5. Therefore, the GROUPER logic that required a combination of procedure codes be reported for assignment into MS–DRGs 260, 261 and 262 under Version 33 was no longer required effective with discharges occurring on or after October 1, 2016 (FY 2017) under Version 34 of the ICD–10 MS–DRGs.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20198), we noted that while the discussion in the FY 2017 IPPS/LTCH PPS final rule focused on the MS–DRGs involving pacemaker procedures under MDC 5, similar GROUPER logic exists in Version 33 of the ICD–10 MS–DRGs under MDC 1 (Diseases and Disorders of the Nervous System) in MS–DRGs 040, 041 and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator and without CC/MCC, respectively) and MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) in MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without MCC, respectively) where procedure code combinations involving cardiac pacemaker device insertions or removals and cardiac pacemaker lead insertions or removals are required to be reported together for assignment into those MS–DRGs. We also noted that, with the exception of when a principal diagnosis is reported from MDC 1, MDC 5, or MDC 21, the procedure codes describing the insertion, removal, replacement, or revision of pacemaker devices are assigned to a medical MS–DRG in the absence of another O.R. procedure according to the GROUPER logic. We referred the reader to the ICD–10 MS–DRG Definitions Manual Version 33, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for complete documentation of the GROUPER logic that was in effect at that time for the Version 33 ICD–10 MS–DRGs discussed earlier.

As discussed in the FY 2019 IPS/LTCH PPS proposed rule (83 FR 20198), for FY 2019, we received a request to assign all procedures involving the insertion of pacemaker devices to surgical MS–DRGs, regardless of the principal diagnosis. The requestor recommended that procedures involving pacemaker insertion be grouped to surgical MS–DRGs within the MDC to which the principal diagnosis is assigned, or that they group to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively). Currently, in Version 35 of the ICD–10 MS–DRGs, procedures involving pacemakers are assigned to MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator and without CC/MCC, respectively) under MDC 1 (Diseases and Disorders of the Nervous System), to MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with MCC and without MCC, respectively), and MS–DRGs 260, 261 and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) under MDC 5 (Diseases and Disorders of the Circulatory System), and to MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively), under MDC 21 (Injuries, Poisoning and Toxic Effects of Drugs), with all other unrelated principal diagnoses resulting in a medical MS–DRG assignment. According to the requestor, the medical MS–DRGs do not provide adequate payment for the pacemaker device, specialized operating suites, time, skills, and other resources involved for pacemaker insertion procedures. Therefore, the requestor recommended that procedures involving pacemaker insertions be grouped to surgical MS–DRGs. We refer readers to the ICD–10 MS–DRG Definitions Manual Version 35, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for complete documentation of the GROUPER logic for the MS–DRGs discussed earlier.

The following procedure codes describe procedures involving the insertion of a cardiac rhythm related device which are classified as a type of pacemaker insertion under the ICD–10 MS–DRGs. These four codes are assigned to MS–DRGs 040, 041, and 042, as well as MS–DRGs 907, 908, and 909, and are designated as O.R. procedures.

ICD–10–PCS code	Code description
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.

We examined cases from the September update of the FY 2017 MedPAR claims data for cases involving pacemaker insertion procedures reporting the above ICD–10–PCS codes in MS–DRGs 040, 041 and 042 under MDC 1. Our findings are shown in the following table.

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 1

MS–DRG in MDC 1	Number of cases	Average length of stay	Average costs
MS–DRG 040—All cases	4,462	10.4	$26,877
MS–DRG 040—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	13	14.2	55,624
MS–DRG 040—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	2	3.5	15,826
MS–DRG 040—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	0	0	0
MS–DRG 040—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0
MS–DRG 041—All cases	5,648	5.2	16,927
MS–DRG 041—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	12	6.4	22,498
MS–DRG 041—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	4	5	17,238
MS–DRG 041—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	0	0	0
MS–DRG 041—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0
MS–DRG 042—All cases	2,154	3.1	13,730
MS–DRG 042—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	5	8	18,183
MS–DRG 042—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0
MS–DRG 042—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	0	0	0
MS–DRG 042—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0

The following table is a summary of the findings shown above from our review of MS–DRGs 040, 041 and 042 and the total number of cases reporting a pacemaker insertion procedure.

MS–DRGS FOR CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 1

MS–DRG in MDC 1	Number of cases	Average length of stay	Average costs
MS–DRGs 040, 041, and 042—All cases	12,264	6.7	$19,986
MS–DRGs 040, 041, and 042—Cases with a pacemaker insertion procedure	36	9.1	32,906

We found a total of 12,264 cases in MS–DRGs 040, 041, and 042 with an average length of stay of 6.7 days and average costs of $19,986. We found a total of 36 cases in MS–DRGs 040, 041, and 042 reporting procedure codes describing the insertion of a pacemaker device with an average length of stay of 9.1 days and average costs of $32,906.

We then examined cases involving pacemaker insertion procedures reporting those same four ICD–10–PCS procedure codes 0JH60PZ, 0JH63PZ, 0JH80PZ and 0JH83PZ in MS–DRGs 907, 908, and 909 under MDC 21. Our findings are shown in the following table.

MS–DRGS FOR CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 21

MS–DRG in MDC 21	Number of cases	Average length of stay	Average costs
MS–DRG 907–All cases	7,405	10.1	$28,997
MS–DRG 907—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	7	11.1	60,141
MS–DRG 908—All cases	8,519	5.2	14,282
MS–DRG 908—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	4	3.8	35,678
MS–DRG 909—All cases	3,224	3.1	9,688
MS–DRG 909—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	2	2	42,688

We note that there were no cases found where procedure codes 0JH63PZ, 0JH80PZ or 0JH83PZ were reported in MS–DRGs 907, 908 and 909 under MDC 21 and, therefore, they are not displayed in the table.

The following table is a summary of the findings shown above from our review of MS–DRGs 907, 908, and 909 and the total number of cases reporting a pacemaker insertion procedure.

MS–DRGs FOR CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 21

MS–DRG in MDC 21	Number of cases	Average length of stay	Average costs
MS–DRGs 907, 908 and 909—All cases	19,148	6.7	$19,199
MS–DRGs 907, 908 and 909—Cases with a pacemaker insertion procedure	13	7.5	49,929

We found a total of 19,148 cases in MS–DRGs 907, 908, and 909 with an average length of stay of 6.7 days and average costs of $19,199. We found a total of 13 cases in MS–DRGs 907, 908, and 909 reporting pacemaker insertion procedures with an average length of stay of 7.5 days and average costs of $49,929.

We also examined cases involving pacemaker insertion procedures reporting the following procedure codes that are assigned to MS–DRGs 242, 243, and 244 under MDC 5.

ICD–10–PCS code	Code description
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.
0JH607Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.
0JH634Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH635Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.
0JH636Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH637Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH804Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH805Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.
0JH806Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH807Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.
0JH834Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH835Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH836Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH837Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.

Our data findings are shown in the following table. We note that procedure codes displayed with an asterisk (*) in the table are designated as non-O.R. procedures affecting the MS–DRG.

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 5

MS–DRG in MDC 5	Number of cases	Average length of stay	Average costs
MS–DRG 242—All cases	18,205	6.9	$26,414
MS–DRG 242—Cases with procedure code 0JH604Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach)	2,518	7.7	25,004
MS–DRG 242—Cases with procedure code 0JH605Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach)	306	7.7	24,454
MS–DRG 242—Cases with procedure code 0JH606Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach)	13,323	6.7	25,497
MS–DRG 242—Cases with procedure code 0JH607Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach)	1,528	8.1	37,060
MS–DRG 242—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	5	16.6	59,334
MS–DRG 242—Cases with procedure code 0JH634Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach)	65	8.5	26,789

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 5—Continued

MS–DRG in MDC 5	Number of cases	Average length of stay	Average costs
MS–DRG 242—Cases with procedure code 0JH635Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach)	10	7	35,104
MS–DRG 242—Cases with procedure code 0JH636Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach)	313	6.4	23,699
MS–DRG 242—Cases with procedure code 0JH637Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest Subcutaneous tissue and fascia, percutaneous approach)	82	7.1	35,382
MS–DRG 242—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	2	12.5	32,405
MS–DRG 242—Cases with procedure code 0JH804Z* (Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach)	25	14.4	43,080
MS–DRG 242—Cases with procedure code 0JH805Z* (Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach)	2	4	26,949
MS–DRG 242—Cases with procedure code 0JH806Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach)	50	6.8	25,306
MS–DRG 242—Cases with procedure code 0JH807Z (Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach)	5	21.2	67,908
MS–DRG 242—Cases with procedure code 0JH836Z (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach)	1	5	36,111
MS–DRG 243—All cases	24,586	4	18,669
MS–DRG 243—Cases with procedure code 0JH604Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach)	2,537	4.7	17,118
MS–DRG 243—Cases with procedure code 0JH605Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach)	271	4.4	17,268
MS–DRG 243—Cases with procedure code 0JH606Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach)	19,921	3.9	18,306
MS–DRG 243—Cases with procedure code 0JH607Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach)	1,236	4.4	28,658
MS–DRG 243—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	6	4.2	20,994
MS–DRG 243—Cases with procedure code 0JH634Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach)	55	5.2	16,784
MS–DRG 243—Cases with procedure code 0JH635Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach)	15	4.1	17,938
MS–DRG 243—Cases with procedure code 0JH636Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach)	431	3.7	16,164
MS–DRG 243—Cases with procedure code 0JH637Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach)	58	5	28,926
MS–DRG 243—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	3	8.3	23,717
MS–DRG 243—Cases with procedure code 0JH804Z* (Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach)	10	8.2	20,871
MS–DRG 243—Cases with procedure code 0JH805Z* (Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach)	1	4	15,739
MS–DRG 243—Cases with procedure code 0JH806Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach)	57	4.4	18,787
MS–DRG 243—Cases with procedure code 0JH807Z (Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach)	3	4	19,653
MS–DRG 243—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	1	7	16,224
MS–DRG 243—Cases with procedure code 0JH836Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach)	1	2	14,005
MS–DRG 244—All cases	15,974	2.7	15,670
MS–DRG 244—Cases with procedure code 0JH604Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach)	1,045	3.2	14,541
MS–DRG 244—Cases with procedure code 0JH605Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach)	127	3	13,208
MS–DRG 244—Cases with procedure code 0JH606Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach)	14,092	2.7	15,596
MS–DRG 244—Cases with procedure code 0JH607Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach)	303	2.8	26,221
MS–DRG 244—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	2	4.5	9,248
MS–DRG 244—Cases with procedure code 0JH634Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach)	32	2.8	11,525
MS–DRG 244—Cases with procedure code 0JH635Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach)	1	2	30,100
MS–DRG 244—Cases with procedure code 0JH636Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach)	320	2.6	13,670

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 5—Continued

MS–DRG in MDC 5	Number of cases	Average length of stay	Average costs
MS–DRG 244—Cases with procedure code 0JH637Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach)	20	2.7	19,218
MS–DRG 244—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	1	3	12,120
MS–DRG 244—Cases with procedure code 0JH805Z* (Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach)	1	1	21,604
MS–DRG 244—Cases with procedure code 0JH806Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach)	36	3.2	16,492
MS–DRG 244—Cases with procedure code 0JH836Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach)	1	3	12,160

The following table is a summary of the findings shown above from our review of MS–DRGs 242, 243, and 244 and the total number of cases reporting a pacemaker insertion procedure.

MS–DRGS FOR CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 5

MS–DRG in MDC 5	Number of cases	Average length of stay	Average costs
MS–DRGs 242, 243 and 244—All cases	58,765	4.6	$20,253
MS–DRGs 242, 243, and 244—Cases with a pacemaker insertion procedure	*58,822	4.6	20,270

*The figure is not adjusted for cases reporting more than one pacemaker insertion procedure code. The figure represents the frequency in which the number of pacemaker insertion procedures was reported.

We found a total of 58,765 cases in MS–DRGs 242, 243, and 244 with an average length of stay of 4.6 days and average costs of $20,253. We found a total of 58,822 cases reporting pacemaker insertion procedures in MS–DRGs 242, 243, and 244 with an average length of stay of 4.6 days and average costs of $20,270. We note that the analysis performed is by procedure code, and because multiple pacemaker insertion procedures may be reported on a single claim, the total number of these pacemaker insertion procedure cases exceeds the total number of all cases found across MS–DRGs 242, 243, and 244 (58,822 procedures versus 58,765 cases).

We then analyzed claims for cases reporting a procedure code describing (1) the insertion of a pacemaker device only, (2) the insertion of a pacemaker lead only, and (3) both the insertion of a pacemaker device and a pacemaker lead across all the MDCs except MDC 5 to determine the number of cases currently grouping to medical MS–DRGs and the potential impact of these cases moving into the surgical unrelated MS–DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively). Our findings are shown in the following table.

PACEMAKER INSERTION PROCEDURES IN MEDICAL MS–DRGS

All MDCs except MDC 5	Number of cases	Average length of stay	Average costs
Procedures for insertion of pacemaker device	2,747	9.5	$29,389
Procedures for insertion of pacemaker lead	2,831	9.4	29,240
Procedures for insertion of pacemaker device with insertion of pacemaker lead	2,709	9.4	29,297

We found a total of 2,747 cases reporting the insertion of a pacemaker device in 177 medical MS–DRGs with an average length of stay of 9.5 days and average costs of $29,389 across all the MDCs except MDC 5. We found a total of 2,831 cases reporting the insertion of a pacemaker lead in 175 medical MS–DRGs with an average length of stay of 9.4 days and average costs of $29,240 across all the MDCs except MDC 5. We found a total of 2,709 cases reporting both the insertion of a pacemaker device and the insertion of a pacemaker lead in 170 medical MS–DRGs with an average length of stay of 9.4 days and average costs of $29,297 across all the MDCs except MDC 5.

We also analyzed claims for cases reporting a procedure code describing the insertion of a pacemaker device with a procedure code describing the insertion of a pacemaker lead in all the surgical MS–DRGs across all the MDCs except MDC 5. Our findings are shown in the following table.

PACEMAKER INSERTION PROCEDURES IN SURGICAL MS–DRGS

All MDCs except MDC 5	Number of cases	Average length of stay	Average costs
Procedures for insertion of pacemaker device with insertion of pacemaker lead	3,667	12.8	$48,856

We found a total of 3,667 cases reporting the insertion of a pacemaker device and the insertion of a pacemaker lead in 194 surgical MS–DRGs with an average length of stay of 12.8 days and average costs of $48,856 across all the MDCs except MDC 5.

For cases where the insertion of a pacemaker device, the insertion of a pacemaker lead or the insertion of both a pacemaker device and lead were reported on a claim grouping to a medical MS–DRG, the average length of stay and average costs were generally higher for these cases when compared to the average length of stay and average costs for all the cases in their assigned MS–DRGs. For example, we found 113 cases reporting both the insertion of a pacemaker device and lead in MS–DRG 378 (G.I. Hemorrhage with CC), with an average length of stay of 7.1 days and average costs of $23,711. The average length of stay for all cases in MS–DRG 378 was 3.6 days and the average cost for all cases in MS–DRG 378 was $7,190. The average length of stay for cases reporting both the insertion of a pacemaker device and lead were twice as long as the average length of stay for all the cases in MS–DRG 378 (7.1 days versus 3.6 days). In addition, the average costs for the cases reporting both the insertion of a pacemaker device and lead were approximately $16,500 higher than the average costs of all the cases in MS–DRG 378 ($23,711 versus $7,190). We refer readers to Table 6P.1c associated with the proposed rule (which is available via the internet on the CMS website) for the detailed report of our findings across the other medical MS–DRGs. We note that the average costs and average length of stay for cases reporting the insertion of a pacemaker device, the insertion of a pacemaker lead or the insertion of both a pacemaker device and lead are reflected in Columns D and E, while the average costs and average length of stay for all cases in the respective MS–DRG are reflected in Columns I and J.

The claims data results from our analysis of this request showed that if we were to support restructuring the GROUPER logic so that pacemaker insertion procedures that include a combination of the insertion of the pacemaker device with the insertion of the pacemaker lead are designated as an O.R. procedure across all the MDCs, we would expect approximately 2,709 cases to move or ''shift'' from the medical MS–DRGs where they are currently grouping into the surgical unrelated MS–DRGs 981, 982, and 983.

Our clinical advisors reviewed the data results and recommended that pacemaker insertion procedures involving a complete pacemaker system (insertion of pacemaker device combined with insertion of pacemaker lead) warrant classification into surgical MS–DRGs because the patients receiving these devices demonstrate greater treatment difficulty and utilization of resources when compared to procedures that involve the insertion of only the pacemaker device or the insertion of only the pacemaker lead. We note that the request we addressed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24981 through 24984) was to determine if some procedure code combinations were excluded from the ICD–10 MS–DRG assignments for MS–DRGs 242, 243, and 244. We proposed and, upon considering public comments received, finalized an alternate approach that we believed to be less complicated. We also stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56806) that we would continue to monitor the MS–DRGs for pacemaker insertion procedures as we receive ICD–10 claims data. Upon further review, we stated that we believe that recreating the procedure code combinations for pacemaker insertion procedures would allow for the grouping of these procedures to the surgical MS–DRGs, which we believe is warranted to better recognize the resources and complexity of performing these procedures. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20203), we proposed to recreate pairs of procedure code combinations involving both the insertion of a pacemaker device with the insertion of a pacemaker lead to act as procedure code combination pairs or ''clusters'' in the GROUPER logic that are designated as O.R. procedures outside of MDC 5 when reported together.

Comment: Commenters supported the proposal to recreate pairs of procedure code combinations involving both the insertion of a pacemaker device with the insertion of a pacemaker lead to act as procedure code combination pairs or ''clusters'' in the GROUPER logic that are designated as O.R. procedures outside of MDC 5 when reported together. One commenter specifically expressed its appreciation of CMS' efforts to update the MS–DRG GROUPER logic to better recognize the resources and complexity of pacemaker device and lead procedures. Another commenter disagreed with the proposal to use pacemaker code pairs for assignment to a surgical MS–DRG, stating it would be more appropriate to designate each pacemaker device and pacemaker lead procedure code as an O.R. procedure to allow initial insertions and replacement of individual components to group to surgical MS–DRGs within all MDCs. According to the commenter, this designation would compensate providers for the cost of the device and the resources utilized in the performance of initial insertions and the replacement of individual components.

Response: We appreciate the commenters' support. With regard to the commenter who disagreed with the proposal to utilize pacemaker code pairs for assignment to a surgical MS–DRG and suggested that the GROUPER logic designate each pacemaker device and pacemaker lead procedure code as an O.R. procedure to allow initial insertions and replacement of individual components to group to surgical MS–DRGs within all MDCs, we note that, as displayed in Table 6P.1c. associated with the FY 2019 IPPS/LTCH PPS proposed rule (which is available via the internet on the CMS website), our claims analysis for cases reporting a procedure code describing the insertion of a pacemaker device only demonstrated a total of six cases across all the medical MS–DRGs, and for cases reporting a procedure code describing the insertion of a pacemaker lead only, the data demonstrated a total of four cases across all the medical MS–DRGs. As a result, there were a total of only 10 cases where a stand-alone code for insertion of a pacemaker device procedure or a stand-alone code for insertion of a pacemaker lead procedure was reported. Those 10 cases grouped to 10 different medical MS–DRGs, of which 8 included a CC or MCC diagnosis. Therefore, it is not clear how much of the average costs, the average length of stay, the complexity of service, and resource utilization for those cases

are attributable to the insertion of the pacemaker device/lead procedure versus the severity of illness.

After consideration of the public comments we received, we are finalizing our proposal to recreate pairs of procedure code combinations involving both the insertion of a pacemaker device with the insertion of a pacemaker lead to act as procedure code combination pairs or ''clusters'' in the GROUPER logic that are designated as O.R. procedures outside of MDC 5 when reported together under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

We also proposed to designate all the procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual stand-alone code based on the recommendation of our clinical advisors as noted in the proposed rule and earlier in this section and consistent with how these procedures were classified under the Version 33 ICD–10 MS–DRG GROUPER logic.

Comment: A number of commenters supported the proposal to designate all the procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual stand-alone code. However, other commenters opposed the proposal. One commenter acknowledged that the complexity of inserting a full pacemaker system is greater than when inserting a pacemaker lead or generator. However, this commenter asserted that the complexity does not increase significantly and that the placement of a lead or generator still requires the use of an operating room, sterile field, anesthesiology, and preparing the patient. The commenter believed that the placement of a pacemaker lead or device does require the use of an operating room and expressed concern that CMS would designate the procedures as a non-O.R. procedure.

Response: We appreciate the commenters' support. With regard to the commenter who expressed concern that we proposed to designate procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual stand-alone code, we note that historically, these procedures have been designated as non-O.R. procedures. As we noted in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20203), our proposal to designate all the procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual stand-alone code is consistent with how these procedures were classified under the Version 33 ICD–10 MS–DRG GROUPER logic. In addition, our clinical advisors continue to support the non-O.R. designation because, as the commenter noted in its own comments, while these procedures may require a sterile field, anesthesia and preparing the patient, the complexity of inserting a pacemaker lead or generator alone is less than that of inserting a full pacemaker system and the former can be performed in settings such as cardiac catheterization laboratories.

After consideration of the public comments we received, we are finalizing our proposal to designate all the procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual stand-alone code outside of MDC 5 under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

In the proposed rule, we referred readers to Table 6P.1d, Table 6P.1e, and Table 6P.1f. associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for (1) a complete list of the proposed procedure code combinations or ''pairs''; (2) a complete list of the procedure codes describing the insertion of a pacemaker device; and (3) a complete list of the procedure codes describing the insertion of a pacemaker lead. We invited public comments on our lists of procedure codes that we proposed to include for restructuring the ICD–10 MS–DRG GROUPER logic for pacemaker insertion procedures.

In addition, we proposed to maintain the current GROUPER logic for MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with MCC and without MCC, respectively) where the listed procedure codes as shown in the ICD–10 MS–DRG Definitions Manual Version 35, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*, describing a pacemaker device insertion, continue to be designated as ''non-O.R. affecting the MS–DRG'' because they are reported when a pacemaker device requires replacement and have a corresponding diagnosis from MDC 5. Also, we proposed to maintain the current GROUPER logic for MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) so that cases reporting any one of the listed ICD–10–PCS procedure codes as shown in the ICD–10 MS–DRG Definitions Manual Version 35 describing procedures involving pacemakers and related procedures and associated devices will continue to be assigned to those MS DRGs under MDC 5 because they are reported when a pacemaker device requires revision and they have a corresponding circulatory system diagnosis.

Comment: Commenters agreed with the proposed lists of procedure codes for restructuring the ICD–10 MS DRG GROUPER logic for pacemaker insertion procedures. One commenter also suggested the addition of ICD–10–PCS procedure code 02H63MZ (Insertion of cardiac lead into right atrium, percutaneous approach) and ICD–10–PCS procedure code 02H73MZ (Insertion of cardiac lead into left atrium, percutaneous approach) to Tables 6P.1d. and Table 6P.1f. that were associated with the proposed rule. The commenter noted that the tables included the open and percutaneous endoscopic approaches but did not include the percutaneous approach.

Response: We appreciate the commenters' support. We agree with the commenter to add ICD–10–PCS procedure codes 02H63MZ and 02H73MZ to Table 6P.1d and as reflected in Table 6P.1f. associated with this final rule (which is available via the internet on the CMS website), to be included for the pacemaker insertion code pairs and as stand-alone codes for the insertion of a pacemaker lead. The codes are consistent with the other insertion of cardiac lead procedures and were inadvertently omitted from the initial list.

After consideration of the public comments we received, we are finalizing the lists of the procedure codes in Tables 6P.1d., Table 6P.1e., and Table 6P.1f associated with the proposed rule, with the addition of ICD–10–PCS procedure codes 02H63MZ and 02H73MZ to be included for the pacemaker insertion code pairs and as stand-alone codes for the insertion of a pacemaker lead, as reflected in Tables 6P.1.d. and 6P.1.f. associated with this final rule. We also are finalizing our proposal to maintain the current GROUPER logic for MS–DRGs 258 and 259 and for MS–DRGs 260, 261, and 262

under the ICD–10 Version 36, effective October 1, 2018.

We noted in the proposed rule that, while the requestor did not include the following procedure codes in its request, these codes are also currently designated as O.R. procedure codes and are assigned to MS–DRGs 260, 261, and 262 under MDC 5.

ICD–10–PCS code	Code description
02PA0MZ	Removal of cardiac lead from heart, open approach.
02PA3MZ	Removal of cardiac lead from heart, percutaneous approach.
02PA4MZ	Removal of cardiac lead from heart, percutaneous endoscopic approach.
02WA0MZ	Revision of cardiac lead in heart, open approach.
02WA3MZ	Revision of cardiac lead in heart, percutaneous approach.
02WA4MZ	Revision of cardiac lead in heart, percutaneous endoscopic approach.
0JPT0PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, open approach.
0JPT3PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, percutaneous approach.
0JWT0PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach.
0JWT3PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach.

In the proposed rule, we solicited public comments on whether these procedure codes describing the removal or revision of a cardiac lead and removal or revision of a cardiac rhythm related (pacemaker) device should also be designated as non-O.R. procedure codes for FY 2019 when reported as a single, individual stand-alone code with a principal diagnosis outside of MDC 5 for consistency in the classification among these devices.

Comment: One commenter recommended that CMS not finalize the proposed designation of the procedure codes listed in the above table describing the removal or revisions of a cardiac lead and the removal or revision of a cardiac rhythm related (pacemaker) device from O.R. procedures to non-O.R. procedures when reported as a single, individual stand-alone code when reported with a principal diagnosis outside of MDC 5. Another commenter expressed concern that the rationale for the proposal was not clear and warranted additional clarification about the data used to arrive at this recommendation. According to this commenter, regardless of the principal diagnosis, the resources for procedures involving insertion, removal or revision of a pacemaker generator or lead are the same. The commenter further noted that revisions are often more complex and require greater resources. The commenter recommended that CMS continue to designate the procedures as O.R. procedures and further explain the proposal.

Response: We appreciate the commenter's feedback. We note that while we were soliciting comments on the procedure codes listed in the table above that describe the removal or revision of a cardiac lead and the removal or revision of a cardiac rhythm related (pacemaker) device, we did not specifically recommend a change to the designation of the procedure codes at this time. We agree with the commenter that the removal or revision of a cardiac lead or pacemaker generator can be more complex and require greater resources than an initial insertion procedure.

After consideration of the public comments we received, we are maintaining the O.R. designation of the procedure codes listed in the above table under the ICD–10 MS–DRGs Version 36, effective October 1, 2018. As additional claims data become available, we will continue to analyze these procedures.

We also note in the proposed rule that, while the requestor did not include the following procedure codes in its request, the codes in the following table became effective October 1, 2016 (FY 2017) and also describe procedures involving the insertion of a pacemaker. Specifically, the following list includes procedure codes that describe an intracardiac or ''leadless'' pacemaker. These procedure codes are designated as O.R. procedure codes and are currently assigned to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with MCC and without MCC, respectively) under MDC 5.

ICD–10–PCS code	Code description
02H40NZ	Insertion of intracardiac pacemaker into coronary vein, open approach.
02H43NZ	Insertion of intracardiac pacemaker into coronary vein, percutaneous approach.
02H44NZ	Insertion of intracardiac pacemaker into coronary vein, percutaneous endoscopic approach.
02H60NZ	Insertion of intracardiac pacemaker into right atrium, open approach.
02H63NZ	Insertion of intracardiac pacemaker into right atrium, percutaneous approach.
02H64NZ	Insertion of intracardiac pacemaker into right atrium, percutaneous endoscopic approach.
02H70NZ	Insertion of intracardiac pacemaker into left atrium, open approach.
02H73NZ	Insertion of intracardiac pacemaker into left atrium, percutaneous approach.
02H74NZ	Insertion of intracardiac pacemaker into left atrium, percutaneous endoscopic approach.
02HK0NZ	Insertion of intracardiac pacemaker into right ventricle, open approach.
02HK3NZ	Insertion of intracardiac pacemaker into right ventricle, percutaneous approach.
02HK4NZ	Insertion of intracardiac pacemaker into right ventricle, percutaneous endoscopic approach.
02HL0NZ	Insertion of intracardiac pacemaker into left ventricle, open approach.
02HL3NZ	Insertion of intracardiac pacemaker into left ventricle, percutaneous Approach.
02HL4NZ	Insertion of intracardiac pacemaker into left ventricle, percutaneous endoscopic approach.
02WA0NZ	Revision of intracardiac pacemaker in heart, open approach.
02WA3NZ	Revision of intracardiac pacemaker in heart, percutaneous approach.
02WA4NZ	Revision of intracardiac pacemaker in heart, percutaneous endoscopic approach.
02WAXNZ	Revision of intracardiac pacemaker in heart, external approach.
02H40NZ	Insertion of intracardiac pacemaker into coronary vein, open approach.

ICD–10–PCS code	Code description
02H43NZ	Insertion of intracardiac pacemaker into coronary vein, percutaneous approach.

We examined claims data for procedures involving an intracardiac pacemaker reporting any of the above codes across all MS–DRGs. Our findings are shown in the following table.

INTRACARDIAC PACEMAKER PROCEDURES

Across all MS–DRGs	Number of cases	Average length of stay	Average costs
Procedures for intracardiac pacemaker	1,190	8.6	$38,576

We found 1,190 cases reporting a procedure involving an intracardiac pacemaker with an average length of stay of 8.6 days and average costs of $38,576. Of these 1,190 cases, we found 1,037 cases in MS–DRGs under MDC 5. We also found that the 153 cases that grouped to MS–DRGs outside of MDC 5 grouped to surgical MS–DRGs; therefore, another O.R. procedure was also reported on the claim. However, in the FY 2019 IPPS/LTCH PPS proposed rule, we solicited public comments on whether these procedure codes describing the insertion and revision of intracardiac pacemakers should also be considered for classification into all surgical unrelated MS–DRGs outside of MDC 5 for FY 2019.

Comment: Commenters supported classifying the procedure codes listed in the table above describing the insertion and revision of intracardiac pacemakers into all surgical unrelated MS–DRGs outside of MDC 5.

Response: We appreciate the commenters' feedback. We note that while we solicited comments on the procedure codes listed in the table above that describe the insertion of an intracardiac pacemaker device, we did not specifically recommend a change to the designation of the procedure codes at this time. We also note that, currently, the procedures are already classified within the GROUPER logic as extensive O.R. procedures. Therefore, if one of the procedure codes is reported with a principal diagnosis outside of MDC 5, the case will group to one of the unrelated surgical MS–DRGs.

After consideration of the public comments we received, we are maintaining the O.R. designation of the procedure codes listed in the above table under the ICD–10 MS–DRGs Version 36, effective October 1, 2018. As additional claims data become available, we will continue to analyze these procedures.

b. Drug-Coated Balloons in Endovascular Procedures

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38111), we discontinued new technology add-on payments for the LUTONIX® and IN.PACT™ Admiral™ drug-coated balloon (DCB) technologies, effective for FY 2018, because the technology no longer met the newness criterion for new technology add-on payments. For FY 2019, we received a request to reassign cases that utilize a drug-coated balloon in the performance of an endovascular procedure involving the treatment of superficial femoral arteries for peripheral arterial disease from the lower severity level MS–DRG 254 (Other Vascular Procedures without CC/MCC) and MS–DRG 253 (Other Vascular Procedures with CC) to the highest severity level MS–DRG 252 (Other Vascular Procedures with MCC). We also received a request to revise the title of MS–DRG 252 to ''Other Vascular Procedures with MCC or Drug-Coated Balloon Implant''.

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20205), there are currently 36 ICD–10–PCS procedure codes that describe the performance of endovascular procedures involving treatment of the superficial femoral arteries that utilize a drug-coated balloon, which are listed in the following table.

ICD–10–PCS code	Code description
047K041	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047K0D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach.
047K0Z1	Dilation of right femoral artery using drug-coated balloon, open approach.
047K341	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047K3D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047K3Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous approach.
047K441	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047L041	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047L0D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach.
047L0Z1	Dilation of left femoral artery using drug-coated balloon, open approach.
047L341	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047L3D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047L3Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous approach.
047L441	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach.

ICD–10–PCS code	Code description
047M041	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047M0D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach.
047M0Z1	Dilation of right popliteal artery using drug-coated balloon, open approach.
047M341	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047M3D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047M3Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach.
047M441	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach.
047N041	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047N0D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach.
047N0Z1	Dilation of left popliteal artery using drug-coated balloon, open approach.
047N341	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047N3D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047N3Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach.
047N441	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach.

The requestor performed its own analysis of claims data and expressed concern that it found that the average costs of cases using a drug-coated balloon in the performance of percutaneous endovascular procedures involving treatment of patients who have been diagnosed with peripheral arterial disease are significantly higher than the average costs of all of the cases in the MS–DRGs where these procedures are currently assigned. The requestor also expressed concern that payments may no longer be adequate because the new technology add-on payments have been discontinued and may affect patient access to these procedures.

We first examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting any 1 of the 36 ICD–10–PCS procedure codes listed in the immediately preceding table that describe the use of a drug-coated balloon in the performance of endovascular procedures in MS–DRGs 252, 253, and 254. Our findings are shown in the following table.

MS–DRGs for Other Vascular Procedures With Drug-Coated Balloon

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 252—All cases	33,583	7.6	$23,906
MS–DRG 252—Cases with drug-coated balloon	870	8.8	30,912
MS–DRG 253—All cases	25,714	5.4	18,986
MS–DRG 253—Cases with drug-coated balloon	1,532	5.4	23,051
MS–DRG 254—All cases	12,344	2.8	13,287
MS–DRG 254—Cases with drug-coated balloon	488	2.4	17,445

As shown in this table, there were a total of 33,583 cases in MS–DRG 252, with an average length of stay of 7.6 days and average costs of $23,906. There were 870 cases in MS–DRG 252 reporting the use of a drug-coated balloon in the performance of an endovascular procedure, with an average length of stay of 8.8 days and average costs of $30,912. The total number of cases in MS–DRG 253 was 25,714, with an average length of stay of 5.4 days and average costs of $18,986. There were 1,532 cases in MS–DRG 253 reporting the use of a DCB in the performance of an endovascular procedure, with an average length of stay of 5.4 days and average costs of $23,051. The total number of cases in MS–DRG 254 was 12,344, with an average length of stay of 2.8 days and average costs of $13,287. There were 488 cases in MS–DRG 254 reporting the use of a DCB in the performance of an endovascular procedure, with an average length of stay of 2.4 days and average costs of $17,445.

The results of our data analysis show that there is not a very high volume of cases reporting the use of a drug-coated balloon in the performance of endovascular procedures compared to all of the cases in the assigned MS–DRGs. The data results also show that the average length of stay for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures in MS–DRGs 253 and 254 is lower compared to the average length of stay for all of the cases in the assigned MS–DRGs, while the average length of stay for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures in MS–DRG 252 is slightly higher compared to all of the cases in MS–DRG 252 (8.8 days versus 7.6 days). Lastly, the data results showed that the average costs for cases reporting the use of a drug-coated balloon in the performance of percutaneous endovascular procedures were higher compared to all of the cases in the assigned MS–DRGs. Specifically, for MS–DRG 252, the average costs for cases reporting the use of a DCB in the performance of endovascular procedures were $30,912 versus the average costs of $23,906 for all cases in MS–DRG 252, a difference of $7,006. For MS–DRG 253, the average costs for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures were $23,051 versus the average costs of $18,986 for all cases in MS–DRG 253, a difference

of $4,065. For MS–DRG 254, the average costs for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures were $17,445 versus the average costs of $13,287 for all cases in MS–DRG 254, a difference of $4,158.

The following table is a summary of the findings discussed above from our review of MS–DRGs 252, 253 and 254 and the total number of cases that used a drug-coated balloon in the performance of the procedure across MS–DRGs 252, 253, and 254.

MS–DRGs for Other Vascular Procedures and Cases With Drug-Coated Balloon

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 252, 253, and 254—All cases	71,641	6.0	$20,310
MS–DRGs 252, 253, and 254—Cases with drug-coated balloon	2,890	6.0	24,569

As shown in this table, there were a total of 71,641 cases across MS–DRGs 252, 253, and 254, with an average length of stay of 6.0 days and average costs of $20,310. There were a total of 2,890 cases across MS–DRGs 252, 253, and 254 reporting the use of a drug-coated balloon in the performance of the procedure, with an average length of stay of 6.0 days and average costs of $24,569. The data analysis showed that cases reporting the use of a drug-coated balloon in the performance of the procedure across MS–DRGs 252, 253 and 254 have similar lengths of stay (6.0 days) compared to the average length of stay for all of the cases in MS–DRGs 252, 253, and 254. The data results also showed that the cases reporting the use of a drug-coated balloon in the performance of the procedure across these MS–DRGs have higher average costs ($24,569 versus $20,310) compared to the average costs for all of the cases across these MS–DRGs.

We stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20207) that the results of our claims data analysis and the advice from our clinical advisors did not support reassigning cases reporting the use of a drug-coated balloon in the performance of these procedures from the lower severity level MS–DRGs 253 and 254 to the highest severity level MS–DRG 252 at this time. We further stated that, if we were to reassign cases that utilize a drug-coated balloon in the performance of these types of procedures from MS–DRG 254 to MS–DRG 252, the cases would result in overpayment and also would have a shorter length of stay compared to all of the cases in MS–DRG 252. While the cases reporting the use of a drug-coated balloon in the performance of these procedures are higher compared to the average costs for all cases in their assigned MS–DRGs, it is not by a significant amount. We stated that we believe that as use of a drug-coated balloon becomes more common, the costs will be reflected in the data. Our clinical advisors also agreed that it would not be clinically appropriate to reassign cases for patients from the lowest severity level (without CC/MCC) MS–DRG to the highest severity level (with MCC) MS–DRG in the absence of additional data to better determine the resource utilization for this subset of patients. Therefore, for these reasons, we proposed to not reassign cases reporting the use of a drug-coated balloon in the performance of endovascular procedures from MS–DRGs 253 and 254 to MS–DRG 252.

Comment: A number of commenters supported maintaining the current classification of cases involving the use of a drug-coated balloon in the performance of endovascular procedures. The commenters stated that CMS' proposal was reasonable, given the data, ICD–10–PCS procedure codes, and information provided.

Response: We appreciate the commenters' support.

Comment: One commenter recommended that further data analysis be conducted after the new ICD–10–PCS procedure codes for endovascular procedures utilizing a drug-coated balloon in the upper extremity become effective on October 1, 2018, in order to determine if MS–DRG structure and assignment modifications are warranted in the future.

Response: We agree with the commenter that continued monitoring of the cases reporting the use of a drug-coated balloon in the performance of endovascular procedures in the lower extremity, along with analysis of the new ICD–10–PCS procedure codes that identify the use of a drug-coated balloon in the upper extremity, would be advantageous. As claims data become available, we will be able to evaluate the resource utilization of these procedures more effectively.

Comment: One commenter believed that an analysis of the average costs of cases performed with and without the use of drug-coated balloons in MS–DRGs 252, 253, and 254 justified assigning cases, including cases involving the use of drug-coated balloons in the performance of the procedure, to MS–DRGs 252 or 253, and not to MS–DRG 254. The commenter indicated that claims data showed the average costs of MS–DRG 253 for all cases is $18,986, while the average cost of cases utilizing drug-coated balloons in the performance of the procedure assigned to MS–DRG 254 is $17,445. The commenter believed that, while the average length-of-stay is lower for these cases, the average costs are consistent with that of MS–DRG 253. Therefore, the commenter suggested that CMS reassign these cases to MS–DRG 253 as a more appropriate reflection of the hospital resources utilized for these cases.

Response: Our clinical advisors reviewed the data, and again determined that it would not be clinically appropriate to reassign cases for patients from the lowest severity level (without CC/MCC) MS–DRG to the higher severity level (with CC) MS–DRG in the absence of additional data to better determine the resource utilization for this subset of patients. We reiterate that we believe as use of the drug-coated balloon in the performance of endovascular procedures becomes more common, the costs will be reflected in the data. In addition, as noted above, new ICD–10–PCS procedure codes that describe the use of a drug-coated balloon in the upper extremity are effective with discharges occurring on or after October 1, 2018. As such, we will continue to monitor cases reporting the use of a drug-coated balloon in the performance of endovascular procedures and determine if future MS–DRG structure and assignment modifications are supported.

After consideration of the public comments we received, we are finalizing our proposal to not reassign cases reporting the use of a drug-coated balloon in the performance of endovascular procedures from MS–DRGs 253 and 254 to MS–DRG 252 for FY 2019.

We noted in the proposed rule that because 24 of the 36 ICD–10–PCS procedure codes describing the use of a

drug-coated balloon in the performance of endovascular procedures also include the use of an intraluminal device, we conducted further analysis to determine the number of cases reporting an intraluminal device with the use of a drug-coated balloon in the performance of the procedure versus the number of cases reporting the use of a drug-coated balloon alone. We analyzed the number of cases across MS–DRGs 252, 253, and 254 reporting: (1) The use of an intraluminal device (stent) with use of a drug-coated balloon in the performance of the procedure; (2) the use of a drug-eluting intraluminal device (stent) with the use of a drug-coated balloon in the performance of the procedure; and (3) the use of a drug-coated balloon only in the performance of the procedure. Our findings are shown in the following table.

MS–DRGs FOR OTHER VASCULAR PROCEDURES AND CASES WITH DRUG-COATED BALLOON

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 252, 253 and 254—All cases	71,641	6.0	$20,310
MS–DRGs 252, 253 and 254—Cases with intraluminal device with drug-coated balloon	522	6.0	28,418
MS–DRGs 252, 253 and 254—Cases with drug-eluting intraluminal device with drug-coated balloon	447	6.0	26,098
MS–DRGs 252, 253 and 254—Cases with drug-coated balloon only	2,705	6.1	24,553

As shown in this table, there were a total of 71,641 cases across MS–DRGs 252, 253, and 254, with an average length of stay of 6.0 days and average costs of $20,310. There were 522 cases across MS–DRGs 252, 253, and 254 reporting the use of an intraluminal device with use of a drug-coated balloon in the performance of the procedure, with an average length of stay of 6.0 days and average costs of $28,418. There were 447 cases across MS–DRGs 252, 253, and 254 reporting the use of a drug-eluting intraluminal device with use of a drug-coated balloon in the performance of the procedure, with an average length of stay of 6.0 days and average costs of $26,098. Lastly, there were 2,705 cases across MS–DRGs 252, 253, and 254 reporting the use of a drug-coated balloon alone in the performance of the procedure, with an average length of stay of 6.1 days and average costs of $24,553.

The data showed that the 2,705 cases in MS–DRGs 252, 253, and 254 reporting the use of a drug-coated balloon alone in the performance of the procedure have lower average costs compared to the 969 cases in MS–DRGs 252, 253, and 254 reporting the use of an intraluminal device (522 cases) or a drug-eluting intraluminal device (447 cases) with a drug-coated balloon in the performance of the procedure ($24,553 versus $28,418 and $26,098, respectively.) The data also showed that the cases reporting the use of a drug-coated balloon alone in the performance of the procedure have a comparable average length of stay compared to the cases reporting the use of an intraluminal device or a drug-eluting intraluminal device with a drug-coated balloon in the performance of the procedure (6.1 days versus 6.0 days).

In summary, as we stated in the proposed rule, we believe that further analysis of endovascular procedures involving the treatment of superficial femoral arteries for peripheral arterial disease that utilize a drug-coated balloon in the performance of the procedure would be advantageous. As additional claims data become available, we will be able to more fully evaluate the differences in cases where a procedure utilizes a drug-coated balloon alone in the performance of the procedure versus cases where a procedure utilizes an intraluminal device or a drug-eluting intraluminal device in addition to a drug-coated balloon in the performance of the procedure.

5. MDC 6 (Diseases and Disorders of the Digestive System)

a. Benign Lipomatous Neoplasm of Kidney

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20207), we received a request to reassign ICD–10–CM diagnosis code D17.71 (Benign lipomatous neoplasm of kidney) from MDC 06 (Diseases and Disorders of the Digestive System) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). The requestor stated that this diagnosis code is used to describe a kidney neoplasm and believed that because the ICD–10–CM code is specific to the kidney, a more appropriate assignment would be under MDC 11. In FY 2015, under the ICD–9–CM classification, there was not a specific diagnosis code for a benign lipomatous neoplasm of the kidney. The only diagnosis code available was ICD–9–CM diagnosis code 214.3 (Lipoma of intra-abdominal organs), which was assigned to MS–DRGs 393, 394, and 395 (Other Digestive System Diagnoses with MCC, with CC, and without CC/MCC, respectively) under MDC 6. Therefore, when we converted from the ICD–9 based MS–DRGs to the ICD–10 MS–DRGs, there was not a specific code available that identified the kidney from which to replicate. As a result, ICD–10–CM diagnosis code D17.71 was assigned to those same MS–DRGs (MS–DRGs 393, 394, and 395) under MDC 6.

While reviewing the MS–DRG classification of ICD–10–CM diagnosis code D17.71, we also reviewed the MS–DRG classification of another diagnosis code organized in subcategory D17.7, ICD–10–CM diagnosis code D17.72 (Benign lipomatous neoplasm of other genitourinary organ). ICD–10–CM diagnosis code D17.72 is currently assigned under MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) to MS–DRGs 606 and 607 (Minor Skin Disorders with and without MCC, respectively). Similar to the replication issue with ICD–10–CM diagnosis code D17.71, with ICD–10–CM diagnosis code D17.72, under the ICD–9–CM classification, there was not a specific diagnosis code to identify a benign lipomatous neoplasm of genitourinary organ. The only diagnosis code available was ICD–9–CM diagnosis code 214.8 (Lipoma of other specified sites), which was assigned to MS–DRGs 606 and 607 under MDC 09. Therefore, when we converted from the ICD–9 based MS–DRGs to the ICD–10 MS–DRGs, there was not a specific code available that identified another genitourinary organ (other than the kidney) from which to replicate. As a result, ICD–10–CM diagnosis code D17.72 was assigned to those same MS–DRGs (MS–DRGs 606 and 607) under MDC 9.

In the proposed rule, we proposed to reassign ICD–10–CM diagnosis code D17.71 from MS–DRGs 393, 394, and 395 (Other Digestive System Diagnoses with MCC, with CC, and without CC/MCC, respectively) under MDC 06 to

MS–DRGs 686, 687, and 688 (Kidney and Urinary Tract Neoplasms with MCC, with CC, and without CC/MCC, respectively) under MDC 11 because this diagnosis code is used to describe a kidney neoplasm. We also proposed to reassign ICD–10–CM diagnosis code D17.72 from MS–DRGs 606 and 607 under MDC 09 to MS–DRGs 686, 687, and 688 under MDC 11 because this diagnosis code is used to describe other types of neoplasms classified to the genitourinary tract that do not have a specific code identifying the site. Our clinical advisors agreed that the conditions described by the ICD–10–CM diagnosis codes provide specific anatomic detail involving the kidney and genitourinary tract and, therefore, if reclassified under this proposed MDC and reassigned to these MS–DRGs, would improve the clinical coherence of the patients assigned to these groups.

Comment: Commenters agreed with CMS' proposals to reassign ICD–10–CM diagnosis code D17.71 that describes benign lipomatous neoplasm of the kidney from MDC 6 to MDC 11, and to reassign ICD–10–CM diagnosis code D17.72 that describes benign lipomatous neoplasm of other genitourinary tract organ from MDC 9 to MDC 11. The commenters stated the proposals were reasonable, given the ICD–10–CM diagnosis codes and information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposals to reassign ICD–10–CM diagnosis code D17.71 from MS–DRGs 393, 394, and 395 under MDC 6 to MS–DRGs 686, 687, and 688 under MDC 11, and to reassign ICD–10–CM diagnosis code D17.72 from MS–DRGs 606 and 607 under MDC 9 to MS–DRGs 686, 687, and 688 under MDC 11 in the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

b. Bowel Procedures

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20208), we received a request to reassign the following 8 ICD–10–PCS procedure codes that describe repositioning of the colon and takedown of end colostomy from MS–DRGs 344, 345, and 346 (Minor Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively):

ICD–10–PCS code	Code description
0DSK0ZZ	Reposition ascending colon, open approach.
0DKL4ZZ	Reposition ascending colon, percutaneous endoscopic approach.
0DSL0ZZ	Reposition transverse colon, open approach.
0DSL4ZZ	Reposition transverse colon, percutaneous endoscopic approach.
0DSM0ZZ	Reposition descending colon, open approach.
0DSM4ZZ	Reposition descending colon, percutaneous endoscopic approach.
0DSN0ZZ	Reposition sigmoid colon, open approach.
0DSN4ZZ	Reposition sigmoid colon, percutaneous endoscopic approach.

The requestor indicated that the resources required for procedures identifying repositioning of specified segments of the large bowel are more closely aligned with other procedures that group to MS–DRGs 329, 330, and 331, such as repositioning of the large intestine (unspecified segment).

We analyzed the claims data from the September 2017 update of the FY 2017 Med PAR file for MS–DRGs 344, 345 and 346 for all cases reporting the 8 ICD–10–PCS procedure codes listed in the table above. Our findings are shown in the following table:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 344—All cases	1,452	9.5	$20,609
MS–DRG 344—All cases with a specific large bowel reposition procedure	52	9.6	23,409
MS–DRG 345—All cases	2,674	5.6	11,552
MS–DRG 345—All cases with a specific large bowel reposition	246	6	14,915
MS–DRG 346—All cases	990	3.8	8,977
MS–DRG 346—All cases with a specific large bowel reposition procedure	223	4.5	12,279

The data showed that the average length of stay and average costs for cases that reported a specific large bowel reposition procedure were generally consistent with the average length of stay and average costs for all of the cases in their assigned MS–DRG.

We then examined the claims data in the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 329, 330 and 331. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 329, 330, and 331—All cases	112,388	8.4	$21,382
MS–DRG 329—All cases	33,640	13.3	34,015
MS–DRG 330—All cases	52,644	7.3	17,896
MS–DRG 331—All cases	26,104	4.1	12,132

As shown in this table, across MS–DRGs 329, 330, and 331, we found a total of 112,388 cases, with an average length of stay of 8.4 days and average costs of $21,382. We stated in the FY 2019 IPPS/LTCH PPS proposed rule that the results of our analysis indicate that the resources required for cases reporting the specific large bowel repositioning procedures are more aligned with those resources required for all cases assigned to MS–DRGs 344, 345, and 346, with the average costs being lower than the average costs for all cases assigned to MS–DRGs 329, 330, and 331. Our clinical advisors also indicated that the 8 specific bowel repositioning procedures are best aligned with those in MS–DRGs 344, 345, and 346. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20209), we proposed to maintain the current assignment of the 8 specific bowel repositioning procedures in MS–DRGs 344, 345, and 346 for FY 2019.

Comment: Commenters supported CMS' proposal to maintain the current assignment of the 8 specific bowel repositioning procedures in MS DRGs 344, 345, and 346 for FY 2019.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current assignment of the 8 specific bowel repositioning procedures in MS DRGs 344, 345, and 346 for FY 2019.

In conducting our analysis of MS–DRGs 329, 330, and 331, we also examined the subset of cases reporting one of the bowel procedures listed in the following table as the only O.R. procedure.

ICD–10–PCS code	Code description
0DQK0ZZ	Repair ascending colon, open approach.
0DQK4ZZ	Repair ascending colon, percutaneous endoscopic approach.
0DQL0ZZ	Repair transverse colon, open approach.
0DQL4ZZ	Repair transverse colon, percutaneous endoscopic approach.
0DQM0ZZ	Repair descending colon, open approach.
0DQM4ZZ	Repair descending colon, percutaneous endoscopic approach.
0DQN0ZZ	Repair sigmoid colon, open approach.
0DQN4ZZ	Repair sigmoid colon, percutaneous endoscopic approach.
0DSB0ZZ	Reposition ileum, open approach.
0DSB4ZZ	Reposition ileum, percutaneous endoscopic approach.
0DSE0ZZ	Reposition large intestine, open approach.
0DSE4ZZ	Reposition large intestine, percutaneous endoscopic approach.

This approach can be useful in determining whether resource use is truly associated with a particular procedure or whether the procedure frequently occurs in cases with other procedures with higher than average resource use. As shown in the following table, we identified 398 cases reporting a bowel procedure as the only O.R. procedure, with an average length of stay of 6.3 days and average costs of $13,595 across MS–DRGs 329, 330, and 331, compared to the overall average length of stay of 8.4 days and average costs of $21,382 for all cases in MS–DRGs 329, 330, and 331.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 329, 330 and 331—All cases	112,388	8.4	$21,382
MS–DRGs 329, 330 and 331—All cases with a bowel procedure as only O.R. procedure	398	6.3	13,595
MS–DRG 329—All cases	33,640	13.3	34,015
MS–DRG 329—Cases with a bowel procedure as only O.R. procedure	86	8.3	19,309
MS–DRG 330—All cases	52,644	7.3	17,896
MS–DRG 330—Cases with a bowel procedure as only O.R. procedure	183	6.9	13,617
MS–DRG 331—All cases	26,104	4.1	12,132
MS–DRG 331—Cases with a bowel procedure as only O.R. procedure	129	4.3	9,754

We stated in the FY 2019 IPPS/LTCH PPS proposed rule that the resources required for these cases are more aligned with the resources required for cases assigned to MS–DRGs 344, 345, and 346 than with the resources required for cases assigned to MS–DRGs 329, 330, and 331. Our clinical advisors also agreed that these cases are more clinically aligned with cases in MS–DRGs 344, 345, and 346, as they are minor procedures relative to the major bowel procedures assigned to MS–DRGs 329, 330, and 331. Therefore, in the proposed rule, we proposed to reassign the 12 ICD–10–PCS procedure codes listed above from MS–DRGs 329, 330, and 331 to MS–DRGs 344, 345, and 346.

Comment: Commenters disagreed with CMS' proposal to reassign the 12 ICD–10–PCS procedure codes listed above from MS–DRGs 329, 330, and 331 to MS DRGs 344, 345, and 346. The commenters recommended that changes to these MS–DRGs be delayed until a thorough data analysis is conducted. The commenters further recommended that any future analysis include a thorough review of the principal diagnoses for cases involving these ICD–10–PCS codes, as the associated diagnosis significantly impacts the resource utilization and complexity of the procedure performed and MS–DRG assignment. The commenters noted that the root operation of ''Reposition'' may be used for the takedown of a stoma, as well as to treat a specific medical condition such as malrotation of the intestine, and that ''Repair'' is the root operation of last resort when no other ICD–10–PCS root operation applies and, therefore, is used for a wide range of procedures of varying complexity.

Commenters also noted that several questions and answers regarding these ICD–10–PCS procedure codes were published in *Coding Clinic* for ICD–10–CM/PCS between late 2016 and the end of 2017, and stated that because 2 full

years of data were not available subsequent to publication of this advice, CMS' analysis and proposed MS–DRG modifications may be based on unreliable data.

Response: Upon further review, we agree with the commenters that the availability of a full 2 years of data would allow us to conduct a more comprehensive analysis upon which to consider potential modifications to these MS–DRGs. Therefore, we believe it would be preferable to wait until these data are available before finalizing changes to the MS–DRG assignment for these bowel procedures.

After consideration of the public comments we received, we are not finalizing our proposal to reassign the 12 ICD–10–PCS procedure codes listed above from MS–DRGs 329, 330, and 331 to MS–DRGs 344, 345, and 346 for FY 2019.

6. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Spinal Fusion

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38036), we announced our plans to review the ICD–10 logic for the MS–DRGs where procedures involving spinal fusion are currently assigned for FY 2019. After publication of the FY 2018 IPPS/LTCH PPS final rule, we received a comment suggesting that CMS publish findings from this review and discuss possible future actions. The commenter agreed that it is important to be able to fully evaluate the MS–DRGs to which all spinal fusion procedures are currently assigned with additional claims data, particularly considering the 33 clinically invalid codes that were identified through the rulemaking process (82 FR 38034 through 38035) and the 87 codes identified from the upper and lower joint fusion tables in the ICD–10–PCS classification and discussed at the September 12, 2017 ICD–10 Coordination and Maintenance Committee that were proposed to be deleted effective October 1, 2018 (FY 2019). The agenda and handouts from that meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.*

According to the commenter, deleting the 33 procedure codes describing clinically invalid spinal fusion procedures for FY 2018 partially resolves the issue for data used in setting the FY 2020 payment rates. However, the commenter also noted that the problem will not be fully resolved until the FY 2019 claims are available for FY 2021 ratesetting (due to the 87 codes identified at the ICD–10 Coordination and Maintenance Committee meeting for deletion effective October 1, 2018 (FY 2019)).

The commenter noted that it analyzed claims data from the FY 2016 MedPAR data set and was surprised to discover a significant number of discharges reporting 1 of the 87 clinically invalid codes that were identified and discussed by the ICD–10 Coordination and Maintenance Committee among the following spinal fusion MS–DRGs.

MS–DRG	Description
453	Combined Anterior/Posterior Spinal Fusion with MCC.
454	Combined Anterior/Posterior Spinal Fusion with CC.
455	Combined Anterior/Posterior Spinal Fusion without CC/MCC.
456	Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC.
457	Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with CC.
458	Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC.
459	Spinal Fusion Except Cervical with MCC.
460	Spinal Fusion Except Cervical without MCC.
471	Cervical Spinal Fusion with MCC.
472	Cervical Spinal Fusion with CC.
473	Cervical Spinal Fusion without CC/MCC.

In addition, the commenter noted that it also identified a number of discharges for the 33 clinically invalid codes we identified in the FY 2018 IPPS/LTCH PPS final rule in the same MS–DRGs listed above. According to the commenter, its findings of these invalid spinal fusion procedure codes in the FY 2016 claims data comprise approximately 30 percent of all discharges for spinal fusion procedures.

The commenter expressed its appreciation that CMS is making efforts to address coding inaccuracies within the classification and suggested that CMS publish findings from its own review of spinal fusion coding issues in those MS–DRGs where cases reporting spinal fusion procedures are currently assigned and include a discussion of possible future actions in the FY 2019 IPPS/LTCH PPS proposed rule. The commenter believed that such an approach would allow time for stakeholder input on any possible proposals along with time for the invalid codes to be worked out of the datasets. The commenter also noted that publishing CMS' findings will put the agency, as well as the public, in a better position to address any potential payment issues for these services beginning in FY 2021.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20210), we thanked the commenter for acknowledging the steps we have taken in our efforts to address coding inaccuracies within the classification as we continue to refine the ICD–10 MS–DRGs. We did not propose any changes to the MS–DRGs involving spinal fusion procedures for FY 2019. However, in response to the commenter's suggestion and findings, we provided the following results from our analysis of the September 2017 update of the FY 2017 MedPAR claims data for the MS–DRGs involving spinal fusion procedures.

We noted that while the commenter stated that 87 codes were identified from the upper and lower joint fusion tables in the ICD–10–PCS classification and discussed at the September 12, 2017 ICD–10 Coordination and Maintenance Committee meeting to be deleted effective October 1, 2018 (FY 2019), there were 99 spinal fusion codes identified in the meeting materials, as shown in Table 6P.1g associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

As shown in Table 6P.1g associated with the proposed rule, the 99 procedure codes describe spinal fusion procedures that have device value ''Z'' representing No Device for the 6th character in the code. Because a spinal fusion procedure always requires some type of device (for example, instrumentation with bone graft or bone

graft alone) to facilitate the fusion of vertebral bones, these codes are considered clinically invalid and were proposed for deletion at the September 12, 2017 ICD–10 Coordination and Maintenance Committee meeting. We received public comments in support of the proposal to delete the 99 codes describing a spinal fusion without a device, in addition to receiving support for the deletion of other procedure codes describing fusion of body sites other than the spine. A total of 213 procedure codes describing fusion of a specific body part with device value ''Z'' No Device are being deleted effective October 1, 2018 (FY 2019) as shown in Table 6D.—Invalid Procedure Codes associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

We examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting any of the clinically invalid spinal fusion procedures with device value ''Z'' No Device in MS–DRGs 028 (Spinal Procedures with MCC), 029 (Spinal Procedures with CC or Spinal Neurostimulators), and 030 (Spinal Procedures without CC/MCC) under MDC 1 and MS–DRGs 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473 under MDC 8 (that are listed and shown earlier in this section). Our findings are shown in the following tables.

SPINAL FUSION PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 028—All cases	1,927	11.7	$37,524
MS–DRG 028—Cases with invalid spinal fusion procedures	132	13	52,034
MS–DRG 029—All cases	3,426	5.7	22,525
MS–DRG 029—Cases with invalid spinal fusion procedures	171	7.4	33,668
MS–DRG 030—All cases	1,578	3	15,984
MS–DRG 030—Cases with invalid spinal fusion procedures	52	2.6	22,471
MS–DRG 453—All cases	2,891	9.5	70,005
MS–DRG 453—Cases with invalid spinal fusion procedures	823	10.1	84,829
MS–DRG 454—All cases	12,288	4.7	47,334
MS–DRG 454—Cases with invalid spinal fusion procedures	2,473	5.4	59,814
MS–DRG 455—All cases	12,751	3	37,440
MS–DRG 455—Cases with invalid spinal fusion procedures	2,332	3.2	45,888
MS–DRG 456—All cases	1,439	11.5	66,447
MS–DRG 456—Cases with invalid spinal fusion procedures	404	12.5	71,385
MS–DRG 457—All cases	3,644	6	48,595
MS–DRG 457—Cases with invalid spinal fusion procedures	960	6.7	53,298
MS–DRG 458—All cases	1,368	3.6	37,804
MS–DRG 458—Cases with invalid spinal fusion procedures	244	4.1	43,182
MS–DRG 459—All cases	4,904	7.8	43,862
MS–DRG 459—Cases with invalid spinal fusion procedures	726	9	49,387
MS–DRG 460—All cases	59,459	3.4	29,870
MS–DRG 460—Cases with invalid spinal fusion procedures	5,311	3.9	31,936
MS–DRG 471—All cases	3,568	8.4	36,272
MS–DRG 471—Cases with invalid spinal fusion procedures	389	9.9	43,014
MS–DRG 472—All cases	15,414	3.2	21,836
MS–DRG 472—Cases with invalid spinal fusion procedures	1,270	4	25,780
MS–DRG 473—All cases	18,095	1.8	17,694
MS–DRG 473—Cases with invalid spinal fusion procedures	1,185	2.3	19,503

SUMMARY TABLE FOR SPINAL FUSION PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 028, 029, 030, 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473—All cases	142,752	3.9	$31,788
MS–DRGs 028, 029, 030, 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473—Cases with invalid spinal fusion procedures	16,472	5.1	42,929

As shown in this summary table, we found a total of 142,752 cases in MS–DRGs 028, 029, 030, 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473 with an average length of stay of 3.9 days and average costs of $31,788. We found a total of 16,472 cases reporting a procedure code for an invalid spinal fusion procedure with device value ''Z'' No Device across MS–DRGs 028, 029, and 030 under MDC 1 and MS–DRGs 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473 under MDC 8, with an average length of stay of 5.1 days and average costs of $42,929. The results of the data analysis demonstrate that these invalid spinal fusion procedures represent approximately 12 percent of all discharges across the spinal fusion MS–DRGs. Because these procedure codes describe clinically invalid procedures, we would not expect these codes to be reported on any claims data. We stated in the proposed rule that it is unclear why providers assigned procedure codes for spinal fusion procedures with the device value ''Z'' No Device. Our analysis did not examine whether these claims were isolated to a specific provider or whether this inaccurate reporting was widespread among a number of providers.

With regard to possible future action, we indicated in the proposed rule that we will continue to monitor the claims data for resolution of the coding issues previously identified. Because the procedure codes that we analyzed and presented findings for in the FY 2019 IPPS/LTCH PPS proposed rule will no longer be in the classification system, effective October 1, 2018 (FY 2019), the claims data that we examine for FY 2020 may still contain claims with the invalid codes. As such, we will continue to collaborate with the AHA as one of the four Cooperating Parties through the AHA's *Coding Clinic for ICD–10–CM/PCS* and provide further education on spinal fusion procedures and the proper reporting of the ICD–10–PCS spinal fusion procedure codes. We agreed with the commenter that until these coding inaccuracies are no longer reflected in the claims data, it would be premature to propose any MS–DRG modifications for spinal fusion procedures. Possible MS–DRG modifications may include taking into account the approach that was utilized in performing the spinal fusion procedure (for example, open versus percutaneous).

For the reasons described and as stated in the proposed rule and earlier in our discussion, we proposed not to make any changes to the spinal fusion MS–DRGs for FY 2019.

Comment: Commenters agreed with CMS' proposal not to make any changes to the MS–DRGs involving spinal fusion procedures for FY 2019.

Response: We thank the commenters for their support.

Comment: Some commenters noted that confusion has existed as to whether a spinal fusion code may be assigned when no bone graft or bone graft substitute is used (that is, instrumentation only) but the medical record documentation refers to the procedure as a spinal fusion. One commenter recommended that additional refinements be made to the ICD–10–PCS spinal fusion coding guidelines in order to further clarify appropriate reporting of spinal fusion codes. Another commenter asserted that the planned deletion of a total of 213 ICD–10–PCS fusion procedure codes with the device value ''Z'' for ''no device'', effective October 1, 2018, should help remedy the confusion regarding the correct coding of spinal procedures.

Response: We agree with the commenters that accurate coding of spinal fusion procedures has been the subject of confusion in the past, and we will continue to monitor the claims data for spinal fusion procedures. As one of the four Cooperating Parties, we also will continue to collaborate with the American Hospital Association to provide guidance for coding spinal fusion procedures through the Coding Clinic for ICD–10–CM/PCS publication and to review the ICD–10–PCS spinal fusion coding guidelines to determine where further clarifications may be made.

After consideration of the public comments we received, we are finalizing our proposal to not make any changes to the spinal fusion MS–DRGs for FY 2019.

7. MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast): Cellulitis With Methicillin Resistant Staphylococcus Aureus (MRSA) Infection

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20212), we received a request to reassign ICD–10–CM diagnosis codes reported with a principal diagnosis of cellulitis and a secondary diagnosis code of B95.62 (Methicillin resistant Staphylococcus aureus infection as the cause of diseases classified elsewhere) or A49.02 (Methicillin resistant Staphylococcus aureus infection, unspecified site). Currently, these cases are assigned to MS–DRG 602 (Cellulitis with MCC) and MS–DRG 603 (Cellulitis without MCC) in MDC 9. The requestor believed that cases of cellulitis with MSRA infection should be reassigned to MS–DRG 867 (Other Infectious and Parasitic Diseases Diagnoses with MCC) because MS–DRGs 602 and 603 include cases that do not accurately reflect the severity of illness or risk of mortality for patients diagnosed with cellulitis and MRSA. The requestor acknowledged that the organism is not to be coded before the localized infection, but stated in its request that patients diagnosed with cellulitis and MRSA are entirely different from patients diagnosed only with cellulitis. The requestor stated that there is a genuine threat to life or limb in these cases. The requestor further stated that, with the opioid crisis and the frequency of MRSA infection among this population, cases of cellulitis with MRSA should be identified with a specific combination code and assigned to MS–DRG 867.

For the FY 2019 IPPS/LTCH PPS proposed rule, we analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for all cases assigned to MS–DRGs 602 and 603 and subsets of these cases reporting a principal ICD–10–CM diagnosis of cellulitis and a secondary diagnosis code of B95.62 or A49.02. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 602—All cases	26,244	5.8	$10,034
MS–DRG 603—All cases	104,491	3.9	6,128
MS–DRGs 602 and 603—Cases reported with a principal diagnosis of cellulitis and a secondary diagnosis of B95.62	5,364	5.3	8,245
MS–DRGs 602 and 603—Cases reported with a principal diagnosis of cellulitis and a secondary diagnosis of A49.02	309	5.4	8,832

As shown in this table, we examined the subsets of cases in MS–DRGs 602 and 603 reported with a principal diagnosis of cellulitis and a secondary diagnosis code B95.62 or A49.02. Both of these subsets of cases had an average length of stay that was comparable to the average length of stay for all cases in MS–DRG 602 and greater than the average length of stay for all cases in MS–DRG 603, and average costs that were lower than the average costs of all cases in MS–DRG 602 and higher than the average costs of all cases in MS–DRG 603. As we have discussed in prior rulemaking (77 FR 53309), it is a fundamental principle of an averaged payment system that half of the procedures in a group will have above average costs. It is expected that there will be higher cost and lower cost subsets, especially when a subset has low numbers.

To examine the request to reassign ICD–10–CM diagnosis codes reported with a principal diagnosis of cellulitis and a secondary diagnosis code of B95.62 or A49.02 from MS–DRGs 602 and 603 to MS–DRG 867 (which would typically involve also reassigning those cases to the two other severity level MS–DRGs 868 and 869 (Other Infectious

and Parasitic Diseases Diagnoses with CC and Other Infectious and Parasitic Diseases Diagnoses without CC/MCC, respectively)), we then analyzed the data for all cases in MS–DRGs 867, 868 and 869. The results of our analysis are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 867—All cases	2,653	7.5	$14,762
MS–DRG 868—All cases	2,096	4.4	7,532
MS–DRG 869—All cases	499	3.3	5,624

We compared the average length of stay and average costs for MS–DRGs 867, 868, and 869 to the average length of stay and average costs for the subsets of cases in MS–DRGs 602 and 603 reported with a principal diagnosis of cellulitis and a secondary diagnosis code of B95.62 or A49.02. We found that the average length of stay for these subsets of cases was shorter and the average costs were lower than those for all cases in MS–DRG 867, but that the average length of stay and average costs were higher than those for all cases in MS–DRG 868 and MS–DRG 869. We stated in the proposed rule that our findings from the analysis of claims data do not support reassigning cellulitis cases reported with ICD–10–CM diagnosis code B95.62 or A49.02 from MS–DRGs 602 and 603 to MS–DRGs 867, 868 and 869. Our clinical advisors noted that when a principal diagnosis of cellulitis is accompanied by a secondary diagnosis of B95.62 or A49.02 in MS–DRGs 602 or 603, the combination of these primary and secondary diagnoses is the reason for the hospitalization, and the level of acuity of these subsets of patients is similar to other patients in MS–DRGs 602 and 603. Therefore, in the proposed rule, we stated that these cases are more clinically aligned with all cases in MS–DRGs 602 and 603. For these reasons, we did not propose to reassign cellulitis cases reported with ICD–10–CM diagnosis code of B95.62 or A49.02 to MS–DRG 867, 868, or 869 for FY 2019. We invited public comments on our proposal to maintain the current MS–DRG assignment for ICD–10–CM codes B95.62 and A49.02 when reported as secondary diagnoses with a principal diagnosis of cellulitis.

Comment: One commenter supported CMS' proposal to maintain the current MS–DRG assignment for ICD–10–CM codes B95.62 and A49.02 when reported as secondary diagnoses with a principal diagnosis of cellulitis.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG classification for cases reported with ICD–10–CM diagnosis codes B95.62 and A49.02 when reported as secondary diagnoses with a principal diagnosis of cellulitis.

8. MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): Acute Intermittent Porphyria

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20212), we received a request to revise the MS–DRG classification for cases of patients diagnosed with porphyria and reported with ICD–10–CM diagnosis code E80.21 (Acute intermittent (hepatic) porphyria) to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient access to necessary treatments. Porphyria is defined as a group of rare disorders (''porphyrias'') that interfere with the production of hemoglobin that is needed for red blood cells. While some of these disorders are genetic (inborn) and others are acquired, they all result in the abnormal accumulation of hemoglobin building blocks, called porphyrins, which can be deposited in the tissues where they particularly interfere with the functioning of the nervous system and the skin. Treatment for patients suffering from disorders of porphyrin metabolism consists of an intravenous injection of Panhematin® (hemin for injection). ICD–10–CM diagnosis code E80.21 is currently assigned to MS–DRG 642 (Inborn and Other Disorders of Metabolism). (We note that this issue has been discussed previously in the FY 2013 IPPS/LTCH PPS proposed and final rules (77 FR 27904 through 27905 and 77 FR 53311 through 53313, respectively) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28016 and 79 FR 49901, respectively)).

We analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for cases assigned to MS–DRG 642. Our findings are shown in the following table.

MS–DRG 642	Number of cases	Average length of stay	Average costs
MS–DRG 642—All cases	1,801	4.3	$9,157
MS–DRG 642—Cases reporting diagnosis code E80.21 as principal diagnosis	183	5.6	19,244
MS–DRG 642—Cases not reporting diagnosis code E80.21 as principal diagnosis	1,618	4.1	8,016

As shown in this table, cases reporting diagnosis code E80.21 as the principal diagnosis in MS–DRG 642 had higher average costs and longer average lengths of stay compared to the average costs and lengths of stay for all other cases in MS–DRG 642.

To examine the request to reassign cases with ICD–10–CM diagnosis code E80.21 as the principal diagnosis, we analyzed claims data for all cases in MS–DRGs for endocrine disorders, including MS–DRG 643 (Endocrine Disorders with MCC), MS–DRG 644 (Endocrine Disorders with CC), and MS–DRG 645 (Endocrine Disorders without CC/MCC). The results of our analysis are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 643—All cases	9,337	6.3	$11,268

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 644—All cases	11,306	4.2	7,154
MS–DRG 645—All cases	4,297	3.2	5,406

The data results showed that the average length of stay for the subset of cases reporting ICD–10–CM diagnosis code E80.21 as the principal diagnosis in MS–DRG 642 is lower than the average length of stay for all cases in MS–DRG 643, but higher than the average length of stay for all cases in MS–DRGs 644 and 645. The average costs for the subset of cases reporting ICD–10–CM diagnosis code E80.21 as the principal diagnosis in MS–DRG 642 are much higher than the average costs for all cases in MS–DRGs 643, 644, and 645. However, after considering these findings in the context of the current MS–DRG structure, we stated in the FY 2019 IPPS/LTCH PPS proposed rule that we were unable to identify an MS–DRG that would more closely parallel these cases with respect to average costs and length of stay that would also be clinically aligned. We further stated that our clinical advisors believe that, in the current MS–DRG structure, the clinical characteristics of patients in these cases are most closely aligned with the clinical characteristics of patients in all cases in MS–DRG 642. Moreover, given the small number of porphyria cases, we do not believe there is justification for creating a new MS–DRG. Basing a new MS–DRG on such a small number of cases could lead to distortions in the relative payment weights for the MS–DRG because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. In summary, we did not propose to revise the MS–DRG classification for porphyria cases.

Comment: Some commenters supported CMS' proposal to maintain porphyria cases in MS–DRG 642.

Response: We appreciate the commenters' support.

Comment: Other commenters opposed CMS' proposal to not create a new MS–DRG for cases involving ICD–10–CM diagnosis code E80.21. These commenters described significant difficulties encountered by patients with acute porphyria attacks in obtaining Panhematin® when presenting to an inpatient hospital, which they attribute to the strong financial disincentives faced by facilities to treat these cases on an inpatient basis. The commenters asserted that the inpatient stays required for management of acute porphyria attacks are not clinically similar to inpatient stays for other inborn disorders of metabolism (which comprise the cases assigned to MS–DRG 642). The commenters stated that, based on the lower than expected average cost per case and longer than expected length of stay for acute porphyria attacks, it appears that facilities are frequently not providing Panhematin® to patients in this condition, and instead attempting to provide symptom relief and transferring patients to an outpatient setting to receive the drug where they can be adequately paid. The commenters stated that this is in contrast to the standard of care for acute porphyria attacks and can result in devastating long-term health consequences. The commenters suggested that CMS consider alternative mechanisms to ensure adequate payment for cases involving rare diseases. In summary, commenters asserted that creating a new MS–DRG would allow more accurate payment for the cases that remain in MS–DRG 642 and facilitate access to the standard of care for patients with acute porphyria attacks.

Response: We acknowledge the commenters' concerns. As we have stated in prior rulemaking, it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased costs. The MS–DRG system is a system of averages and it is expected that across the diagnostic related groups that within certain groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs.

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20212 through 20213), we recognize the average costs of the small number of porphyria cases are greater than the average costs of the cases in MS–DRG 642 overall. An averaged payment system depends on aggregation of similar cases with a range of costs, and it is therefore usually possible to define subsets with higher values and subsets with lower values. We seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets of diagnoses. In response to the commenters' assertion that these cases are not clinically similar to other cases within the MS–DRG, our clinical advisors continue to believe that MS–DRG 642 represents the most clinically appropriate placement within the current MS–DRG structure at this time because the clinical characteristics of patients in these cases are most closely aligned with the clinical characteristics of patients in all cases in MS–DRG 642.

We are sensitive to the commenters' concerns about access to treatment for beneficiaries who have been diagnosed with this condition. Therefore, as part of our ongoing, comprehensive analysis of the MS–DRGs under ICD–10, we will continue to explore mechanisms through which to address rare diseases and low volume DRGs. However, at this time, for the reasons summarized earlier, we are finalizing our proposal for FY 2019 to maintain the MS–DRG classification for porphyria cases.

9. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Admit for Renal Dialysis

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20213 through 20214),we received a request to review the codes assigned to MS–DRG 685 (Admit for Renal Dialysis) to determine if the MS–DRG should be deleted, or if it should remain as a valid MS–DRG. Currently, the ICD–10–CM diagnosis codes shown in the table below are assigned to MS–DRG 685:

ICD–10–CM code	ICD–10–CM code title
Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter.
Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter.
Z49.31	Encounter for adequacy testing for hemodialysis.

ICD–10–CM code	ICD–10–CM code title
Z49.32	Encounter for adequacy testing for peritoneal dialysis.

The requestor stated that, under ICD–9–CM, diagnosis code V56.0 (Encounter for extracorporeal dialysis) was reported as the principal diagnosis to identify patients who were admitted for an encounter for dialysis. However, under ICD–10–CM, there is no comparable code in which to replicate such a diagnosis. The requestor noted that, while patients continued to be admitted under inpatient status (under certain circumstances) for dialysis services, there is no existing ICD–10–CM diagnosis code within the classification that specifically identifies a patient being admitted for an encounter for dialysis services.

The requestor also noted that three of the four ICD–10–CM diagnosis codes currently assigned to MS–DRG 685 are on the ''Unacceptable Principal Diagnosis'' edit code list in the Medicare Code Editor (MCE). Therefore, these codes are not allowed to be reported as a principal diagnosis for an inpatient admission.

We examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32. Our findings are shown in the following table.

ADMIT FOR RENAL DIALYSIS ENCOUNTER

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 685—All cases	78	4	$8,871
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.01	78	4	8,871
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.02	0	0	0
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.31	0	0	0
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.32	0	0	0

As shown in the table above, for MS–DRG 685, there were a total of 78 cases reporting ICD–10–CM diagnosis code Z49.01, with an average length of stay of 4 days and average costs of $8,871. There were no cases reporting ICD–10–CM diagnosis code Z49.02, Z49.31, or Z49.32.

Our clinical advisors reviewed the clinical issues, as well as the claims data for MS–DRG 685. Based on their review of the data analysis, our clinical advisors recommended that MS–DRG 685 be deleted and ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32 be reassigned. Historically, patients were admitted as inpatients to receive hemodialysis services. However, over time, that practice has shifted to outpatient and ambulatory settings. Because of this change in medical practice, we stated in the FY 2019 IPPS/LTCH PPS proposed rule that we did not believe that it was appropriate to maintain a vestigial MS–DRG, particularly due to the fact that the transition to ICD–10 had resulted in three out of four codes that mapped to the MS–DRG being precluded from being used as principal diagnosis codes on the claim. In addition, our clinical advisors believed that reassigning the ICD–10–CM diagnosis codes from MS–DRG 685 to MS–DRGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC\MCC, respectively) was clinically appropriate because the reassignment would result in an accurate MS–DRG assignment of a specific case or inpatient service and encounter based on acceptable principal diagnosis codes under these MS–DRGs.

Therefore, for FY 2019, because there is no existing ICD–10–CM diagnosis code within the classification system that specifically identifies a patient being admitted for an encounter for dialysis services; and three of the four ICD–10–CM diagnosis codes, Z49.02, Z49.31, and Z49.32, currently assigned to MS–DRG 685 are on the Unacceptable Principal Diagnosis edit code list in the MCE, we proposed to reassign ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32 from MS–DRG 685 to MS–DRGs 698, 699, and 700, and to delete MS–DRG 685.

Comment: Commenters agreed with the proposal to reassign ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32 from MS–DRG 685 to MS–DRGs 698, 699, and 700, and to delete MS–DRG 685.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to delete MS–DRG 685 and reassign ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32 from MS–DRG 685 to MS–DRGs 698, 699, and 700 for FY 2019, without modification.

10. MDC 14 (Pregnancy, Childbirth and the Puerperium)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19834) and final rule (82 FR 38036 through 38037), we noted that the MS–DRG logic involving a vaginal delivery under MDC 14 is technically complex as a result of the requirements that must be met to satisfy assignment to the affected MS–DRGs. As a result, we solicited public comments on further refinement to the following four MS–DRGs related to vaginal delivery: MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C); MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C); MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis); and MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis). In addition, we sought public comments on further refinements to the conditions defined as a complicating diagnosis in MS–DRG 774 and MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications). We indicated that we would review public comments received in response to the solicitation as we continued to evaluate these MS–DRGs under MDC 14 and, if warranted, we would propose refinements for FY 2019. Commenters were instructed to direct comments for consideration to the CMS MS–DRG Classification Change Request Mailbox located at *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2017.

In response to our solicitation for public comments on the MS–DRGs related to vaginal delivery, one commenter recommended that CMS convene a workgroup that would include hospital staff and physicians to systematically review the MDC 14 MS–DRGs and to identify which conditions should appropriately be considered complicating diagnoses. As an interim step, this commenter recommended that CMS consider the following suggestions as a result of its own evaluation of MS–DRGs 767, 774 and 775.

For MS–DRG 767, the commenter recommended that the following ICD–10–CM diagnosis codes and ICD–10–PCS procedure code be removed from the GROUPER logic and provided the rationale for why the commenter suggested removing each code.

SUGGESTIONS FOR MS–DRG 767

[Vaginal delivery with sterilization and/or D&C]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 767
O66.41	Failed attempted vaginal birth after previous cesarean delivery.	This code indicates that the attempt at vaginal delivery has failed.
O71.00	Rupture of uterus before onset of labor, unspecified trimester.	This code indicates that the uterus has ruptured before onset of labor and therefore, a vaginal delivery would not be possible.
O82	Encounter for cesarean delivery without indication	This code indicates the encounter is for a cesarean delivery.
O75.82	Onset (spontaneous) of labor after 37 weeks of gestation but before 39 completed weeks, with delivery by (planned) C-section.	This code indicates this is a cesarean delivery.

SUGGESTIONS FOR MS–DRG 767

[Vaginal delivery with sterilization and/or D&C]

ICD–10–PCS code	Code description	Rationale for removing code from MS–DRG 767
10A07Z6	Abortion of products of conception, vacuum, via natural or artificial opening.	This code indicates the procedure to be an abortion rather than a vaginal delivery.

For MS–DRG 774, the commenter recommended that the following ICD–10–CM diagnosis codes be removed from the GROUPER logic and provided the rationale for why the commenter suggested removing each code.

SUGGESTIONS FOR MS–DRG 774

[Vaginal delivery with complicating diagnoses]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 774
O66.41	Failed attempted vaginal birth after previous cesarean delivery.	This code indicates that the attempt at vaginal delivery has failed.
O71.00	Rupture of uterus before onset of labor, unspecified trimester.	This code indicates that the uterus has ruptured before onset of labor and therefore, a vaginal delivery would not be possible.
O75.82	Onset (spontaneous) of labor after 37 weeks of gestation but before 39 completed weeks, with delivery by (planned) C-section.	This code indicates this is a planned cesarean delivery.
O82	Encounter for cesarean delivery without indication	This code indicates the encounter is for a cesarean delivery.
O80	Encounter for full-term uncomplicated delivery	According to the Official Guidelines for Coding and Reporting, ''Code O80 should be assigned when a woman is admitted for a full term normal delivery and delivers a single, healthy infant without any complications antepartum, during the delivery, or postpartum during the delivery episode.''

For MS–DRG 775, the commenter recommended that the following ICD–10–CM diagnosis codes and ICD–10–PCS procedure code be removed from the GROUPER logic and provided the rationale for why the commenter suggested removing each code.

SUGGESTIONS FOR MS–DRG 775

[Vaginal delivery without complicating diagnoses]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 775
O66.41	Failed attempted vaginal birth after previous cesarean delivery.	This code indicates that the attempt at vaginal delivery has failed.
O69.4XX0	Labor and delivery complicated by vasa previa, not applicable or unspecified.	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX2	Labor and delivery complicated by vasa previa, fetus 2.	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX3	Labor and delivery complicated by vasa previa, fetus 3.	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX4	Labor and delivery complicated by vasa previa, fetus 4.	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX5	Labor and delivery complicated by vasa previa, fetus 5.	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX9	Labor and delivery complicated by vasa previa, other fetus.	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O71.00	Rupture of uterus before onset of labor, unspecified trimester.	This code indicates that the uterus has ruptured before onset of labor and therefore, a vaginal delivery would not be possible.
O82	Encounter for cesarean delivery without indication.	This code indicates the encounter is for a cesarean delivery.

SUGGESTIONS FOR MS–DRG 775

[Vaginal delivery without complicating diagnoses]

ICD–10–PCS code	Code description	Rationale for removing code from MS–DRG 775
10A07Z6	Abortion of Products of Conception, Vacuum, Via Natural or Artificial Opening.	This code indicates the procedure to be an abortion rather than a vaginal delivery.

Another commenter agreed that the MS–DRG logic for a vaginal delivery under MDC 14 is technically complex and provided examples to illustrate these facts. For instance, the commenter noted that the GROUPER logic code lists appear redundant with several of the same codes listed for different MS–DRGs and that the GROUPER logic code list for a vaginal delivery in MS–DRG 774 is comprised of diagnosis codes while the GROUPER logic code list for a vaginal delivery in MS–DRG 775 is comprised of procedure codes. The commenter also noted that several of the ICD–10–CM diagnosis codes shown in the table below that became effective with discharges on and after October 1, 2016 (FY 2017) or October 1, 2017 (FY 2018) appear to be missing from the GROUPER logic code lists for MS–DRGs 781 and 774.

ICD–10–CM code	Code description
O11.4	Pre-existing hypertension with pre-eclampsia, complicating childbirth.
O11.5	Pre-existing hypertension with pre-eclampsia, complicating the puerperium.
012.04	Gestational edema, complicating childbirth.
012.05	Gestational edema, complicating the puerperium.
012.14	Gestational proteinuria, complicating childbirth.
012.15	Gestational proteinuria, complicating the puerperium.
012.24	Gestational edema with proteinuria, complicating childbirth.
012.25	Gestational edema with proteinuria, complicating the puerperium.
O13.4	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating childbirth.
O13.5	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating the puerperium.
O14.04	Mild to moderate pre-eclampsia, complicating childbirth.
O14.05	Mild to moderate pre-eclampsia, complicating the puerperium.
O14.14	Severe pre-eclampsia complicating childbirth.
O14.15	Severe pre-eclampsia, complicating the puerperium.
O14.24	HELLP syndrome, complicating childbirth.
O14.25	HELLP syndrome, complicating the puerperium.
O14.94	Unspecified pre-eclampsia, complicating childbirth.
O14.95	Unspecified pre-eclampsia, complicating the puerperium.
O15.00	Eclampsia complicating pregnancy, unspecified trimester.
O15.02	Eclampsia complicating pregnancy, second trimester.

ICD–10–CM code	Code description
O15.03	Eclampsia complicating pregnancy, third trimester.
O15.1	Eclampsia complicating labor.
O15.2	Eclampsia complicating puerperium, second trimester.
O16.4	Unspecified maternal hypertension, complicating childbirth.
O16.5	Unspecified maternal hypertension, complicating the puerperium.
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs.
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs.
O24.435	Gestational diabetes mellitus in puerperium, controlled by oral hypoglycemic drugs.
O44.20	Partial placenta previa NOS or without hemorrhage, unspecified trimester.
O44.21	Partial placenta previa NOS or without hemorrhage, first trimester.
O44.22	Partial placenta previa NOS or without hemorrhage, second trimester.
O44.23	Partial placenta previa NOS or without hemorrhage, third trimester.
O44.30	Partial placenta previa with hemorrhage, unspecified trimester.
O44.31	Partial placenta previa with hemorrhage, first trimester.
O44.32	Partial placenta previa with hemorrhage, second trimester.
O44.33	Partial placenta previa with hemorrhage, third trimester.
O44.40	Low lying placenta NOS or without hemorrhage, unspecified trimester.
O44.41	Low lying placenta NOS or without hemorrhage, first trimester.
O44.42	Low lying placenta NOS or without hemorrhage, second trimester.
O44.43	Low lying placenta NOS or without hemorrhage, third trimester.
O44.50	Low lying placenta with hemorrhage, unspecified trimester.
O44.51	Low lying placenta with hemorrhage, first trimester.
O44.52	Low lying placenta with hemorrhage, second trimester.
O44.53	Low lying placenta with hemorrhage, third trimester.
O70.20	Third degree perineal laceration during delivery, unspecified.
O70.21	Third degree perineal laceration during delivery, IIIa.
O70.22	Third degree perineal laceration during delivery, IIIb.
O70.23	Third degree perineal laceration during delivery, IIIc.
O86.11	Cervicitis following delivery.
O86.12	Endometritis following delivery.
O86.13	Vaginitis following delivery.
O86.19	Other infection of genital tract following delivery.
O86.20	Urinary tract infection following delivery, unspecified.
O86.21	Infection of kidney following delivery.
O86.22	Infection of bladder following delivery.
O86.29	Other urinary tract infection following delivery.
O86.81	Puerperal septic thrombophlebitis.
O86.89	Other specified puerperal infections.

Lastly, the commenter stated that the list of ICD–10–PCS procedure codes appears comprehensive, but indicated that inpatient coding is not their expertise. We note that it was not clear which list of procedure codes the commenter was specifically referencing. The commenter did not provide a list of any procedure codes for CMS to review or reference a specific MS–DRG in its comment.

Another commenter expressed concern that ICD–10–PCS procedure codes 10D17Z9 (Manual extraction of products of conception, retained, via natural or artificial opening) and 10D18Z9 (Manual extraction of products of conception, retained, via natural or artificial opening endoscopic) are not assigned to the appropriate MS–DRG. ICD–10–PCS procedure codes 10D17Z9 and 10D18Z9 describe the manual removal of a retained placenta and are currently assigned to MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C). According to the commenter, a patient that has a vaginal delivery with manual removal of a retained placenta is not having a sterilization or D&C procedure. The commenter noted that, under ICD–9–CM, a vaginal delivery with manual removal of retained placenta grouped to MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis) or MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis). The commenter suggested CMS review these procedure codes for appropriate MS–DRG assignment under the ICD–10 MS–DRGs.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20217), we thanked the commenters and stated that we appreciated the recommendations and suggestions provided in response to our solicitation for comments on the GROUPER logic for the MS–DRGs involving a vaginal delivery or complicating diagnosis under MDC 14. With regard to the commenter who recommended that we convene a workgroup that would include hospital staff and physicians to systematically review the MDC 14 MS–DRGs and to identify which conditions should appropriately be considered complicating diagnoses, we noted that we formed an internal workgroup comprised of clinical advisors that included physicians, coding specialists, and other IPPS policy staff that assisted in our review of the GROUPER logic for a vaginal delivery and complicating diagnoses. We indicated that we also received clinical input from 3M/Health Information Systems (HIS) staff, which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. We note that our analysis involved other MS–DRGs under MDC 14, in addition to those for which we specifically solicited public comments. As one of the other commenters correctly pointed out, there is redundancy, with several of the same codes listed for different MS–DRGs. Below we provide a summary of our internal analysis with responses to the commenters' recommendations and suggestions incorporated into the applicable sections. We referred readers to the ICD–10 MS–DRG Version 35 Definitions Manual located via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/*

AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending for documentation of the GROUPER logic associated with the MDC 14 MS–DRGs to assist in the review of our discussion that follows.

We started our evaluation of the GROUPER logic for the MS–DRGs under MDC 14 by first reviewing the current concepts that exist. For example, there are ''groups'' for cesarean section procedures, vaginal delivery procedures, and abortions. There also are groups where no delivery occurs, and lastly, there are groups for after the delivery occurs, or the ''postpartum'' period. These groups are then further subdivided based on the presence or absence of complicating conditions or the presence of another procedure. We examined how we could simplify some of the older, complex GROUPER logic and remain consistent with the structure of other ICD–10 MS–DRGs. We identified the following MS–DRGs for closer review, in addition to MS–DRG 767, MS–DRG 768, MS–DRG 774, MS–DRG 775 and MS–DRG 781.

MS–DRG	Description
MS–DRG 765	Cesarean Section with CC/MCC.
MS–DRG 766	Cesarean Section without CC/MCC.
MS–DRG 769	Postpartum and Post Abortion Diagnoses with O.R. Procedure.
MS–DRG 770	Abortion with D&C, Aspiration Curettage or Hysterotomy.
MS–DRG 776	Postpartum and Post Abortion Diagnoses without O.R. Procedure.
MS–DRG 777	Ectopic Pregnancy.
MS–DRG 778	Threatened Abortion.
MS–DRG 779	Abortion without D&C.
MS–DRG 780	False Labor.
MS–DRG 782	Other Antepartum Diagnoses without Medical Complications.

The first issue we reviewed was the GROUPER logic for complicating conditions (MS–DRGs 774 and 781). Because one of the main objectives in our transition to the MS–DRGs was to better recognize the severity of illness of a patient, we believed we could structure the vaginal delivery and other MDC 14 MS–DRGs in a similar way. Therefore, we began working with the concept of vaginal delivery ''with MCC, with CC and without CC/MCC'' to replace the older, ''complicating conditions'' logic.

Next, we compared the additional GROUPER logic that exists between the vaginal delivery and the cesarean section MS–DRGs (MS–DRGs 765, 766, 767, 774, and 775). Currently, the vaginal delivery MS–DRGs take into account a sterilization procedure; however, the cesarean section MS–DRGs do not. Because a patient can have a sterilization procedure performed along with a cesarean section procedure, we adopted a working concept of ''cesarean section with and without sterilization with MCC, with CC and without CC/MCC'', as well as ''vaginal delivery with and without sterilization with MCC, with CC and without CC/MCC''.

We then reviewed the GROUPER logic for the MS–DRGs involving abortion and where no delivery occurs (MS–DRGs 770, 777, 778, 779, 780, and 782). We believed that we could consolidate the groups in which no delivery occurs.

Finally, we considered the GROUPER logic for the MS–DRGs related to the postpartum period (MS–DRGs 769 and 776) and determined that the structure of these MS–DRGs did not appear to require modification.

After we established those initial working concepts for the MS–DRGs discussed above, we examined the list of the ICD–10–PCS procedure codes that comprise the sterilization procedure GROUPER logic for the vaginal delivery MS–DRG 767. We identified the two manual extraction of placenta codes that the commenter had brought to our attention (ICD–10–PCS codes 10D17Z9 and 10D18Z9). We also identified two additional procedure codes, ICD–10–PCS codes 10D17ZZ (Extraction of products of conception, retained, via natural or artificial opening) and 10D18ZZ (Extraction of products of conception, retained, via natural or artificial opening endoscopic) in the list that are not sterilization procedures. Two of the four procedure codes describe manual extraction (removal) of retained placenta and the other two procedure codes describe dilation and curettage procedures. We then identified four more procedure codes in the list that do not describe sterilization procedures. ICD–10–PCS procedure codes 0UDB7ZX (Extraction of endometrium, via natural or artificial opening, diagnostic), 0UDB7ZZ (Extraction of endometrium, via natural or artificial opening), 0UDB8ZX (Extraction of endometrium, via natural or artificial opening endoscopic, diagnostic), and 0UDB8ZZ (Extraction of endometrium, via natural or artificial opening endoscopic) describe dilation and curettage procedures that can be performed for diagnostic or therapeutic purposes. We stated in the proposed rule that we believe that these ICD–10–PCS procedure codes would be more appropriately assigned to MDC 13 (Diseases and Disorders of the Female Reproductive System) in MS–DRGs 744 and 745 (D&C, Conization, Laparaoscopy and Tubal Interruption with and without CC/MCC, respectively) and, therefore, removed them from our working list of sterilization and/or D&C procedures. Because the GROUPER logic for MS–DRG 767 includes both sterilization and/or D&C, we agreed that all the other procedure codes currently included under that logic list of sterilization procedures should remain, with the exception of the two identified by the commenter. Therefore, in the proposed rule, we stated we agreed with the commenter that the manual extraction of retained placenta procedure codes should be reassigned to a more clinically appropriate vaginal delivery MS–DRG because they are not describing sterilization procedures.

Our attention then turned to other MDC 14 GROUPER logic code lists starting with the ''CC for C-section'' list under MS–DRGs 765 and 766 (Cesarean Section with and without CC/MCC, respectively). As noted in the proposed rule and earlier in this section, in conducting our review, we considered how we could utilize the severity level concept (with MCC, with CC, and without CC/MCC) where applicable. Consistent with this approach, we removed the ''CC for C-section'' logic from these MS–DRGs as part of our working concept and efforts to refine MDC 14. We determined it would be less complicated to simply allow the existing ICD–10 MS–DRG CC and MCC

code list logic to apply for these MS–DRGs. Next, we reviewed the logic code lists for ''Malpresentation'' and ''Twins'' and concluded that this logic was not necessary for the cesarean section MS–DRGs because these are describing antepartum conditions and it is the procedure of the cesarean section that determines whether or not a patient would be classified to these MS–DRGs. Therefore, those code lists were also removed for purposes of our working concept. With regard to the ''Operating Room Procedure'' code list, we stated in the proposed rule that we agreed there should be no changes. However, we noted that the title to ICD–10–PCS procedure code 10D00Z0 (Extraction of products of conception, classical, open approach) is being revised, effective October 1, 2018, to replace the term ''classical'' with ''high'' and ICD–10–PCS procedure code 10D00Z1 (Extraction of products of conception, low cervical, open approach) is being revised to replace the term ''low cervical'' to ''low''. These revisions are also shown in Table 6F—Revised Procedure Code Titles associated with the proposed rule and this final rule available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Next, we reviewed the ''Delivery Procedure'' and ''Delivery Outcome'' GROUPER logic code lists for the vaginal delivery MS–DRGs 767, 768, 774, and 775. We identified ICD–10–PCS procedure code 10A0726 (Abortion of products of conception, vacuum, via natural or artificial opening) and ICD–10–PCS procedure code 10S07ZZ (Reposition products of conception, via natural or artificial opening) under the ''Delivery Procedure'' code list as procedure codes that should not be included because ICD–10–PCS procedure code 10A07Z6 describes an abortion procedure and ICD–10–PCS procedure code 10S07ZZ describes repositioning of the fetus and does not indicate a delivery took place. We also noted that, as described in the proposed rule and earlier in this discussion, a commenter recommended that ICD–10–PCS procedure code 10A07Z6 be removed from the GROUPER logic specifically for MS–DRGs 767 and 775. Therefore, we removed these two procedure codes from the logic code list for ''Delivery Procedure'' in MS–DRGs 767, 768, 774, and 775. We stated in the proposed rule that we agreed with the commenter that ICD–10–PCS procedure code 10A07Z6 would be more appropriately assigned to one of the Abortion MS–DRGs. For the remaining procedures currently included in the ''Delivery Procedure'' code list we considered which procedures would be expected to be performed during the course of a standard, uncomplicated delivery episode versus those that would reasonably be expected to require additional resources outside of the delivery room. The list of procedure codes we reviewed is shown in the following table.

ICD–10–PCS code	Code description
0DQP7ZZ	Repair rectum, via natural or artificial opening.
0DQQ0ZZ	Repair anus, open approach.
0DQQ3ZZ	Repair anus, percutaneous approach.
0DQQ4ZZ	Repair anus, percutaneous endoscopic approach.
0DQQ7ZZ	Repair anus, via natural or artificial opening.
0DQQ8ZZ	Repair anus, via natural or artificial opening endoscopic.
0DQR0ZZ	Repair anal sphincter, open approach.
0DQR3ZZ	Repair anal sphincter, percutaneous approach.
0DQR4ZZ	Repair anal sphincter, percutaneous endoscopic approach.

While we acknowledged that these procedures may be performed to treat obstetrical lacerations as discussed in prior rulemaking (81 FR 56853), we stated that we also believe that these procedures would reasonably be expected to require a separate operative episode and would not be performed immediately at the time of the delivery. Therefore, we removed those procedure codes describing repair of the rectum, anus, and anal sphincter shown in the table above from our working concept list of procedures to consider for a vaginal delivery. Our review of the list of diagnosis codes for the ''Delivery Outcome'' as a secondary diagnosis did not prompt any changes. We stated in the proposed rule we agreed that the current list of diagnosis codes continues to appear appropriate for describing the outcome of a delivery.

As the purpose of our analysis and this review was to clarify what constitutes a vaginal delivery to satisfy the ICD–10 MS–DRG logic for the vaginal delivery MS–DRGs, we believed it was appropriate to expect that a procedure code describing the vaginal delivery or extraction of ''products of conception'' procedure and a diagnosis code describing the delivery outcome should be reported on every claim in which a vaginal delivery occurs. This is also consistent with Section I.C.15.b.5 of the ICD–10–CM Official Guidelines for Coding and Reporting, which states ''A code from category Z37, Outcome of delivery, should be included on every maternal record when a delivery has occurred. These codes are not to be used on subsequent records or on the newborn record.'' Therefore, we adopted the working concept that, regardless of the principal diagnosis, if there is a procedure code describing the vaginal delivery or extraction of ''products of conception'' procedure and a diagnosis code describing the delivery outcome, this logic would result in assignment to a vaginal delivery MS–DRG. In the proposed rule, we noted that, as a result of this working concept, there would no longer be a need to maintain the ''third condition'' list under MS–DRG 774. In addition, as noted in the proposed rule and earlier in this discussion, because we were working with the concept of vaginal delivery ''with MCC, with CC, and without CC/MCC'' to replace the older, ''complicating conditions'' logic, there would no longer be a need to maintain the ''second condition'' list of complicating diagnosis under MS–DRG 774.

We then reviewed the GROUPER logic code list of ''Or Other O.R. procedures'' (MS–DRG 768) to determine if any changes to these lists were warranted. Similar to our analysis of the procedures listed under the ''Delivery Procedure'' logic code list, our examination of the procedures currently described in the ''Or Other O.R. procedures'' procedure code list also considered which procedures would be expected to be

performed during the course of a standard, uncomplicated delivery episode versus those that would reasonably be expected to require additional resources outside of the delivery room. Our analysis of all the procedures resulted in the working concept to allow all O.R. procedures to be applicable for assignment to MS–DRG 768, with the exception of the procedure codes for sterilization and/or D&C and ICD–10–PCS procedure codes 0KQM0ZZ (Repair perineum muscle, open approach) and 0UJM0ZZ (Inspection of vulva, open approach), which we determined would be reasonably expected to be performed during a standard delivery episode and, therefore, assigned to MS–DRG 774 or MS–DRG 775. We also noted that, this working concept for MS–DRG 768 would eliminate vaginal delivery cases with an O.R. procedure grouping to the unrelated MS–DRGs because all O.R. procedures would be included in the GROUPER logic procedure code list for ''Or Other O.R. Procedures''.

The next set of MS–DRGs we examined more closely included MS–DRGs 777, 778, 780, 781, and 782. We believed that, because the conditions in these MS–DRGs are all describing antepartum related conditions, we could group the conditions together clinically. Diagnoses described as occurring during pregnancy and diagnoses specifying a trimester or maternal care in the absence of a delivery procedure reported were considered antepartum conditions. We also believed we could better classify these groups of patients based on the presence or absence of a procedure. Therefore, we worked with the concept of ''antepartum diagnoses with and without O.R. procedure''.

As noted in the proposed rule and earlier in the discussion, we adopted a working concept of ''cesarean section with and without sterilization with MCC, with CC, and without CC/MCC.'' This concept is illustrated in the following table and includes our suggested modifications.

SUGGESTED MODIFICATIONS TO MS–DRGS FOR MDC 14

[Pregnancy, childbirth and the puerperium]

DELETE 2 MS–DRGs:
- MS–DRG 765 (Cesarean Section with CC/MCC).
- MS–DRG 766 (Cesarean Section without CC/MCC).

CREATE 6 MS–DRGs:
- MS–DRG XXX (Cesarean Section with Sterilization with MCC).
- MS–DRG XXX (Cesarean Section with Sterilization with CC).
- MS–DRG XXX (Cesarean Section with Sterilization without CC/MCC).
- MS–DRG XXX (Cesarean Section without Sterilization with MCC).
- MS–DRG XXX (Cesarean Section without Sterilization with CC).
- MS–DRG XXX (Cesarean Section without Sterilization without CC/MCC).

As shown in the table, we suggested deleting MS–DRGs 765 and 766. We also suggested creating 6 new MS–DRGs that are subdivided by a 3-way severity level split that includes ''with Sterilization'' and ''without Sterilization''.

We also adopted a working concept of ''vaginal delivery with and without sterilization with MCC, with CC, and without CC/MCC''. This concept is illustrated in the following table and includes our suggested modifications.

SUGGESTED MODIFICATIONS TO MS–DRGS FOR MDC 14

[Pregnancy, childbirth and the puerperium]

DELETE 3 MS–DRGs:
- MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C).
- MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis).
- MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis).

CREATE 6 MS–DRGs:
- MS–DRG XXX (Vaginal Delivery with Sterilization/D&C with MCC).
- MS–DRG XXX (Vaginal Delivery with Sterilization/D&C with CC).
- MS–DRG XXX (Vaginal Delivery with Sterilization/D&C without CC/MCC).
- MS–DRG XXX (Vaginal Delivery without Sterilization/D&C with MCC).
- MS–DRG XXX (Vaginal Delivery without Sterilization/D&C with CC).
- MS–DRG XXX (Vaginal Delivery without Sterilization/D&C without CC/MCC).

As shown in the table, we suggested deleting MS–DRGs 767, 774, and 775. We also suggested creating 6 new MS–DRGs that are subdivided by a 3-way severity level split that includes ''with Sterilization/D&C'' and ''without Sterilization/D&C''.

In addition, as indicated above, we believed that we could consolidate the groups in which no delivery occurs. In the proposed rule, we stated we believe that consolidating MS–DRGs where clinically coherent conditions exist is consistent with our approach to MS–DRG reclassification and our continued refinement efforts. This concept is illustrated in the following table and includes our suggested modifications.

SUGGESTED MODIFICATIONS TO MS–DRGS FOR MDC 14

[Pregnancy, childbirth and the puerperium]

DELETE 5 MS–DRGs:
- MS–DRG 777 (Ectopic Pregnancy).
- MS–DRG 778 (Threatened Abortion).
- MS–DRG 780 (False Labor).
- MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications).
- MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications).

CREATE 6 MS–DRGs:
- MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure with MCC).
- MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure with CC).
- MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC).
- MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure with MCC).
- MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure with CC).
- MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC).

As shown in the table, we suggested deleting MS–DRGs 777, 778, 780, 781, and 782. We also suggested creating 6 new MS–DRGs that are subdivided by a 3-way severity level split that includes ''with O.R. Procedure'' and ''without O.R. Procedure''.

Once we established each of these fundamental concepts from a clinical perspective, we were able to analyze the data to determine if our initial suggested modifications were supported.

To analyze our suggested modifications for the cesarean section and vaginal delivery MS–DRGs, we examined the claims data from the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 765, 766, 767, 768, 774, and 775.

MS–DRGS FOR MDC 14 PREGNANCY, CHILDBIRTH AND THE PUERPERIUM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 765 (Cesarean Section with CC/MCC)—All cases	3,494	4.6	$8,929
MS–DRG 766 (Cesarean Section without CC/MCC)—All cases	1,974	3.1	6,488
MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C)—All cases	351	3.2	7,886
MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C)—All cases	17	6.2	26,164

MS–DRGS FOR MDC 14 PREGNANCY, CHILDBIRTH AND THE PUERPERIUM—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis)—All cases	1,650	3.3	6,046
MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis)—All cases	4,676	2.4	4,769

As shown in the table, there were a total of 3,494 cases in MS–DRG 765, with an average length of stay of 4.6 days and average costs of $8,929. For MS–DRG 766, there were a total of 1,974 cases, with an average length of stay of 3.1 days and average costs of $6,488. For MS–DRG 767, there were a total of 351 cases, with an average length of stay of 3.2 days and average costs of $ 7,886. For MS–DRG 768, there were a total of 17 cases, with an average length of stay of 6.2 days and average costs of $26,164. For MS–DRG 774, there were a total of 1,650 cases, with an average length of stay of 3.3 days and average costs of $6,046. Lastly, for MS–DRG 775, there were a total of 4,676 cases, with an average length of stay of 2.4 days and average costs of $4,769.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the Version 35 ICD–10 MS–DRG GROUPER. The following table reflects our findings for the suggested Cesarean Section MS–DRGs with a 3-way severity level split.

SUGGESTED MS–DRGS FOR CESAREAN SECTION

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 783 (Cesarean Section with Sterilization with MCC)	178	6.4	$12,977
MS–DRG 784 (Cesarean Section with Sterilization with CC)	511	4.1	8,042
MS–DRG 785 (Cesarean Section with Sterilization without CC/MCC)	475	3.0	6,259
MS–DRG 786 (Cesarean Section without Sterilization with MCC)	707	5.9	11,515
MS–DRG 787 (Cesarean Section without Sterilization with CC)	1,887	4.2	7,990
MS–DRG 788 (Cesarean Section without Sterilization without CC/MCC)	1,710	3.3	6,663

As shown in the table, there were a total of 178 cases for the cesarean section with sterilization with MCC group, with an average length of stay of 6.4 days and average costs of $12,977. There were a total of 511 cases for the cesarean section with sterilization with CC group, with an average length of stay of 4.1 days and average costs of $8,042. There were a total of 475 cases for the cesarean section with sterilization without CC/MCC group, with an average length of stay of 3.0 days and average costs of $6,259. For the cesarean section without sterilization with MCC group there were a total of 707 cases, with an average length of stay of 5.9 days and average costs of $11,515. There were a total of 1,887 cases for the cesarean section without sterilization with CC group, with an average length of stay of 4.2 days and average costs of $7,990. Lastly, there were a total of 1,710 cases for the cesarean section without sterilization without CC/MCC group, with an average length of stay of 3.3 days and average costs of $6,663.

The following table reflects our findings for the suggested Vaginal Delivery MS–DRGs with a 3-way severity level split.

SUGGESTED MS–DRGS FOR VAGINAL DELIVERY

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 796 (Vaginal Delivery with Sterilization/D&C with MCC)	25	6.7	$11,421
MS–DRG 797 (Vaginal Delivery with Sterilization/D&C with CC)	63	2.4	6,065
MS–DRG 798 (Vaginal Delivery with Sterilization/D&C without CC/MCC)	126	2.3	6,697
MS–DRG 805 (Vaginal Delivery without Sterilization/D&C with MCC)	406	5.0	9,605
MS–DRG 806 (Vaginal Delivery without Sterilization/D&C with CC)	1,952	2.9	5,506
MS–DRG 807 (Vaginal Delivery without Sterilization/D&C without CC/MCC)	4,105	2.3	4,601

As shown in the table, there were a total of 25 cases for the vaginal delivery with sterilization/D&C with MCC group, with an average length of stay of 6.7 days and average costs of $11,421. There were a total of 63 cases for the vaginal delivery with sterilization/D&C with CC group, with an average length of stay of 2.4 days and average costs of $6,065. There were a total of 126 cases for vaginal delivery with sterilization/D&C without CC/MCC group, with an average length of stay of 2.3 days and average costs of $6,697. There were a total of 406 cases for the vaginal delivery without sterilization/D&C with MCC group, with an average length of stay of 5.0 days and average costs of $9,605. There were a total of 1,952 cases for the vaginal delivery without sterilization/D&C with CC group, with an average length of stay of 2.9 days and average costs of $5,506. There were a total of 4,105 cases for the vaginal delivery without sterilization/D&C without CC/MCC group, with an average length of stay of 2.3 days and average costs of $4,601.

We then reviewed the claims data from the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 777, 778, 780, 781, and 782. Our findings are shown in the following table.

MS–DRGS FOR MDC 14 PREGNANCY, CHILDBIRTH AND THE PUERPERIUM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 777 (Ectopic Pregnancy)—All cases	72	1.9	$7,149
MS–DRG 778 (Threatened Abortion)—All cases	205	2.7	4,001
MS–DRG 780 (False Labor)—All cases	41	2.1	3,045
MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications)—All cases	2,333	3.7	5,817
MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications)—All cases	70	2.1	3,381

As shown in the table, there were a total of 72 cases in MS–DRG 777, with an average length of stay of 1.9 days and average costs of $7,149. For MS–DRG 778, there were a total of 205 cases, with an average length of stay of 2.7 days and average costs of $4,001. For MS–DRG 780, there were a total of 41 cases, with an average length of stay of 2.1 days and average costs of $3,045. For MS–DRG 781, there were a total of 2,333 cases, with an average length of stay of 3.7 days and average costs of $5,817. Lastly, for MS–DRG 782, there were a total of 70 cases, with an average length of stay of 2.1 days and average costs of $3,381.

To compare and analyze the impact of deleting those 5 MS–DRGs and creating 6 new MS–DRGs, we ran a simulation using the Version 35 ICD–10 MS–DRG GROUPER. Our findings below represent what we found and would expect under the suggested modifications. The following table reflects the MS–DRGs for the suggested Other Antepartum Diagnoses MS–DRGs with a 3-way severity level split.

SUGGESTED MS–DRGS FOR OTHER ANTEPARTUM DIAGNOSES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 817 (Other Antepartum Diagnoses with O.R. Procedure with MCC)	60	5.1	$13,117
MS–DRG 818 (Other Antepartum Diagnoses with O.R. Procedure with CC)	66	4.2	10,483
MS–DRG 819 (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC)	44	1.7	5,904
MS–DRG 831 (Other Antepartum Diagnoses without O.R. Procedure with MCC)	786	4.3	7,248
MS–DRG 832 (Other Antepartum Diagnoses without O.R. Procedure with CC)	910	3.5	4,994
MS–DRG 833 (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC)	855	2.7	3,843

Our analysis of claims data from the September 2017 update of the FY 2017 MedPAR file recognized that when the criteria to create subgroups were applied for the 3-way severity level splits for the suggested MS–DRGs, those criteria were not met in all instances. For example, the criteria that there are at least 500 cases in the MCC or CC group was not met for the suggested Vaginal Delivery with Sterilization/D&C 3-way severity level split or the suggested Other Antepartum Diagnoses with O.R. Procedure 3-way severity level split.

However, as we have noted in prior rulemaking (72 FR 47152), we cannot adopt the same approach to refine the maternity and newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these DRGs. While there is not a high volume of these cases represented in the Medicare data, and while we generally advise that other payers should develop MS–DRGs to address the needs of their patients, we believe that our suggested 3-way severity level splits would address the complexity of the current MDC 14 GROUPER logic for a vaginal delivery and takes into account the new and different clinical concepts that exist under ICD–10 for this subset of patients while also maintaining the existing MS–DRG structure for identifying severity of illness, utilization of resources and complexity of service.

However, as an alternative option, we also performed analysis for a 2-way severity level split for the suggested MS–DRGs. Our findings are shown in the following tables.

SUGGESTED MS–DRGS FOR CESAREAN SECTION

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Cesarean Section with Sterilization with CC/MCC)	689	4.7	$9,317
MS–DRG XXX (Cesarean Section with Sterilization without CC/MCC)	475	3.0	6,259
MS–DRG XXX (Cesarean Section without Sterilization with MCC)	2,594	4.7	8,951
MS–DRG XXX (Cesarean Section without Sterilization without CC/MCC)	1,710	3.3	6,663

SUGGESTED MS–DRGS FOR VAGINAL DELIVERY

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Vaginal Delivery with Sterilization/D&C with CC/MCC)	88	3.6	$7,586
MS–DRG XXX (Vaginal Delivery with Sterilization/D&C without CC/MCC)	126	2.3	6,697
MS–DRG XXX (Vaginal Delivery without Sterilization/D&C with MCC)	2,358	3.2	6,212
MS–DRG XXX (Vaginal Delivery without Sterilization/D&C without CC/MCC)	4,105	2.3	4,601

SUGGESTED MS–DRGS FOR OTHER ANTEPARTUM DIAGNOSES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure with MCC)	126	4.7	$11,737
MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC)	44	1.7	5,904
MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure with MCC)	1,696	3.9	6,039
MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC)	855	2.7	3,843

Similar to the analysis performed for the 3-way severity level split, we acknowledged that when the criteria to create subgroups was applied for the alternative 2-way severity level splits for the suggested MS–DRGs, those criteria were not met in all instances. For example, the suggested Vaginal Delivery with Sterilization/D&C and the Other Antepartum Diagnoses with O.R. Procedure alternative option 2-way severity level splits did not meet the criteria for 500 or more cases in the MCC or CC group.

Based on our review, which included support from our clinical advisors, and the analysis of claims data described above, in the FY 2019 IPPS/LTCH PPS proposed rule, we proposed the deletion of 10 MS–DRGs and the creation of 18 new MS–DRGs (as shown below). This proposal was based on the approach described above, which involves consolidating specific conditions and concepts into the structure of existing logic and making additional modifications, such as adding severity levels, as part of our refinement efforts for the ICD–10 MS–DRGs. We indicated in the proposed rule that our proposals are intended to address the vaginal delivery ''complicating diagnosis'' logic and antepartum diagnoses with ''medical complications'' logic with the proposed addition of the existing and familiar severity level concept (with MCC, with CC, and without CC/MCC) to the MDC 14 MS–DRGs to provide the ability to distinguish the varying resource requirements for this subset of patients and allow the opportunity to make more meaningful comparisons with regard to severity across the MS–DRGs. We stated that our proposals, as set forth below, would also simplify the vaginal delivery procedure logic that we identified and commenters acknowledged as technically complex by eliminating the extensive diagnosis and procedure code lists for several conditions that must be met for assignment to the vaginal delivery MS–DRGs. We stated that our proposals also are intended to respond to issues identified and brought to our attention through public comments for consideration in updating the GROUPER logic code lists in MDC 14.

Specifically, we proposed to delete the following 10 MS–DRGs under MDC 14:

- MS–DRG 765 (Cesarean Section with CC/MCC);
- MS–DRG 766 (Cesarean Section without CC/MCC);
- MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C);
- MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis);
- MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis);
- MS–DRG 777 (Ectopic Pregnancy);
- MS–DRG 778 (Threatened Abortion);
- MS–DRG 780 (False Labor);
- MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications); and
- MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications).

We proposed to create the following new 18 MS–DRGs under MDC 14:

- Proposed new MS–DRG 783 (Cesarean Section with Sterilization with MCC);
- Proposed new MS–DRG 784 (Cesarean Section with Sterilization with CC);
- Proposed new MS–DRG 785 (Cesarean Section with Sterilization without CC/MCC);
- Proposed new MS–DRG 786 (Cesarean Section without Sterilization with MCC);
- Proposed new MS–DRG 787 (Cesarean Section without Sterilization with CC);
- Proposed new MS–DRG 788 Cesarean Section without Sterilization without CC/MCC);
- Proposed new MS–DRG 796 (Vaginal Delivery with Sterilization/D&C with MCC);
- Proposed new MS–DRG 797 (Vaginal Delivery with Sterilization/D&C with CC);
- Proposed new MS–DRG 798 (Vaginal Delivery with Sterilization/D&C without CC/MCC);
- Proposed new MS–DRG 805 (Vaginal Delivery without Sterilization/D&C with MCC);
- Proposed new MS–DRG 806 (Vaginal Delivery without Sterilization/D&C with CC);
- Proposed new MS–DRG 807 (Vaginal Delivery without Sterilization/D&C without CC/MCC);
- Proposed new MS–DRG 817 (Other Antepartum Diagnoses with O.R. Procedure with MCC);
- Proposed new MS–DRG 818 (Other Antepartum Diagnoses with O.R. Procedure with CC);
- Proposed new MS–DRG 819 (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC);
- Proposed new MS–DRG 831 (Other Antepartum Diagnoses without O.R. Procedure with MCC);
- Proposed new MS–DRG 832 (Other Antepartum Diagnoses without O.R. Procedure with CC); and
- Proposed new MS–DRG 833 (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC).

The diagrams below illustrate how the proposed MS–DRG logic for MDC 14 would function. The first diagram (Diagram 1.) begins by asking if there is a principal diagnosis from MDC 14. If no, the GROUPER logic directs the case to the appropriate MDC based on the principal diagnosis reported. Next, the logic asks if there is a cesarean section procedure reported on the claim. If yes, the logic asks if there was a sterilization procedure reported on the claim. If yes, the logic assigns the case to one of the proposed new MS–DRGs 783, 784, or 785. If no, the logic assigns the case to one of the proposed new MS–DRGs 786, 787, or 788. If there was not a cesarean section procedure reported on the claim, the logic asks if there was a vaginal delivery procedure reported on the claim. If yes, the logic asks if there was another O.R. procedure other than sterilization, D&C, delivery procedure or a delivery inclusive O.R. procedure. If yes, the logic assigns the case to existing MS–DRG 768. If no, the logic asks if there was a sterilization and/or D&C reported on the claim. If yes, the logic assigns the case to one of the proposed new MS–DRGs 796, 797, or 798. If no, the logic assigns the case to one of the proposed new MS–DRGs 805, 806, or 807. If there was not a vaginal delivery procedure reported on the claim, the GROUPER logic directs you to the other

non-delivery MS–DRGs as shown in Diagram 2.

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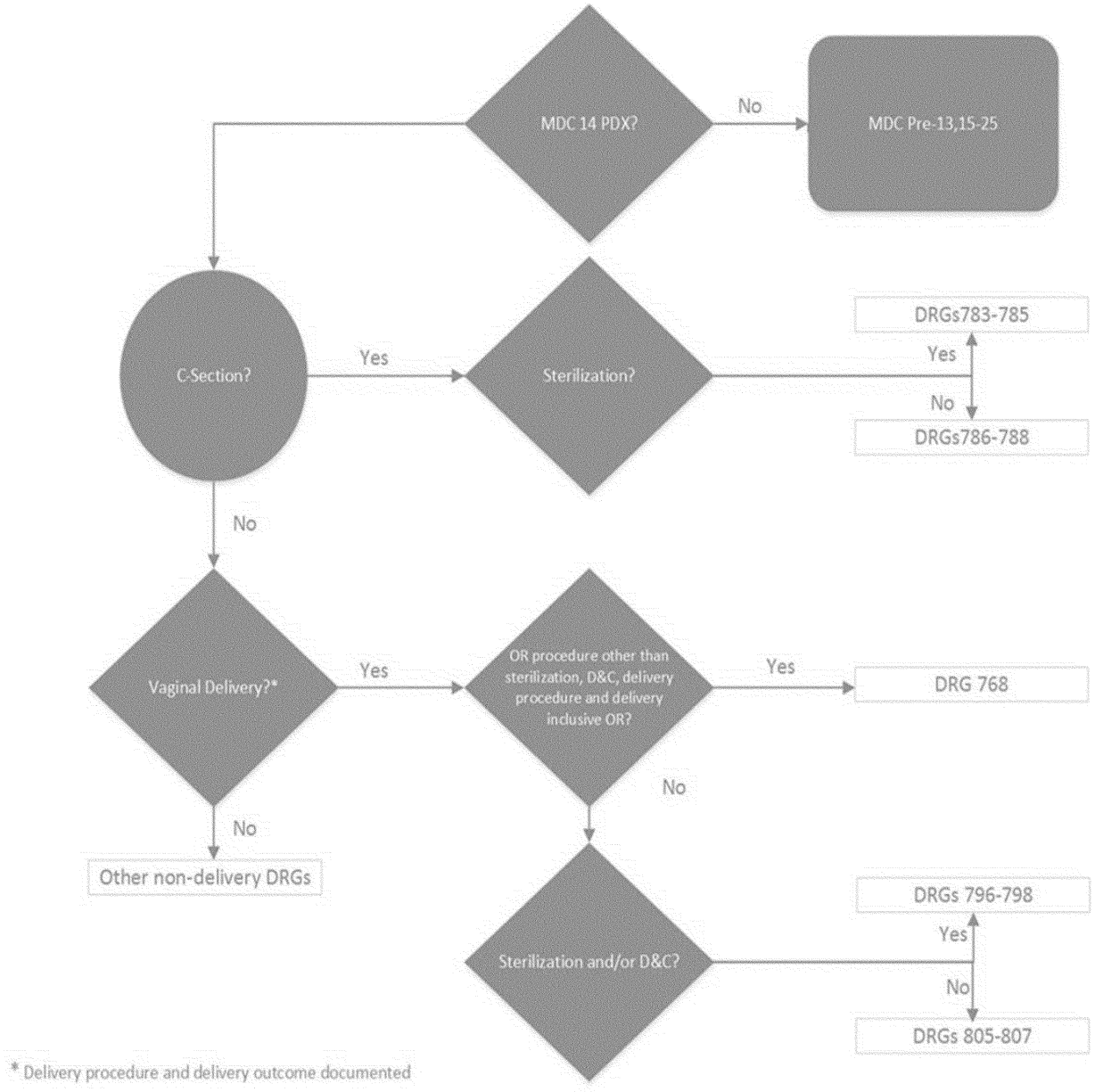
Diagram 1.

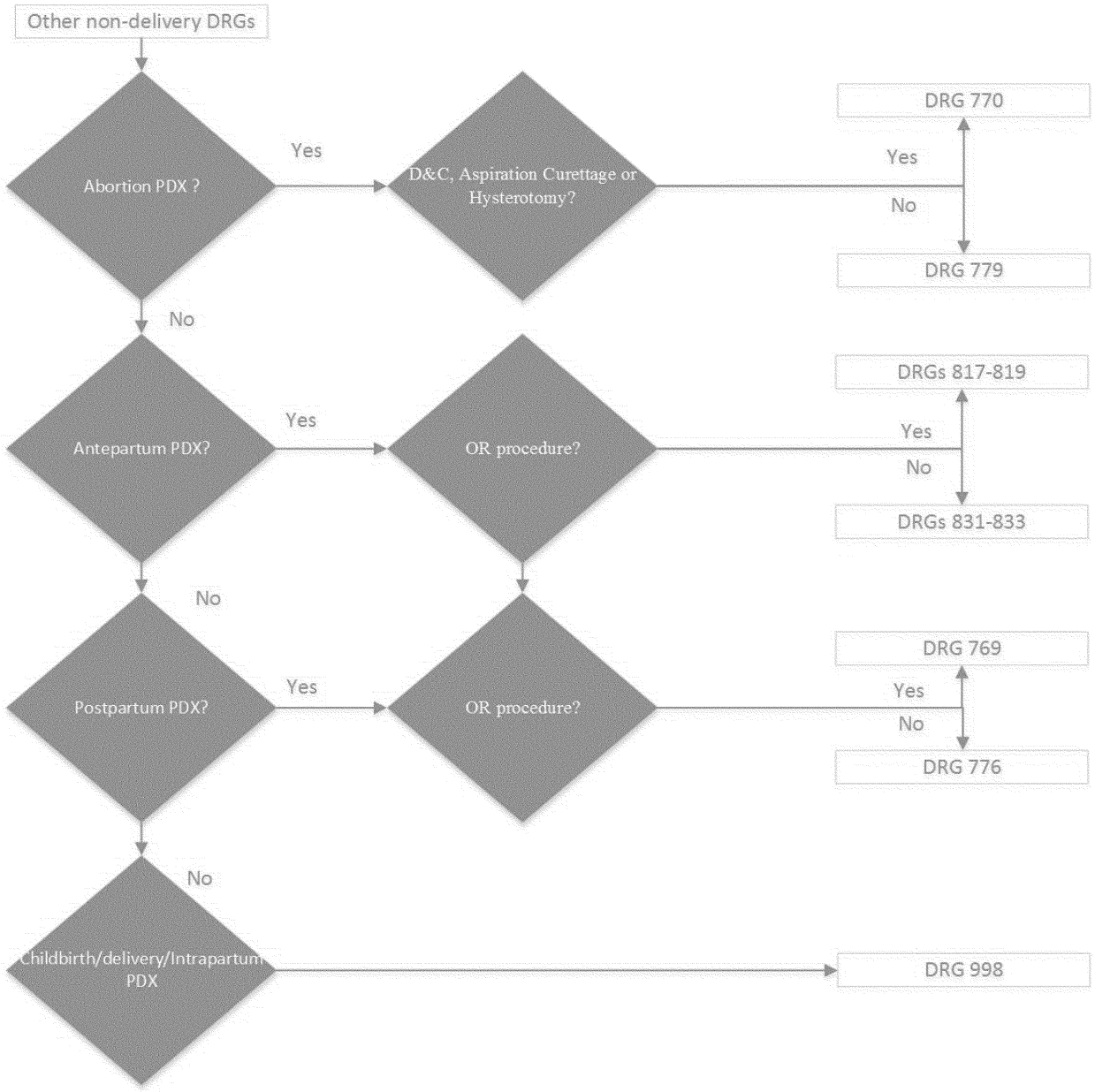


The logic for Diagram 2. begins by asking if there is a principal diagnosis of abortion reported on the claim. If yes, the logic then asks if there was a D&C, aspiration curettage or hysterotomy procedure reported on the claim. If yes, the logic assigns the case to existing MS–DRG 770. If no, the logic assigns the case to existing MS–DRG 779. If there was not a principal diagnosis of abortion reported on the claim, the logic asks if there was a principal diagnosis of an antepartum condition reported on the claim. If yes, the logic then asks if there was an O.R. procedure reported on the claim. If yes, the logic assigns the case to one of the proposed new MS–DRGs 817, 818, or 819. If no, the logic assigns the case to one of the proposed new MS–DRGs 831, 832, or 833. If there was not a principal diagnosis of an antepartum condition reported on the claim, the logic asks if there was a principal diagnosis of a postpartum condition reported on the claim. If yes, the logic then asks if there was an O.R. procedure reported on the claim. If yes, the logic assigns the case to existing MS–DRG 769. If no, the logic assigns the case to existing MS–DRG 776. If there was not a principal diagnosis of a postpartum condition reported on the claim, the logic identifies that there was a principal diagnosis describing childbirth, delivery or an intrapartum condition reported on the claim without

any other procedures, and assigns the case to existing MS–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis).

To assist in detecting coding and MS–DRG assignment errors for MS–DRG 998 that could result when a provider does not report the procedure code for either a cesarean section or a vaginal delivery along with an outcome of delivery diagnosis code, as discussed in section II.F.13.d., we proposed to add a new Questionable Obstetric Admission edit under the MCE. We invited public comments on this proposed MCE edit and we also invited public comments on the need for any additional MCE considerations with regard to the proposed changes for the MDC 14 MS–DRGs.

Diagram 2.



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We referred readers to Tables 6P.1h. through 6P.1k. associated with the proposed rule for the lists of the diagnosis and procedure codes that we proposed to assign to the GROUPER logic for the proposed new MS–DRGs and the existing MS–DRGs under MDC 14. We invited public comments on our proposed list of diagnosis codes, which also addresses the list of diagnosis codes that a commenter identified as missing from the GROUPER logic. We noted that, as a result of our proposed GROUPER logic changes to the vaginal delivery MS–DRGs, which would only take into account the procedure codes for a vaginal delivery and the outcome of delivery secondary diagnosis codes, there is no longer a need to maintain a specific principal diagnosis logic list for those MS–DRGs. Therefore, while we

appreciate the detailed suggestions and rationale submitted by the commenter for why specific diagnosis codes should be removed from the vaginal delivery principal diagnosis logic as displayed earlier in this discussion, we proposed to remove that logic. We invited public comments on this proposal, as well as our proposed list of procedure codes for the proposed revised MDC 14 MS–DRG logic, which would require a procedure code for case assignment. We also invited public comments on the proposed deletion of the 10 MS–DRGs and the proposed creation of 18 new MS–DRGs with a 3-way severity level split listed above in this section, as well as on the potential alternative new MS–DRGs using a 2-way severity level split as also presented above.

Comment: Commenters agreed with CMS' proposal to restructure the MS–DRGs within MDC 14. A few commenters commended CMS on the proposed new structure and GROUPER logic for these MS–DRGs, and believed that the new structure and logic is clearer and clinically appropriate. Another commenter agreed with the proposed new GROUPER logic for MDC 14 for deliveries with the 3-way severity level splits. The commenters anticipated that the new structure and logic will provide more clarity than the current structure.

Response: We appreciate the commenters' support. We agree the proposed new structure and GROUPER logic of the MS–DRGs under MDC 14 will provide more clarity than the current structure and logic.

Comment: Another commenter stated that all of the diagnoses currently assigned to MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis) in the GROUPER logic, along with some of the diagnoses that were noted to appear to be missing from the GROUPER logic (83 FR 20216 through 20217), should be added to the Principal Diagnosis Is Its Own CC Or MCC logic for the proposed new vaginal delivery MS–DRGs 796 (Vaginal Delivery with Sterilization/D&C with MCC), 797 (Vaginal Delivery with Sterilization/D&C with CC), 798 (Vaginal Delivery with Sterilization/D&C without CC/MCC), 805 (Vaginal Delivery without Sterilization/D&C with MCC), 806 (Vaginal Delivery without Sterilization/D&C with CC), and 807 (Vaginal Delivery without Sterilization/D&C without CC/MCC). The commenter provided the following list of diagnosis codes that were noted to appear to be missing from the GROUPER logic, and requested CMS consider adding these diagnosis codes to the Principal Diagnosis Is Its Own CC Or MCC Lists. The commenter believed that the current GROUPER logic for MS–DRG 774 includes diagnoses that could change the MS–DRG assignment of a case from MS–DRG 775 to MS–DRG 774 based on the principal diagnosis. The commenter further expressed concern that these same diagnoses may group to the proposed new MS–DRGs 798 or 807 (without CC/MCC) under the proposed new structure and GROUPER logic for the vaginal delivery MS–DRGs.

ICD–10–CM code	Code description
O11.5	Pre-existing hypertension with pre-eclampsia, complicating the puerperium.
012.04	Gestational edema, complicating childbirth.
012.05	Gestational edema, complicating the puerperium.
012.14	Gestational proteinuria, complicating childbirth.
012.15	Gestational proteinuria, complicating the puerperium.
012.24	Gestational edema with proteinuria, complicating childbirth.
012.25	Gestational edema with proteinuria, complicating the puerperium.
O13.4	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating childbirth.
O13.5	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating the puerperium.
O14.04	Mild to moderate pre-eclampsia, complicating childbirth.
O14.05	Mild to moderate pre-eclampsia, complicating the puerperium.
O14.14	Severe pre-eclampsia complicating childbirth.
O14.15	Severe pre-eclampsia, complicating the puerperium.
O14.24	HELLP syndrome, complicating childbirth.
O14.25	HELLP syndrome, complicating the puerperium.
O14.94	Unspecified pre-eclampsia, complicating childbirth.
O14.95	Unspecified pre-eclampsia, complicating the puerperium.
O15.00	Eclampsia complicating pregnancy, unspecified trimester.
O15.02	Eclampsia complicating pregnancy, second trimester.
O15.03	Eclampsia complicating pregnancy, third trimester.
O15.1	Eclampsia complicating labor.
O15.2	Eclampsia complicating puerperium, second trimester.
O16.4	Unspecified maternal hypertension, complicating childbirth.
O16.5	Unspecified maternal hypertension, complicating the puerperium.

Response: As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20236 through 20239), we proposed to remove the special logic in the GROUPER for processing claims containing a diagnosis code from the Principal Diagnosis Is Its Own CC or MCC Lists. For the reasons stated in section II.F.15.c. of the preamble of this final rule, we are finalizing that proposal, and therefore this logic will no longer apply for FY 2019. We refer readers to section II.F.15.c. of the preamble of this final rule for further discussion of the specific proposal, including summaries of the public comments we received and our responses and our statement of final policy.

With regard to the commenter's concern that the diagnosis codes listed above appear to be missing from the GROUPER logic, we note that, currently, all of the diagnoses codes are included in the MDC 14 Assignment of Diagnosis Codes List. The diagnosis codes that include the terminology ''complicating the puerperium'' are listed under the ''Second Condition—Principal or Secondary Diagnosis'' code list in the diagnosis code logic for MS–DRG 774, and the diagnosis codes that include the terminology ''complicating childbirth'' are listed under the ''Principal Diagnosis'' code list for the diagnosis code logic for MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications). We acknowledge that the diagnosis codes that include the

terminology ''complicating childbirth'' that the commenter referenced were inadvertently omitted, and are not listed in the ICD–10 MS–DRG Definitions Manual Version 35 under the diagnosis code logic list for MS–DRG 774 (or for MS–DRGs 767 (Vaginal Delivery with Sterilization and/or D&C) and 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C)). However, if one of those diagnosis codes is reported with a procedure code from the vaginal delivery code list, the ICD–10 MS–DRG GROUPER Version 35 accurately groups the case to a vaginal delivery MS–DRG.

As stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20220), in our proposal for restructuring the MDC 14 MS–DRGs under the ICD–10 MS–DRGs Version 36, diagnoses described as occurring during pregnancy and diagnoses specifying a trimester or maternal care in the absence of a delivery procedure reported are considered antepartum conditions. Also, as shown in Table 6P.1j. associated with the proposed rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Proposed-Rule-Home-Page-Items/FY2019-IPPS-Proposed-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*), we did not propose to include any diagnosis codes describing a condition as ''complicating childbirth'' in the list of diagnosis codes describing antepartum conditions. Therefore, the diagnosis codes described as ''complicating childbirth'' would be applicable when a patient is admitted for a delivery episode and are subject to MS–DRG assignment to proposed MS–DRGs describing a cesarean or vaginal delivery.

Comment: Another commenter agreed with CMS' initiative to restructure the MS–DRGs and GROUPER logic under MDC 14. However, the commenter expressed concerns with the proposed GROUPER logic, and requested CMS consider all of the issues prior to implementing the proposed new MS–DRGs and GROUPER logic. The commenter believed that grouping a vaginal delivery by procedure codes describing a delivery and a diagnosis code describing the outcome of delivery did not seem appropriate. The commenter stated that it is necessary to determine if a case should be assigned to a vaginal delivery MS–DRG based on the combination of principal diagnoses and procedure codes versus the combination of a procedure code with an outcome of delivery code. The commenter recommended that the first consideration should consist of identification of a principal diagnosis code within the O00–O08 code range (Pregnancy with Abortive Outcome) and then proceeding with grouping those cases to the Abortion MS–DRGs 770 (Abortion with D&C, Aspiration Curettage or Hysterotomy) and 779 (Abortion without D&C), prior to possibly grouping the cases to the cesarean or vaginal delivery MS–DRGs. The commenter provided the example of a blighted ovum that may be treated with ICD–10–PCS procedure codes 10D07Z6 (Extraction of products of conception, vacuum, via natural or artificial opening) or 10D07Z8 (Extraction of products of conception, other, via natural or artificial opening), which are reported for vaginal deliveries.

Response: We appreciate the commenter's support for the effort to restructure the MS–DRGs and GROUPER logic under MDC 14. However, with respect to the commenter's concerns regarding the proposed new GROUPER logic for a vaginal delivery, we disagree with the commenter that it is necessary to determine if cases should be assigned to a vaginal delivery MS–DRG based on the combination of principal diagnoses and procedure codes versus the combination of a procedure code with an outcome of delivery code. One of the underlying purposes of the effort to restructure the vaginal delivery MS–DRGs was to simplify the complex logic currently associated with the vaginal delivery MS–DRGs, which includes multiple code lists for principal and secondary diagnoses. Based on the proposed new structure and GROUPER logic of the MS–DRGs under MDC 14, to identify that a vaginal delivery occurred, the logic does not have to consider or depend on the reason the patient was admitted. Rather, the GROUPER logic is structured to account for the fact that a delivery took place during that hospitalization. The delivery MS–DRGs (whether cesarean or vaginal) are specifically intended for that reason. With regard to the example provided by the commenter, we note that ICD–10–PCS procedure codes 10D07Z6 and 10D07Z8 are designated as non-O.R. procedures that affect the MS–DRG assignment of specific MS–DRGs. ICD–10–PCS procedure codes 10D07Z6 and 10D07Z8 impact the MS–DRG assignment of the vaginal delivery MS–DRGs. However, ICD–10–CM diagnosis code O02.0 (Blighted ovum and nonhydatidiform mole) is identified as a proposed antepartum condition, as shown in Table 6P.1j. associated with the proposed rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Proposed-Rule-Home-Page-Items/FY2019-IPPS-Proposed-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*) and, therefore, as depicted in the commenter's example, if a patient has a principal diagnosis of a blighted ovum and either ICD–10–PCS procedure code 10D07Z6 or 10D07Z8 is reported, the proposed new GROUPER logic would result in an MS–DRG case assignment to one of the proposed new MS–DRGs 831, 832, or 833 (Other Antepartum Diagnoses without O.R. Procedure with MCC, with CC or without CC/MCC, respectively) and not a vaginal delivery MS–DRG. The diagnosis of a blighted ovum does not result in a viable pregnancy and, therefore, an outcome of delivery diagnosis code would not be reported. An illustration of how this proposed new GROUPER logic would apply for antepartum conditions was represented in Diagram 2 of the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20225).

Comment: One commenter expressed concern about the proposed relative weights for several of the proposed new MS–DRGs under MDC 14. The commenter stated that the low volume of the procedures assigned to these MS–DRGs accounted for volatility in the relative weights. With regard to proposed new MS–DRGs 817, 818, and 819 (Other Antepartum Diagnoses with O.R. Procedure with MCC, CC, and without CC/MCC, respectively), the commenter stated that the proposed relative weights for these MS–DRGs are significantly lower than the proposed relative weights of the surgical MS–DRGs to which the procedure codes proposed to be assigned to these proposed new MS–DRGs would map for non-obstetrical patients. This commenter also stated that the relative weights for proposed new MS–DRGs 806 and 807 (Vaginal Delivery without Sterilization/D&C with CC and without CC/MCC, respectively) are lower than the current relative weights for MS–DRGs 774 and 775 (Vaginal Delivery with and without Complicating Diagnosis, respectively), and believed the relative weight for proposed new MS–DRG 805 (Vaginal Delivery without Sterilization/D&C with MCC) is likely inadequate for the resources required to care for patients with MCC severity level designations. The commenter suggested that CMS maintain the relative weights for proposed new MS–DRGs 806 and 807 at the same value of

the current MS–DRGs, and establish a relative weight for proposed new MS–DRG 805 that is more comparable with those values of medical MS–DRGs with MCC severity level designations. The commenter further noted that the relative weights for proposed new MS–DRGs 797 and 798 (Vaginal Delivery with Sterilization/D&C with CC and without CC/MCC, respectively) are the same value, but believed the relative weight should be greater for proposed new MS–DRG 797. The commenter also believed that the relative weight for proposed new MS–DRG 786 (Cesarean Section without Sterilization with MCC) is insufficient for the required resources necessary to perform these procedures and provide the appropriate care to patients, and requested CMS establish a relative weight with a value more consistent with values of surgical MS–DRGs with MCC severity level designations. The commenter also requested that CMS maintain the relative weights for MS–DRG 787 (Cesarean Section without Sterilization with CC) at the same value of current MS–DRG 765 (Cesarean Section with CC/MCC), and the relative weight for proposed new MS–DRG 833 (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC) at the same value of current MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications).

Response: It is to be expected that when MS–DRGs are restructured, resulting in a different case-mix within the new MS–DRGs, the relative weights of the MS–DRGs will change as a result. With respect to the comment about the low volume of cases, as we have noted in the proposed rule, we were unable to use our usual criterion of ensuring that there are at least 500 cases in the MCC or CC group to refine the maternity MS–DRGs because of the extremely low volume of Medicare patients cases reflected in claims data for these DRGs. While there is not a high volume of these cases represented in the Medicare data, and while we generally advise that other payers should develop MS–DRGs to address the needs of their patients, we continue to believe that the restructured MS–DRGs within MDC 14 serve important purposes to account for the new and different clinical concepts that exist under ICD–10 for this subset of patients while also maintaining the existing MS–DRG structure for identifying severity of illness, utilization of resources, and complexity of service. We believe that even though some of the resulting MS–DRGs have relatively low volumes in the Medicare population, using our established methodology for developing DRG relative weights is the most appropriate approach for the new MS–DRGs within MDC 14. With regard to the comment about MS–DRGs 797 and 798, we note that the average cost per case for MS–DRG 797 was lower than the average cost per case for MS–DRG 798. Therefore, we blended the data for these two MS–DRGs to avoid nonmonotonocity, in which the lower severity MS–DRG has a higher relative weight than the higher severity MS–DRG. For these reasons, we are not finalizing a change to the calculation of the relative weights for the MS–DRGs under MDC 14.

After consideration of the public comments we received, we are finalizing our proposals, without modification, including the list of diagnosis codes assigned to the MS–DRGs under the restructuring of the vaginal delivery MS–DRGs under MDC 14, which we note also addresses the list of diagnosis codes that a commenter identified and were noted in the proposed rule as appearing to be missing from the GROUPER logic.

We also invited public comments on our proposal to reassign ICD–10–PCS procedure codes 0UDB7ZX, 0UDB7ZZ, 0UDB8ZX, and 0UDB8ZZ that describe dilation and curettage procedures from MS–DRG 767 under MDC 14 to MS–DRGs 744 and 745 under MDC 13.

Comment: Commenters supported CMS' proposal to reassign ICD–10–PCS procedure codes 0UDB7ZX, 0UDB7ZZ, 0UDB8ZX, and 0UDB8ZZ from MS–DRG 767 to MS–DRGs 744 and 745.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–PCS procedure codes 0UDB7ZX, 0UDB7ZZ, 0UDB8ZX, and 0UDB8ZZ that describe dilation and curettage procedures from MS–DRG 767 under MDC 14 to MS–DRGs 744 and 745 under MDC 13 in the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

After consideration of the public comments we received, we are finalizing our proposed list of diagnosis and procedure codes for assignment to the revised MDC 14 MS–DRGs including the deletion of 10 MS–DRGs and the creation of 18 new MS–DRGs in the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

11. MDC 18 (Infectious and Parasitic Diseases (Systematic or Unspecified Sites): Systemic Inflammatory Response Syndrome (SIRS) of Non-Infectious Origin

ICD–10–CM diagnosis codes R65.10 (Systemic Inflammatory Response Syndrome (SIRS) of non-infectious origin without acute organ dysfunction) and R65.11 (Systemic Inflammatory Response Syndrome (SIRS) of non-infectious origin with acute organ dysfunction) are currently assigned to MS–DRGs 870 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours), 871 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours with MCC), and 872 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours without MCC) under MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites). As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20226), our clinical advisors noted that these diagnosis codes are specifically describing conditions of a non-infectious origin, and recommended that they be reassigned to a more clinically appropriate MS–DRG.

We examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases in MS–DRGs 870, 871, and 872. Our findings are shown in the following table.

SEPTICEMIA OR SEVERE SEPSIS WITH AND WITHOUT MECHANICAL VENTILATION >96 HOURS WITH AND WITHOUT MCC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 870—All cases	31,658	14.3	$42,981
MS–DRG 871—All cases	566,531	6.3	13,002
MS–DRG 872—All cases	150,437	4.3	7,532

As shown in this table, we found a total of 31,658 cases in MS–DRG 870, with an average length of stay of 14.3 days and average costs of $42,981. We found a total of 566,531 cases in MS–DRG 871, with an average length of stay

of 6.3 days and average costs of $13,002. Lastly, we found a total of 150,437 cases in MS–DRG 872, with an average length of stay of 4.3 days and average costs of $7,532.

We then examined claims data in MS–DRGs 870, 871, or 872 for cases reporting an ICD–10–CM diagnosis code of R65.10 or R65.11. Our findings are shown in the following table.

SIRS of Non-Infectious Origin With and Without Acute Organ Dysfunction

MS–DRGs 870, 871 and 872	Number of cases	Average length of stay	Average costs
MS–DRGs 870, 871, and 872—Cases reporting a principal diagnosis code of R65.10	1,254	3.8	$6,615
MS–DRGs 870, 871, and 872—Cases reporting a principal diagnosis code of R65.11	138	4.8	9,655
MS–DRGs 870, 871, and 872—Cases reporting a secondary diagnosis code of R65.10	1,232	5.5	10,670
MS–DRGs 870, 871, and 872—Cases reporting a secondary diagnosis code of R65.11	117	6.2	12,525

As shown in this table, we found a total of 1,254 cases reporting a principal diagnosis code of R65.10 in MS–DRGs 870, 871, and 872, with an average length of stay of 3.8 days and average costs of $6,615. We found a total of 138 cases reporting a principal diagnosis code of R65.11 in MS–DRGs 870, 871, and 872, with an average length of stay of 4.8 days and average costs of $9,655. We found a total of 1,232 cases reporting a secondary diagnosis code of R65.10 in MS–DRGs 870, 871, and 872, with an average length of stay of 5.5 days and average costs of $10,670. Lastly, we found a total of 117 cases reporting a secondary diagnosis code of R65.11 in MS–DRGs 870, 871, and 872, with an average length of stay of 6.2 days and average costs of $12,525.

The claims data included a total of 1,392 cases in MS–DRGs 870, 871, and 872 that reported a principal diagnosis code of R65.10 or R65.11. We noted in the FY 2019 IPPS/LTCH PPS proposed rule that these 1,392 cases appear to have been coded inaccurately according to the ICD–10–CM Official Guidelines for Coding and Reporting at Section I.C.18.g., which specifically state: ''The systemic inflammatory response syndrome (SIRS) can develop as a result of certain non-infectious disease processes, such as trauma, malignant neoplasm, or pancreatitis. When SIRS is documented with a non-infectious condition, and no subsequent infection is documented, the code for the underlying condition, such as an injury, should be assigned, followed by code R65.10, Systemic inflammatory response syndrome (SIRS) of non-infectious origin without acute organ dysfunction or code R65.11, Systemic inflammatory response syndrome (SIRS) of non-infectious origin with acute organ dysfunction.'' Therefore, according to the Coding Guidelines, ICD–10–CM diagnosis codes R65.10 and R65.11 should not be reported as the principal diagnosis on an inpatient claim.

We have acknowledged in past rulemaking the challenges with coding for SIRS (and sepsis) (71 FR 24037). In addition, we note that there has been confusion with regard to how these codes are displayed in the ICD–10 MS–DRG Definitions Manual under MS–DRGs 870, 871, and 872, which may also impact the reporting of these conditions. For example, in Version 35 of the ICD–10 MS–DRG Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*, the logic for case assignment to MS–DRGs 870, 871, and 872 is comprised of a list of several diagnosis codes, of which ICD–10–CM diagnosis codes R65.10 and R65.11 are included. Because these codes are listed under the heading of ''Principal Diagnosis'', it may appear that these codes are to be reported as a principal diagnosis for assignment to MS–DRGs 870, 871, or 872. However, the Definitions Manual display of the GROUPER logic assignment for each diagnosis code is for grouping purposes only. The GROUPER (and, therefore, documentation in the MS–DRG Definitions Manual) was not designed to account for coding guidelines or coverage policies. Since the inception of the IPPS, the data editing function has been a separate and independent step in the process of determining a DRG assignment. Except for extreme data integrity issues that prevent a DRG from being assigned, such as an invalid principal diagnosis, the DRG assignment GROUPER does not edit for data integrity. Prior to assigning the MS–DRG to a claim, the MACs apply a series of data integrity edits using programs such as the Medicare Code Editor (MCE). The MCE is designed to identify cases that require further review before classification into an MS–DRG. These data integrity edits address issues such as data validity, coding rules, and coverage policies. The separation of the MS–DRG grouping and data editing functions allows the MS–DRG GROUPER to remain stable during a fiscal year even though coding rules and coverage policies may change during the fiscal year. As such, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38050 through 38051), we finalized our proposal to add ICD–10–CM diagnosis codes R65.10 and R65.11 to the Unacceptable Principal Diagnosis edit in the MCE as a result of the Official Guidelines for Coding and Reporting related to SIRS, in efforts to improve coding accuracy for these types of cases.

To address the issue of determining a more appropriate MS–DRG assignment for ICD–10–CM diagnosis codes R65.10 and R65.11, we reviewed alternative options under MDC 18. Our clinical advisors determined the most appropriate option is MS–DRG 864 (Fever) because the conditions that are assigned here describe conditions of a non-infectious origin.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20227), we proposed to reassign ICD–10–CM diagnosis codes R65.10 and R65.11 to MS–DRG 864 and to revise the title of MS–DRG 864 to ''Fever and Inflammatory Conditions'' to better reflect the diagnoses assigned there.

PROPOSED REVISED MS–DRG 864 (FEVER AND INFLAMMATORY CONDITIONS)

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 864—All cases	12,144	3.4	$6,232

Comment: Commenters supported the proposal to reassign ICD–10–CM diagnosis codes R65.10 and R65.11 to MS–DRG 864 and to revise the title of MS–DRG 864 to ''Fever and Inflammatory Conditions''.

Response: We thank the commenters for their support.

Comment: One commenter questioned the proposed logic for ICD–10–CM diagnosis codes R65.10 and R65.11 within MS–DRG 864. The commenter noted that the diagnosis codes are included on the unacceptable principal diagnoses code edit list in the MCE and specifically inquired if cases reporting diagnosis code R65.10 or R65.11 as a secondary diagnosis would result in assignment to MS–DRG 864.

Response: The GROUPER logic assignment for each diagnosis code as a principal diagnosis is for grouping purposes only. The GROUPER was not designed to account for coding guidelines or coverage policies. The MCE is designed to identify cases that require further review before classification into an MS–DRG. Therefore, the MS–DRG logic must specifically require a condition to group based on whether it is reported as a principal diagnosis or a secondary diagnosis, and consider any procedures that are reported, in addition to consideration of the patient's age, sex and discharge status in order to affect the MS–DRG assignment.

As noted in the ICD–10 MS–DRG Definitions Manual Version 35, Appendix B—Diagnosis Code/MDC/MS–DRG Index, each diagnosis code is listed with the MDC and the MS–DRGs to which the diagnosis is used to define the logic of the DRG either as a principal diagnosis or a secondary diagnosis. For diagnosis codes R65.10 and R65.11, the ICD–10 MS DRG Definitions Manual displays MDC 18 and MS–DRGs 870–872, as described previously. As discussed in the proposed rule, because the diagnosis are codes listed under the heading of ''Principal Diagnosis'' in the ICD–10 MS DRG Definitions Manual, it may appear to indicate that these codes are to be reported as a principal diagnosis for assignment to these MS–DRGs. However, the Definitions Manual display of the GROUPER logic assignment for each diagnosis code is for grouping purposes only and does not correspond to coding guidelines for reporting the principal diagnosis. In other words, cases will group according to the GROUPER logic, regardless of any coding guidelines or coverage policies. It is the MCE and other payer specific edits that identify inconsistencies in the coding guidelines or coverage policies. Under our proposed change to the ICD–10 MS–DRGs Version 36, cases reporting diagnosis code R65.10 or R65.11 as a secondary diagnosis would result in assignment to MS–DRG 864 when one of the other listed diagnosis codes in the MS–DRG 864 logic is reported as the principal diagnosis.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–CM diagnosis codes R65.10 and R65.11 to MS–DRG 864 and to revise the title of MS–DRG 864 to ''Fever and Inflammatory Conditions''.

12. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): Corrosive Burns

ICD–10–CM Coding Guidelines include ''Code first'' sequencing instructions for cases reporting a principal diagnosis of toxic effect (ICD–10–CM codes T51 through T65) and a secondary diagnosis of corrosive burn (ICD–10–CM codes T21.40 through T21.79). As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20227), we received a request to reassign these cases from MS–DRGs 901 (Wound Debridements for Injuries with MCC), 902 (Wound Debridements for Injuries with CC), 903 (Wound Debridements for Injuries without CC/MCC), 904 (Skin Grafts for Injuries with CC/MCC), 905 (Skin Grafts for Injuries without CC/MCC), 917 (Poisoning and Toxic Effects of Drugs with MCC), and 918 (Poisoning and Toxic Effects of Drugs without MCC) to MS–DRGs 927 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation >96 Hours with Skin Graft), 928 (Full Thickness Burn with Skin Graft or Inhalation Injury with CC/MCC), 929 (Full Thickness Burn with Skin Graft or Inhalation Injury without CC/MCC), 933 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation >96 Hours without Skin Graft), 934 (Full Thickness Burn without Skin Graft or Inhalation Injury), and 935 (Nonextensive Burns).

The requestor noted that, for corrosion burns codes T21.40 through T21.79, ICD–10–CM Coding Guidelines instruct to ''Code first (T51 through T65) to identify chemical and intent.'' Because code first notes provide sequencing directive, when patients are admitted with corrosive burns (which can be full thickness and extensive), toxic effect codes T51 through T65 must be sequenced first followed by codes for the corrosive burns. This causes full-thickness and extensive burns to group to MS–DRGs 901 through 905 when excisional debridement and split thickness skin grafts are performed, and to MS–DRGs 917 and 918 when procedures are not performed. This is in contrast to cases reporting a principal diagnosis of corrosive burn, which group to MS–DRGs 927 through 935.

The requestor stated that MS–DRGs 456 (Spinal Fusion except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC), 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with CC), and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC) are grouped based on the procedure performed in combination with the principal diagnosis or secondary diagnosis (secondary scoliosis). The requestor stated that when codes for corrosive burns are reported as secondary diagnoses in conjunction with principal diagnoses codes T5l through T65, particularly when skin grafts are performed, they would be more appropriately assigned to MS–DRGs 927 through 935.

We analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for all cases assigned to MS–DRGs 901, 902, 903, 904, 905, 917, and 918, and subsets of these cases with principal diagnosis of toxic effect with secondary diagnosis of corrosive burn. We noted in the proposed rule that we found no cases from this subset in MS–DRGs 903, 907, 908, and 909 and, therefore, did not include the results for these MS–DRGs in the table below. We also analyzed all cases assigned to MS–DRGs 927, 928, 929, 933, 934, and 935 and those cases that reported a principal diagnosis of corrosive burn. Our findings are shown in the following two tables.

MDC 21 INJURIES, POISONINGS AND TOXIC EFFECTS OF DRUGS

MS–DRGs	Number of cases	Average length of stay	Average costs
All Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn—Across all MS–DRGs	55	5.5	$18,077
MS–DRG 901—All cases	968	13	31,479
MS–DRG 901—Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn	1	8	12,388
MS–DRG 902—All cases	1,775	6.6	14,206
MS–DRG 902—Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn	8	10.3	20,940
MS–DRG 904—All cases	905	9.8	23,565
MS–DRG 904—Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn	8	6.4	22,624
MS–DRG 905—All cases	263	4.9	13,291
MS–DRG 905—Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn	2	2.5	7,682
MS–DRG 906—All cases	458	4.8	13,555
MS–DRG 906—Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn	1	5	7,409
MS–DRG 917—All cases	31,730	4.8	10,280
MS–DRG 917—Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn	6	4.8	7,336
MS–DRG 918—All cases	19,819	3	5,529
MS–DRG 918—Cases with principal diagnosis of toxic effect and secondary diagnosis of corrosive burn	28	3.5	5,643

As shown in this table, there were a total of 55 cases with a principal diagnosis of toxic effect and a secondary diagnosis of corrosive burn across MS–DRGs 901, 902, 903, 904, 905, 917, and 918. When comparing this subset of codes relative to those of each MS–DRG as a whole, we noted that, in most of these MS–DRGs, the average costs and average length of stay for this subset of cases were roughly equivalent to or lower than the average costs and average length of stay for cases in the MS–DRG as a whole, while in one case, they were higher. As we have noted in prior rulemaking (77 FR 53309) and elsewhere in the proposed rule and this final rule, it is a fundamental principle of an averaged payment system that half of the procedures in a group will have above average costs. It is expected that there will be higher cost and lower cost subsets, especially when a subset has low numbers. We stated in the proposed rule that the results of this analysis indicate that these cases are appropriately placed within their current MDC.

Our clinical advisors reviewed this request and indicated that patients with a principal diagnosis of toxic effect and a secondary diagnosis of corrosive burn have been exposed to an irritant or corrosive substance and, therefore, are clinically similar to those patients in MDC 21. Furthermore, our clinical advisors did not believe that the size of this subset of cases justifies the significant changes to the GROUPER logic that would be required to address the commenter's request, which would involve rerouting cases when the primary and secondary diagnoses are in different MDCs.

MDC 22 BURNS

MS–DRG	Number of cases	Average length of stay	Average costs
All cases with principal diagnosis of corrosive burn—Across all MS–DRGs	60	8.5	$19,456
MS–DRG 927—All cases	159	28.1	128,960
MS–DRG 927—Cases with principal diagnosis of corrosive burn	1	41	75,985
MS–DRG 928—All cases	1,021	15.1	42,868
MS–DRG 928—Cases with principal diagnosis of corrosive burn	13	13.2	31,118
MS–DRG 929—All cases	295	7.9	21,600
MS–DRG 929—Cases with principal diagnosis of corrosive burn	4	12.5	18,527
MS–DRG 933—All cases	121	4.6	21,291
MS–DRG 933—Cases with principal diagnosis of corrosive burn	1	7	91,779
MS–DRG 934—All cases	503	6.1	13,286
MS–DRG 934—Cases with principal diagnosis of corrosive burn	11	5.8	13,280
MS–DRG 935—All cases	1,705	5.2	13,065
MS–DRG 935—Cases with principal diagnosis of corrosive burn	29	5	9,822

To address the request of reassigning cases with a principal diagnosis of toxic effect and secondary diagnosis of corrosive burn, we reviewed the data for all cases in MS–DRGs 927, 928, 929, 933, 934, and 935 and those cases reporting a principal diagnosis of corrosive burn. We found a total of 60 cases reporting a principal diagnosis of corrosive burn, with an average length of stay of 8.5 days and average costs of $19,456. We stated in the proposed rule that our clinical advisors believe that these cases reporting a principal diagnosis of corrosive burn are appropriately placed in MDC 22 as they are clinically aligned with other patients in this MDC. We further stated that, in

summary, the results of our claims data analysis and the advice from our clinical advisors do not support reassigning cases in MS–DRGs 901, 902, 903, 904, 905, 917, and 918 reporting a principal diagnosis of toxic effect and a secondary diagnosis of corrosive burn to MS–DRGs 927, 928, 929, 933, 934 and 935. Therefore, we did not propose to reassign these cases.

Comment: One commenter supported the proposal to maintain the current MS–DRG structure for cases reporting a principal diagnosis of toxic effect (ICD–10–CM codes T51 through T65) and a secondary diagnosis of corrosive burn (ICD–10–CM codes T21.40 through T21.79). Another commenter suggested that the 60 identified cases that CMS used in its analysis were incorrectly coded. The commenter noted that ICD–10–CM coding guidelines under each code for corrosion burn state ''Code first (T51–T65) to identify chemical and intent.'' The commenter stated that corrosive burns cannot be sequenced as the principal diagnosis because the coding guidelines must be followed. The commenter stated that the toxic effect codes T51–T65 must be sequenced first, which causes these cases to group to MS–DRGs 901 through 905 and 917 and 918 instead of the more appropriate burn MS–DRGs. The commenter stated that it appears that when codes T51–T65 are the principal diagnosis, the cases group to MDC 21 (Injuries, Poisoning. and Toxic Effects of Drugs), and then to MS–DRGs 901 through 905 and 917 and 918.

Response: We appreciate the commenter's support. With regard to the commenter who raised concerns about the coding guidelines and display of codes in the ICD–10 MS–DRG Definitions Manual, we note that the GROUPER logic was not designed to account for coding guidelines. With regard to the display of code lists in the ICD–10 MS–DRG Definitions Manual, the MS–DRG logic must specifically require a condition to group based on whether it is reported as a principal diagnosis or a secondary diagnosis and consider any procedures that are reported in order to affect the MS–DRG assignment. However, as stated previously, the GROUPER logic is not dependent on coding guidelines. The purpose of the GROUPER is to group cases into particular MS–DRGs. We recognize that, over time, the desire to create or modify existing GROUPER logic in response to coding guidelines has become more common. As we continue our efforts to refine the ICD–10 MS–DRGs, we will consider alternate approaches to ensure the integrity of both the GROUPER logic and coding guidelines. Based on the data available at this time, we do not believe that it is appropriate to change the MS–DRG assignment for the procedures identifying corrosive burns identified earlier.

After consideration of the public comments we received, we are finalizing our proposal to maintain the current MS–DRG structure for cases reporting a principal diagnosis of toxic effect (ICD–10–CM codes T51 through T65) and a secondary diagnosis of corrosive burn (ICD–10–CM codes T21.40 through T21.79).

13. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38045), we made available the FY 2018 ICD–10 MCE Version 35 manual file. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 35 (and ICD–10 MS–DRGs) are posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* through the FY 2018 IPPS Final Rule Home Page.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20229), we addressed the MCE requests we received by the November 1, 2017 deadline. We also discussed the proposals we were making based on our internal review and analysis. In this FY 2019 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to the MCE requests and proposals presented based on internal reviews and analyses in the proposed rule, our responses to those comments, and our finalized policies.

In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, we routinely make changes to the MCE. In the past, in both the IPPS proposed and final rules, we only provided the list of changes to the MCE that were brought to our attention after the prior year's final rule. We historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting. These changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file. Therefore, we are making available the FY 2019 ICD–10 MCE Version 36 Manual file, along with the link to the mainframe and computer software for the MCE Version 36 (and ICD–10 MS DRGs), on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html*.

a. Age Conflict Edit

In the MCE, the Age Conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age Conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age of 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 12–55 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Perinatal/Newborn Diagnoses Category

Under the ICD–10 MCE, the Perinatal/Newborn Diagnoses category under the Age Conflict edit considers the age of 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 to be inclusive. This includes conditions that have their origin in the fetal or perinatal period (before birth through the first 28 days

after birth) even if morbidity occurs later. For that reason, the diagnosis codes on this Age Conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20229), we indicated that, in the ICD–10–CM classification, there are 14 diagnosis codes that describe specific suspected conditions that have been evaluated and ruled out during the newborn period and are currently not on the Perinatal/Newborn Diagnoses Category edit code list. We consulted with staff at the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes. The NCHS' staff confirmed that the following diagnosis codes are appropriate to add to the edit code list for the Perinatal/Newborn Diagnoses Category.

ICD–10–CM code	Code description
Z05.0	Observation and evaluation of newborn for suspected cardiac condition ruled out.
Z05.1	Observation and evaluation of newborn for suspected infectious condition ruled out.
Z05.2	Observation and evaluation of newborn for suspected neurological condition ruled out.
Z05.3	Observation and evaluation of newborn for suspected respiratory condition ruled out.
Z05.41	Observation and evaluation of newborn for suspected genetic condition ruled out.
Z05.42	Observation and evaluation of newborn for suspected metabolic condition ruled out.
Z05.43	Observation and evaluation of newborn for suspected immunologic condition ruled out.
Z05.5	Observation and evaluation of newborn for suspected gastrointestinal condition ruled out.
Z05.6	Observation and evaluation of newborn for suspected genitourinary condition ruled out.
Z05.71	Observation and evaluation of newborn for suspected skin and subcutaneous tissue condition ruled out.
Z05.72	Observation and evaluation of newborn for suspected musculoskeletal condition ruled out.
Z05.73	Observation and evaluation of newborn for suspected connective tissue condition ruled out.
Z05.8	Observation and evaluation of newborn for other specified suspected condition ruled out.
Z05.9	Observation and evaluation of newborn for unspecified suspected condition ruled out.

Therefore, we proposed to add the ICD–10–CM diagnosis codes listed in the table above to the Age Conflict edit under the Perinatal/Newborn Diagnoses Category edit code list. We also proposed to continue to include the existing diagnosis codes currently listed under the Perinatal/Newborn Diagnoses Category edit code list.

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in the table above to the Age Conflict edit under the Perinatal/Newborn Diagnoses Category edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the ICD–10–CM diagnosis codes listed in the table above to the Age Conflict edit under the Perinatal/Newborn Diagnoses Category edit code list. We also are finalizing our proposal to continue to include the existing list of codes on the Perinatal/Newborn Diagnoses Category edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

(2) Pediatric Diagnoses Category

Under the ICD–10 MCE, the Pediatric Diagnoses Category for the Age Conflict edit considers the age range of 0 to 17 years inclusive. For that reason, the diagnosis codes on this Age Conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.F.15. of the preamble of the proposed rule, Table 6C.—Invalid Diagnosis Codes associated with the proposed rule and this final (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the diagnoses that will no longer be effective as of October 1, 2018. Included in this table is an ICD–10–CM diagnosis code currently listed on the Pediatric Diagnoses Category edit code list, ICD–10–CM diagnosis code Z13.4 (Encounter for screening for certain developmental disorders in childhood). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20230), we proposed to remove this code from the Pediatric Diagnoses Category edit code list. We also proposed to continue to include the other existing diagnosis codes currently listed under the Pediatric Diagnoses Category edit code list.

Comment: Commenters agreed with the proposal to remove ICD–10–CM diagnosis code Z13.4 from the Pediatric Diagnoses Category edit code list because this code will no longer be effective as of October 1, 2018.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove ICD–10–CM diagnosis code Z13.4 from the Pediatric Diagnoses Category edit code list. We also are finalizing our proposal to maintain the other existing codes on the Pediatric Diagnoses Category edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

(3) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity Diagnoses Category for the Age Conflict edit considers the age range of 12 to 55 years inclusive. For that reason, the diagnosis codes on this Age Conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.F.15. of the preamble of the proposed rule, Table 6A.—New Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the new diagnoses codes that had been approved to date, which will be effective with discharges occurring on and after October 1, 2018. The following table lists the new ICD–10–CM diagnosis codes included in Table 6A associated with pregnancy and maternal care that we stated we believe are appropriate to add to the Maternity Diagnoses Category edit code list under the Age Conflict edit. Therefore, in the proposed rule, we proposed to add these codes to the Maternity Diagnoses Category edit code list under the Age Conflict edit.

ICD–10–CM code	Code description
F53.0	Postpartum depression.
F53.1	Puerperal psychosis.
O30.131	Triplet pregnancy, trichorionic/triamniotic, first trimester.
O30.132	Triplet pregnancy, trichorionic/triamniotic, second trimester.
O30.133	Triplet pregnancy, trichorionic/triamniotic, third trimester.
O30.139	Triplet pregnancy, trichorionic/triamniotic, unspecified trimester.
O30.231	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, first trimester.
O30.232	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, second trimester.
O30.233	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, third trimester.
O30.239	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, unspecified trimester.
O30.831	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, first trimester.
O30.832	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, second trimester.
O30.833	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, third trimester.
O30.839	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, unspecified trimester.
O86.00	Infection of obstetric surgical wound, unspecified.
O86.01	Infection of obstetric surgical wound, superficial incisional site.
O86.02	Infection of obstetric surgical wound, deep incisional site.
O86.03	Infection of obstetric surgical wound, organ and space site.
O86.04	Sepsis following an obstetrical procedure.
O86.09	Infection of obstetric surgical wound, other surgical site.

In addition, as discussed in section II.F.15. of the preamble of the proposed rule, Table 6C.—Invalid Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the diagnosis codes that will no longer be effective as of October 1, 2018. Included in this table are two ICD–10–CM diagnosis codes currently listed on the Maternity Diagnoses Category edit code list: ICD–10–CM diagnosis codes F53 (Puerperal psychosis) and O86.0 (Infection of obstetric surgical wound). In the proposed rule, we proposed to remove these codes from the Maternity Diagnoses Category Edit code list. We also proposed to continue to include the other existing diagnosis codes currently listed under the Maternity Diagnoses Category edit code list.

Comment: Commenters agreed with the proposal to add the diagnosis codes listed in the table above to the Maternity Diagnoses Category edit code list. Commenters also agreed with the proposal to remove ICD–10–CM diagnosis codes F53 and O86.0 from the Maternity Diagnoses Category edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the table above to the Maternity Diagnoses Category edit code list and our proposal to remove ICD–10–CM diagnosis codes F53 and O86.0 from the Maternity Diagnoses Category edit code list. We also are finalizing our proposal to maintain the other existing codes on the Maternity Diagnoses Category edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

b. Sex Conflict Edit

In the MCE, the Sex Conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

(1) Diagnoses for Females Only Edit

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20231), we indicated that we received a request to consider the addition of the following ICD–10–CM diagnosis codes to the list for the Diagnoses for Females Only edit.

ICD–10–CM code	Code description
Z30.015	Encounter for initial prescription of vaginal ring hormonal contraceptive.
Z31.7	Encounter for procreative management and counseling for gestational carrier.
Z98.891	History of uterine scar from previous surgery.

The requestor noted that, currently, ICD–10–CM diagnosis code Z30.44 (Encounter for surveillance of vaginal ring hormonal contraceptive device) is on the Diagnoses for Females Only edit code list and suggested that ICD–10–CM diagnosis code Z30.015, which also describes an encounter involving a vaginal ring hormonal contraceptive, be added to the Diagnoses for Females Only edit code list as well. In addition, the requestor suggested that ICD–10–CM diagnosis codes Z31.7 and Z98.891 be added to the Diagnoses for Females Only edit code list.

We reviewed ICD–10–CM diagnosis codes Z30.015, Z31.7, and Z98.891, and we agreed with the requestor that it is clinically appropriate to add these three ICD–10–CM diagnosis codes to the Diagnoses for Females Only edit code list because the conditions described by these codes are specific to and consistent with the female sex.

In addition, as discussed in section II.F.15. of the preamble of the proposed rule, Table 6A.—New Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed

the new diagnosis codes that had been approved to date, which will be effective with discharges occurring on and after October 1, 2018. The following table lists the new diagnosis codes that are associated with conditions consistent with the female sex. We proposed to add these ICD–10–CM diagnosis codes to the Diagnoses for Females Only edit code list under the Sex Conflict edit.

ICD–10–CM code	Code description
F53.0	Postpartum depression.
F53.1	Puerperal psychosis.
N35.82	Other urethral stricture, female.
N35.92	Unspecified urethral stricture, female.
O30.131	Triplet pregnancy, trichorionic/triamniotic, first trimester.
O30.132	Triplet pregnancy, trichorionic/triamniotic, second trimester.
O30.133	Triplet pregnancy, trichorionic/triamniotic, third trimester.
O30.139	Triplet pregnancy, trichorionic/triamniotic, unspecified trimester.
O30.231	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, first trimester.
O30.232	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, second trimester.
O30.233	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, third trimester.
O30.239	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, unspecified trimester.
O30.831	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, first trimester.
O30.832	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, second trimester.
O30.833	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, third trimester.
O30.839	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, unspecified trimester.
O86.00	Infection of obstetric surgical wound, unspecified.
O86.01	Infection of obstetric surgical wound, superficial incisional site.
O86.02	Infection of obstetric surgical wound, deep incisional site.
O86.03	Infection of obstetric surgical wound, organ and space site.
O86.04	Sepsis following an obstetrical procedure.
O86.09	Infection of obstetric surgical wound, other surgical site.
Q51.20	Other doubling of uterus, unspecified.
Q51.21	Other complete doubling of uterus.
Q51.22	Other partial doubling of uterus.
Q51.28	Other doubling of uterus, other specified.
Z13.32	Encounter for screening for maternal depression.

Comment: Commenters supported the proposals to add ICD–10–CM diagnosis codes Z30.015, Z31.7 and Z98.891 and the ICD–10–CM diagnosis codes listed in the table above to the Diagnoses for Females Only edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposals to add ICD–10–CM diagnosis codes Z30.015, Z31.7 and Z98.891 and the ICD–10–CM diagnosis codes listed in the table above to the Diagnoses for Females Only edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

In addition, as discussed in section II.F.15. of the preamble of the proposed rule, Table 6C.—Invalid Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the diagnosis codes that are no longer effective as of October 1, 2018. Included in this table were the following three ICD–10–CM diagnosis codes currently listed on the Diagnoses for Females Only edit code list.

ICD–10–CM code	Code description
F53	Puerperal psychosis.
O86.0	Infection of obstetric surgical wound.
Q51.2	Other doubling of uterus, unspecified.

Because these three ICD–10–CM diagnosis codes will no longer be effective as of October 1, 2018, we proposed to remove them from the Diagnoses for Females Only edit code list under the Sex Conflict edit.

Comment: Commenters supported the proposal to remove ICD–10–CM diagnosis codes F53, O86.0, and Q51.2, from the Diagnoses for Females Only edit code list, as they are no longer valid effective October 1, 2018. One commenter also noted that there were typographical errors in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20232) for diagnosis codes O86.0 and Q51.2, where an extra zero was inadvertently included as a fifth digit.

Response: We appreciate the commenters' support. We agree with the commenter that there were typographical errors in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20232) for diagnosis codes O86.0 and Q51.2, where an extra zero was inadvertently included as a fifth digit, and have corrected these errors in the table presented in this final rule preamble.

After consideration of the public comments we received, we are finalizing our proposal to remove ICD–10–CM diagnosis codes F53, O86.0, and Q51.2, from the Diagnoses for Females Only edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

(2) Procedures for Females Only Edit

As discussed in section II.F.15. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule, Table 6B.—New Procedure Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the procedure codes that had been approved to date, which will be effective with discharges occurring on and after October 1, 2018. In the proposed rule, we proposed to add the three ICD–10–PCS procedure codes in the following table describing procedures associated with the female sex to the Procedures for Females Only edit code list.

ICD–10–PCS code	Code description
0UY90Z0	Transplantation of uterus, allogeneic, open approach.
0UY90Z1	Transplantation of uterus, syngeneic, open approach.
0UY90Z2	Transplantation of uterus, zooplastic, open approach.

We also proposed to continue to include the existing procedure codes currently listed under the Procedures for Females Only edit code list.

Comment: Commenters supported the proposal to add ICD–10–PCS procedure codes 0UY90Z0, 0UY90Z1 and 0UY90Z2 to the Procedures for Females Only edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 0UY90Z0, 0UY90Z1 and 0UY90Z2 to the Procedures for Females Only edit code list. We also are finalizing our proposal to maintain the existing list of codes on the Procedures for Females Only edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

(3) Diagnoses for Males Only Edit

As discussed in section II.F.15. of the preamble of the proposed rule, Table 6A.—New Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the new diagnosis codes that had been approved to date, which will be effective with discharges occurring on and after October 1, 2018. The following table lists the new diagnosis codes that are associated with conditions consistent with the male sex. In the proposed rule, we proposed to add these ICD–10–CM diagnosis codes to the Diagnoses for Males Only edit code list under the Sex Conflict edit.

ICD–10–CM code	Code description
N35.016	Post-traumatic urethral stricture, male, overlapping sites.
N35.116	Postinfective urethral stricture, not elsewhere classified, male, overlapping sites.
N35.811	Other urethral stricture, male, meatal.
N35.812	Other urethral bulbous stricture, male.
N35.813	Other membranous urethral stricture, male.
N35.814	Other anterior urethral stricture, male, anterior.
N35.816	Other urethral stricture, male, overlapping sites.
N35.819	Other urethral stricture, male, unspecified site.
N35.911	Unspecified urethral stricture, male, meatal.
N35.912	Unspecified bulbous urethral stricture, male.
N35.913	Unspecified membranous urethral stricture, male.
N35.914	Unspecified anterior urethral stricture, male.
N35.916	Unspecified urethral stricture, male, overlapping sites.
N35.919	Unspecified urethral stricture, male, unspecified site.
N99.116	Postprocedural urethral stricture, male, overlapping sites.
R93.811	Abnormal radiologic findings on diagnostic imaging of right testicle.
R93.812	Abnormal radiologic findings on diagnostic imaging of left testicle.
R93.813	Abnormal radiologic findings on diagnostic imaging of testicles, bilateral.
R93.819	Abnormal radiologic findings on diagnostic imaging of unspecified testicle.

We also proposed to continue to include the existing diagnosis codes currently listed under the Diagnoses for Males Only edit code list.

Comment: Commenters supported the proposal to add the ICD–10–CM diagnosis codes listed in the table above to the Diagnoses for Males Only edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the ICD–10–CM diagnosis codes listed in the table above to the Diagnoses for Males Only edit code list. We also are finalizing our proposal to maintain the existing list of codes on the Diagnoses for Males Only edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

c. Manifestation Code as Principal Diagnosis Edit

In the ICD–10–CM classification system, manifestation codes describe the manifestation of an underlying disease, not the disease itself and, therefore, should not be used as a principal diagnosis.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20232), we noted that, as discussed in section II.F.15. of the preamble of the proposed rule, Table 6A.—New Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the new diagnosis codes that had been approved to date which will be effective with discharges

occurring on and after October 1, 2018. Included in this table are ICD–10–CM diagnosis codes K82.A1 (Gangrene of gallbladder in cholecystitis) and K82.A2 (Perforation of gallbladder in cholecystitis). We proposed to add these two ICD–10–CM diagnosis codes to the Manifestation Code as Principal Diagnosis edit code list because the type of cholecystitis would be required to be reported first. We also proposed to continue to include the existing diagnosis codes currently listed under the Manifestation Code as Principal Diagnosis edit code list. We invited public comments on our proposals.

Comment: Commenters supported the proposal to add ICD–10–CM diagnosis codes K82.A1 and K82.A2 to the Manifestation Code as Principal Diagnosis edit code list and to continue to include the existing diagnosis codes currently listed under the Manifestation Code as Principal Diagnosis edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–CM diagnosis codes K82.A1 and K82.A2 to the Manifestation Code as Principal Diagnosis edit code list and to continue to include the existing diagnosis codes currently listed under the Manifestation Code as Principal Diagnosis edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

d. Questionable Admission Edit

In the MCE, some diagnoses are not usually sufficient justification for admission to an acute care hospital. For example, if a patient is assigned ICD–10–CM diagnosis code R03.0 (Elevated blood pressure reading, without diagnosis of hypertension), the patient would have a questionable admission because an elevated blood pressure reading is not normally sufficient justification for admission to a hospital.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20233), we noted that, as discussed in section II.F.10. of the preamble of the proposed rule, we were proposing several modifications to the MS–DRGs under MDC 14 (Pregnancy, Childbirth and the Puerperium). We stated in the proposed rule that one aspect of these proposed modifications involves the GROUPER logic for the cesarean section and vaginal delivery MS–DRGs. We referred readers to section II.F.10. of the preamble of the proposed rule for a detailed discussion of the proposals regarding these MS–DRG modifications under MDC 14 and the relation to the MCE.

If a patient presents to the hospital and either a cesarean section or a vaginal delivery occurs, it is expected that, in addition to the specific type of delivery code, an outcome of delivery code is also assigned and reported on the claim. The outcome of delivery codes are ICD–10–CM diagnosis codes that are to be reported as secondary diagnoses as instructed in Section I.C.15.b.5 of the ICD–10–CM Official Guidelines for Coding and Reporting which states: ''A code from category Z37, Outcome of delivery, should be included on every maternal record when a delivery has occurred. These codes are not to be used on subsequent records or on the newborn record.'' Therefore, to encourage accurate coding and appropriate MS–DRG assignment in alignment with the proposed modifications to the delivery MS–DRGs, we proposed to create a new ''Questionable Obstetric Admission Edit'' under the Questionable Admission edit to read as follows:

''b. Questionable obstetric admission

ICD–10–PCS procedure codes describing a cesarean section or vaginal delivery are considered to be a questionable admission *except* when reported with a corresponding secondary diagnosis code describing the outcome of delivery.

Procedure code list for cesarean section

10D00Z0 Extraction of Products of Conception, High, Open Approach
10D00Z1 Extraction of Products of Conception, Low, Open Approach
10D00Z2 Extraction of Products of Conception, Extraperitoneal, Open Approach

Procedure code list for vaginal delivery

10D07Z3 Extraction of Products of Conception, Low Forceps, Via Natural or Artificial Opening
10D07Z4 Extraction of Products of Conception, Mid Forceps, Via Natural or Artificial Opening
10D07Z5 Extraction of Products of Conception, High Forceps, Via Natural or Artificial Opening
10D07Z6 Extraction of Products of Conception, Vacuum, Via Natural or Artificial Opening
10D07Z7 Extraction of Products of Conception, Internal Version, Via Natural or Artificial Opening
10D07Z8 Extraction of Products of Conception, Other, Via Natural or Artificial Opening
10D17Z9 Manual Extraction of Products of Conception, Retained, Via Natural or Artificial Opening
10D18Z9 Manual Extraction of Products of Conception, Retained, Via Natural or Artificial Opening Endoscopic
10E0XZZ Delivery of Products of Conception, External Approach

Secondary diagnosis code list for outcome of delivery

Z37.0 Single live birth
Z37.1 Single stillbirth
Z37.2 Twins, both liveborn
Z37.3 Twins, one liveborn and one stillborn
Z37.4 Twins, both stillborn
Z37.50 Multiple births, unspecified, all liveborn
Z37.51 Triplets, all liveborn
Z37.52 Quadruplets, all liveborn
Z37.53 Quintuplets, all liveborn
Z37.54 Sextuplets, all liveborn
Z37.59 Other multiple births, all liveborn
Z37.60 Multiple births, unspecified, some liveborn
Z37.61 Triplets, some liveborn
Z37.62 Quadruplets, some liveborn
Z37.63 Quintuplets, some liveborn
Z37.64 Sextuplets, some liveborn
Z37.69 Other multiple births, some liveborn
Z37.7 Other multiple births, all stillborn
Z37.9 Outcome of delivery, unspecified''

We proposed that the three ICD–10–PCS procedure codes listed in the following table would be used to establish the list of codes for the proposed Questionable Obstetric Admission edit logic for cesarean section.

ICD–10–PCS Procedure Codes for Cesarean Section Under the Proposed Questionable Obstetric Admission Edit Code List in the MCE

ICD–10–PCS code	Code description
10D00Z0	Extraction of products of conception, high, open approach.
10D00Z1	Extraction of products of conception, low, open approach.
10D00Z2	Extraction of products of conception, extraperitoneal, open approach.

We proposed that the nine ICD–10–PCS procedure codes listed in the following table would be used to establish the list of codes for the proposed new Questionable Obstetric

Admission edit logic for vaginal delivery.

ICD–10–PCS PROCEDURE CODES FOR VAGINAL DELIVERY UNDER THE PROPOSED QUESTIONABLE OBSTETRIC ADMISSION EDIT CODE LIST IN THE MCE

ICD–10–PCS code	Code description
10D07Z3	Extraction of products of conception, low forceps, via natural or artificial opening.
10D07Z4	Extraction of products of conception, mid forceps, via natural or artificial opening.
10D07Z5	Extraction of products of conception, high forceps, via natural or artificial opening.
10D07Z6	Extraction of products of conception, vacuum, via natural or artificial opening.
10D07Z7	Extraction of products of conception, internal version, via natural or artificial opening.
10D07Z8	Extraction of products of conception, other, via natural or artificial opening.
10D17Z9	Manual extraction of products of conception, retained, via natural or artificial opening.
10D18Z9	Manual extraction of products of conception, retained, via natural or artificial opening.
10E0XZZ	Delivery of products of conception, external approach.

We proposed that the 19 ICD–10–CM diagnosis codes listed in the following table would be used to establish the list of secondary diagnosis codes for the proposed new Questionable Obstetric Admission edit logic for outcome of delivery.

ICD–10–CM SECONDARY DIAGNOSIS CODES FOR OUTCOME OF DELIVERY UNDER THE PROPOSED QUESTIONABLE OBSTETRIC ADMISSION EDIT CODE LIST IN THE MCE

ICD–10–CM code	Code description
Z37.0	Single live birth.
Z37.1	Single stillbirth.
Z37.2	Twins, both liveborn.
Z37.3	Twins, one liveborn and one stillborn.
Z37.4	Twins, both stillborn.
Z37.50	Multiple births, unspecified, all liveborn.
Z37.51	Triplets, all liveborn.
Z37.52	Quadruplets, all liveborn.
Z37.53	Quintuplets, all liveborn.
Z37.54	Sextuplets, all liveborn.
Z37.59	Other multiple births, all liveborn.
Z37.60	Multiple births, unspecified, some liveborn.
Z37.61	Triplets, some liveborn.
Z37.62	Quadruplets, some liveborn.
Z37.63	Quintuplets, some liveborn.
Z37.64	Sextuplets, some liveborn.
Z37.69	Other multiple births, some liveborn.
Z37.7	Other multiple births, all liveborn.
Z37.9	Outcome of delivery, unspecified.

Comment: Commenters supported creating the new Questionable Obstetric Admission edit. Commenters also supported the list of diagnoses and procedure codes that we proposed to include for the proposed new edit. However, a few commenters expressed concern with several of the procedure codes that were proposed for inclusion under the vaginal delivery procedure code list. Specifically, the commenters identified that ICD–10–PCS procedure codes 10D17Z9 and 10D18Z9 may be reported for other clinical indications, in the absence of an outcome of delivery diagnosis code. Therefore, the commenter stated that the edit would be triggered erroneously for those case scenarios.

Response: We appreciate the commenters' support. We reviewed the procedure codes for which the commenters expressed concern under the vaginal delivery procedure code list (ICD–10–PCS procedure codes 10D17Z9 and 10D18Z9) and agree that there may be instances in which the procedure codes could be reported in the absence of an outcome of delivery diagnosis code. Therefore, we believe it is appropriate to remove these two procedure codes from the vaginal delivery procedure code list for the edit. In addition, we reviewed ICD–10–PCS procedure codes 10D07Z6 and 10D07Z8 and believe the procedures could potentially be performed for other clinical indications, in the absence of an outcome of delivery code, and erroneously trigger the proposed edit if reported.

After consideration of the public comments we received, we are finalizing our proposal to create the new Questionable Obstetric Admission edit. We also are finalizing our proposal to include ICD–10–PCS procedure codes 10D00Z0, 10D00Z1, and 10D00Z2 listed above for the ''Procedure code list for cesarean section'' portion of the edit. We are finalizing our proposal to include the procedure codes listed above for vaginal delivery with modifications. Specifically, we are not including ICD–10–PCS procedure codes 10D07Z6, 10D07Z87, 10D17Z9 and 10D18Z9 in the ''Procedure code list for vaginal delivery'' portion of the edit and finalizing the inclusion of the remaining

procedure codes listed above. In addition, we are finalizing our proposal to include the diagnosis codes listed above under the ''Secondary diagnosis code list for outcome of delivery'' portion of the edit. We are finalizing these changes as described above under the ICD–10 MCE Version 36, effective October 1, 2018.

e. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status, but does not actually describe a current illness or injury. There also are codes that are not specific manifestations, but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20234), we noted that, as discussed in section II.F.9. of the preamble of the proposed rule, ICD–10–CM diagnosis codes Z49.02 (Encounter for fitting and adjustment of peritoneal dialysis catheter), Z49.31 (Encounter for adequacy testing for hemodialysis), and Z49.32 (Encounter for adequacy testing for peritoneal dialysis) are currently on the Unacceptable Principal Diagnosis edit code list. We proposed to add diagnosis code Z49.01 (Encounter for fitting and adjustment of extracorporeal dialysis catheter) to the Unacceptable Principal Diagnosis edit code list because this is an encounter code that would more likely be performed in an outpatient setting.

Comment: Some commenters supported the proposal to add ICD–10–CM diagnosis code Z49.01 to the Unacceptable Principal Diagnosis edit code list. However, some commenters recommended that CMS reconsider the proposal. These commenters did not dispute the fact that this code is more likely to be reported in the outpatient setting. However, they stated that the proposal to add it to the edit appeared to conflict with the proposal that was discussed in section II.F.9. for MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) and MS–DRG 685 (Admit for Renal Dialysis). According to the commenters, CMS proposed to only reassign diagnosis code Z49.01 as a principal diagnosis in the proposal to delete MS–DRG 685 and reassign diagnosis code Z49.01 to MS–DRGs 698, 699 and 700.

Response: We appreciate the commenters' support. With regard to the commenters who recommended that we reconsider the proposal to add diagnosis code Z49.01 to the Unacceptable Principal Diagnoses edit code list, we believe there is some confusion with respect to the proposal that was discussed in section II.F.9. of the preamble of the proposed rule. The proposal was to reassign diagnosis codes Z49.01, Z49.02, Z49.31 and Z49.32 to MS–DRGs 698, 699 and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC and without CC/MCC, respectively) with the proposed deletion of MS–DRG 685. We are unable to determine what aspect of the proposal that was discussed in section II.F. 9. of the preamble of the proposed rule was unclear. For example, it is not clear if the commenters' confusion relates to the GROUPER logic for MS–DRGs 698, 699, and 700 as shown in the ICD–10 MS–DRG Definitions Manual. As discussed elsewhere in this final rule, in the ICD–10 MS–DRG Definitions Manual, diagnosis codes listed under the heading of ''Principal Diagnosis'' may appear to indicate that those codes are to be reported as a principal diagnosis for assignment to the respective MS–DRG. However, the Definitions Manual display of the GROUPER logic assignment for each diagnosis code is for grouping purposes only and does not correspond to coding guidelines for reporting the principal diagnosis. In other words, cases will group according to the GROUPER logic, regardless of any coding guidelines or coverage policies. It is the MCE and other payer-specific edits that identify inconsistencies in the coding guidelines or coverage policies.

We also noted in the proposed rule that, as discussed in section II.F.15. of the preamble of the proposed rule, Table 6C.—Invalid Diagnosis Codes associated with the proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) listed the diagnosis codes that will no longer be effective as of October 1, 2018. As previously noted, included in this table is an ICD–10–CM diagnosis code Z13.4 (Encounter for screening for certain developmental disorders in childhood) which is currently listed on the Unacceptable Principal Diagnoses edit code list. We proposed to remove this code from the Unacceptable Principal Diagnosis edit code list.

We also proposed to continue to include the other existing diagnosis codes currently listed under the Unacceptable Principal Diagnosis edit code list.

Comment: Commenters supported the proposal to remove ICD–10–CM diagnosis code Z13.4 from the Unacceptable Principal diagnoses category edit code list because it will be an invalid code effective October 1, 2018.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–CM diagnosis code Z49.01 to the Unacceptable Principal Diagnosis edit code list. We also are finalizing our proposal to remove ICD–10–CM diagnosis code Z13.4 from the Unacceptable Principal Diagnosis edit code list. In addition, we are finalizing our proposal to maintain the other existing codes on the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 36, effective October 1, 2018.

Comment: One commenter requested that CMS review a coverage edit in the MCE manual and software. According to the commenter, CMS began covering multiple myeloma on January 1, 2016 under the condition of coverage with evidence development (CED) as shown in guidance located at: *https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-MM.html*. The commenter noted that the applicable procedure codes along with diagnosis codes C90.00 (Multiple myeloma not having achieved remission) and C90.01 (Multiple myeloma in remission) are listed as ''non-covered'' in the MCE manual and encouraged CMS to review further and make any necessary updates as needed to ensure claims are processed appropriately.

Response: We thank the commenter for bringing this to our attention. Upon review, guidance was issued on January 27, 2016 for allogeneic hematopoietic stem cell transplant (HSCT) for certain Medicare beneficiaries with multiple myeloma under CED. This guidance is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/allo-MM.html*. We agree with the commenter and, therefore, are removing the following noncovered procedure edit from the ICD–10 MCE Version 36 manual, effective October 1, 2018:

''*E. Non-covered procedure codes*

The procedures shown below are identified as non-covered procedures only when any code from the diagnoses list shown below is present as either a principal or secondary diagnosis.

Procedures

30230G2 Transfuse Allo Rel Bone Marrow in Periph Vein, Open
30230G3 Transfuse Allo Unr Bone Marrow in Periph Vein, Open
30230G4 Transfuse Allo Unsp Bone Marrow in Periph Vein, Open
30230Y2 Transfuse Allo Rel Hemat Stem Cell in Periph Vein, Open
30230Y3 Transfuse Allo Unr Hemat Stem Cell in Periph Vein, Open
30230Y4 Transfuse Allo Unsp Hemat Stem Cell in Periph Vein, Open
30233G2 Transfuse Allo Rel Bone Marrow in Periph Vein, Perc
30233G3 Transfuse Allo Unr Bone Marrow in Periph Vein, Perc
30233G4 Transfuse Allo Unsp Bone Marrow in Periph Vein, Perc
30233Y2 Transfuse Allo Rel Hemat Stem Cell in Periph Vein, Per
30233Y3 Transfuse Allo Unr Hemat Stem Cell in Periph Vein, Perc
30233Y4 Transfuse Allo Unsp Hemat Stem Cell in Periph Vein, Perc
30240G2 Transfuse Allo Rel Bone Marrow in Central Vein, Open
30240G3 Transfuse Allo Unr Bone Marrow in Central Vein, Open
30240G4 Transfuse Allo Unsp Bone Marrow in Central Vein, Open
30240Y2 Transfuse Allo Rel Hemat Stem Cell in Central Vein, Open
30240Y3 Transfuse Allo Unr Hemat Stem Cell in Central Vein, Open
30240Y4 Transfuse Allo Unsp Hemat Stem Cell in Central Vein, Open
30243G2 Transfuse Allo Rel Bone Marrow in Central Vein, Perc
30243G3 Transfuse Allo Unr Bone Marrow in Central Vein, Perc
30243G4 Transfuse Allo Unsp Bone Marrow in Central Vein, Perc
30243Y2 Transfuse Allo Rel Hemat Stem Cell in Central Vein, Perc
30243Y3 Transfuse Allo Unr Hemat Stem Cell in Central Vein, Perc
30243Y4 Transfuse Allo Unsp Hemat Stem Cell in Central Vein, Perc
30250G1 Transfuse Nonaut Bone Marrow in Periph Art, Open
30250Y1 Transfuse Nonaut Hemat Stem Cell in Periph Art, Open
30253G1 Transfuse Nonaut Bone Marrow in Periph Art, Perc
30253Y1 Transfuse Nonaut Hemat Stem Cell in Periph Art, Perc
30260G1 Transfuse Nonaut Bone Marrow in Central Art, Open
30260Y1 Transfuse Nonaut Hemat Stem Cell in Central Art, Open
30263G1 Transfuse Nonaut Bone Marrow in Central Art, Perc
30263Y1 Transfuse Nonaut Hemat Stem Cell in Central Art, Perc

Diagnoses

C9000 Multiple myeloma not having achieved remission
C9001 Multiple myeloma in remission''

This update will also be reflected in the ICD–10 MCE software Version 36 effective October 1, 2018.

f. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054), we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment, and analysis aspects. We have engaged a contractor to assist in the review of the limited coverage and noncovered procedure edits in the MCE that may also be present in other claims processing systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what are already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE.

We have noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235), we indicated that we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we discussed in the FY 2018 IPPS/LTCH PPS final rule, we recognize a need to further examine the current list of edits and the definitions of those edits. We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2018 for FY 2020.

14. Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this final rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in

cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we proposed to make in the FY 2019 IPPS/LTCH PPS proposed rule, as discussed in section II.F.10. of the preamble of this final rule, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235), we proposed to revise the surgical hierarchy for MDC 14 (Pregnancy, Childbirth & the Puerperium) as follows: In MDC 14, we proposed to delete MS–DRGs 765 and 766 (Cesarean Section with and without CC/MCC, respectively) and MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C) from the surgical hierarchy. We proposed to sequence proposed new MS–DRGs 783, 784, and 785 (Cesarean Section with Sterilization with MCC, with CC and without CC/MCC, respectively) above proposed new MS–DRGs 786, 787, and 788 (Cesarean Section without Sterilization with MCC, with CC and without CC/MCC, respectively). We proposed to sequence proposed new MS–DRGs 786, 787, and 788 (Cesarean Section without Sterilization with MCC, with CC and without CC/MCC, respectively) above MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C). We also proposed to sequence proposed new MS–DRGs 796, 797, and 798 (Vaginal Delivery with Sterilization/D&C with MCC, with CC and without CC/MCC, respectively) below MS–DRG 768 and above MS–DRG 770 (Abortion with D&C, Aspiration Curettage or Hysterotomy). Finally, we proposed to sequence proposed new MS–DRGs 817, 818, and 819 (Other Antepartum Diagnoses with O.R. procedure with MCC, with CC and without CC/MCC, respectively) below MS–DRG 770 and above MS–DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure). Our proposals for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 36 are illustrated in the following table.

PROPOSED SURGICAL HIERARCHY: MDC 14

[Pregnancy, childbirth and the puerperium]

Proposed New MS–DRGs 783–785	Cesarean Section with Sterilization.
Proposed New MS–DRGs 786–788	Cesarean Section without Sterilization.
MS–DRG 768	Vaginal Delivery with O.R. Procedures.
Proposed New MS–DRGs 796–798	Vaginal Delivery with Sterilization/D&C.
MS–DRG 770	Abortion with D&C, Aspiration Curettage or Hysterotomy.
Proposed New MS–DRGs 817–819	Other Antepartum Diagnoses with O.R. Procedure.
MS–DRG 769	Postpartum and Post Abortion Diagnoses with O.R. Procedure.

Comment: Commenters supported the proposed additions, deletions, and sequencing for the surgical hierarchy under MDC 14.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposed changes to Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 36 as illustrated in the table above effective October 1, 2018.

As with other MS–DRG related issues, we encourage commenters to submit requests to examine ICD–10 claims pertaining to the surgical hierarchy via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2018 for FY 2020 consideration.

15. Changes to the MS–DRG Diagnosis Codes for FY 2019

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2019

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20236), we indicated that the following tables identifying the proposed additions and deletions to the MCC severity levels list and the proposed additions and deletions to the CC severity levels list for FY 2019 were available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Table 6I.1—Proposed Additions to the MCC List—FY 2019;

Table 6I.2—Proposed Deletions to the MCC List—FY 2019;

Table 6J.1—Proposed Additions to the CC List—FY 2019; and

Table 6J.2—Proposed Deletions to the CC List—FY 2019.

We invited public comments on our proposed severity level designations for the diagnosis codes listed in Table 6I.1. and Table 6J.1. We noted that, for Table 6I.2. and Table 6J.2., the proposed deletions are a result of code expansions, with the exception of diagnosis codes B20 and J80, which are the result of proposed severity level designation changes. Therefore, the diagnosis codes on these lists will no longer be valid codes, effective FY 2019.

We referred readers to the Tables 6I.1, 6I.2, 6J.1, and 6J.2 associated with the proposed rule, which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Comment: Commenters supported the proposed additions and deletions for the diagnosis codes, and their corresponding severity level designations that were listed in Tables 6I.1, 6I.2, 6J.1, and 6J.2. associated with the FY 2019 IPPS/LTCH PPS proposed rule. However, a few commenters expressed concern with the proposed severity level designation change to diagnosis code B20, and recommended CMS conduct further analysis prior to finalizing any proposals.

Response: We appreciate the commenters' support. We refer readers to section II.F.16.b. of the preamble of this final rule for the detailed discussion of public comments related to the proposals and final statement of policy involving diagnosis codes B20 and J80.

Comment: One commenter disagreed with CMS' proposal to designate diagnosis codes K35.20 (Acute appendicitis with generalized peritonitis, without abscess) and T81.44XA (Sepsis following a procedure, initial encounter) as CC severity levels, and recommended CMS reconsider the conditions and classify the severity levels as MCCs. The commenter noted that the predecessor code for diagnosis code K35.20 is diagnosis code K35.2 (Acute appendicitis with generalized peritonitis), which is classified as a MCC severity level designation. Therefore, the commenter also believed that diagnosis code K35.20 should be designated as a MCC severity level. Additionally, the commenter stated that diagnosis code T81.44XA should be classified as an MCC severity level because sepsis is defined as a life-threatening organ dysfunction caused by a host response to infection.

Response: While we acknowledge that our process in assigning a severity level designation for a diagnosis code generally begins with identifying the designation of the predecessor code assignment, we believe that any new or revised clinical concepts included in the new diagnosis codes should also be considered when making a severity level designation. We reviewed diagnosis codes K35.20 and T81.44XA and our clinical advisors continue to support the CC severity level designation of these diagnosis codes. The commenter is correct that, effective October 1, 2018, diagnosis code K35.20 has been expanded from the current diagnosis code K35.2. However, we also note that, effective October 1, 2018, diagnosis code K35.2 has been expanded to create new diagnosis code K35.21 (Acute appendicitis with generalized peritonitis, with abscess). In addition, effective October 1, 2018, diagnosis code K35.3 (Acute appendicitis with localized peritonitis) has been expanded to create new diagnosis codes K35.30 (Acute appendicitis with localized peritonitis, without perforation or gangrene), K35.31 (Acute appendicitis with localized peritonitis and gangrene, without perforation), K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) and K35.33 (Acute appendicitis with perforation and localized peritonitis, with abscess). Consistent with our usual process, in reviewing all of these newly expanded conditions, our clinical advisors considered the additional clinical concepts now included with each diagnosis code in evaluating the appropriate proposed severity level assignments. Our clinical advisors believed that the new diagnosis codes for acute appendicitis described as ''with abscess'' or ''with perforation'' were clinically qualified for the MCC severity level designation, while acute appendicitis ''without abscess'' or ''without perforation'' were clinically qualified for the CC severity level designation because cases with abscess or perforation would be expected to require more clinical resources and time to treat while those cases ''without abscess'' or ''without perforation'' are not as severe clinical conditions. As such, we disagree with the commenter that, based on the designation of its predecessor code alone, diagnosis code K35.20 should be designated as an MCC severity level instead of a CC for FY 2019. With regard to diagnosis code T81.44XA, our clinical advisors maintain that a CC severity level designation is most appropriate because the new code is clinically consistent with the predecessor code, T81.4XXA (Infection following a procedure, initial encounter), which also has a CC severity level designation. Currently, under Version 35 of the ICD–10 MS–DRGs, diagnosis code T81.4XXA contains several inclusion terms (conditions for which the code may be reported), one of which is ''sepsis following a procedure''. Our clinical advisors do not believe that the creation of a unique diagnosis code to specifically identify this condition within the classification introduces a new clinical concept requiring a higher level of resources. The new diagnosis code provides additional detail as to the *type* of infection following a procedure. However, it is considered to be clinically similar to the current diagnosis code describing an infection following a procedure. We also note that an additional five new diagnosis codes describing infections of varying degrees following a procedure were created for FY 2019 based on the other inclusion terms that currently exist at diagnosis code T81.4XXA.

As shown in the table below and in Table 6J.1. associated with the proposed rule, a total of six new diagnosis codes were proposed to be designated at the CC severity level based on review of the predecessor code (T81.4XXA), clinical coherence, and resource considerations.

ICD–10–CM code	Code description
T81.40XA	Infection following a procedure, unspecified, initial encounter.
T81.41XA	Infection following a procedure, superficial incisional surgical site, initial encounter.
T81.42XA	Infection following a procedure, deep incisional surgical site, initial encounter.
T81.43XA	Infection following a procedure, organ and space surgical site, initial encounter.
T81.44XA	Sepsis following a procedure, initial encounter.
T81.49XA	Infection following a procedure, other surgical site, initial encounter.

Therefore, for the reasons discussed above, our clinical advisors continue to support the proposed CC severity level designation for diagnosis code T81.44XA for FY 2019.

In addition, because these diagnosis codes identified by the commenter are new, we do not have any claims data for further analysis. Once we have additional claims data to allow us to conduct further review, we can continue to examine these conditions to determine if their impact on resource use is equal to or above the expected value of a CC severity level designation.

After consideration of the public comments we received, we are finalizing our proposal to designate diagnosis codes K35.20 and T81.44XA as CC severity levels. We also are finalizing our other proposed additions and deletions with their corresponding severity level designations for FY 2019. We refer readers to Tables 6I.1., 6I.2, 6J.1, and 6J.2. associated with this final rule, which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

c. Principal Diagnosis Is Its Own CC or MCC

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38060), we provided the public with notice of our plans to conduct a comprehensive review of the CC and MCC lists for FY 2019. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38056 through 38057), we also finalized our proposal to maintain the existing lists of principal diagnosis codes in Table 6L.—Principal Diagnosis Is Its Own MCC List and Table 6M.—Principal Diagnosis Is Its Own CC List for FY 2018, without any changes to the existing lists, noting our plans to conduct a comprehensive review of the CC and MCC lists for FY 2019 (82 FR 38060). We stated that having multiple lists for CC and MCC diagnoses when reported as a principal and/or secondary diagnosis may not provide an accurate representation of resource utilization for the MS–DRGs.

We also stated that the purpose of the Principal Diagnosis Is Its Own CC or MCC Lists was to ensure consistent MS–DRG assignment between the ICD–9–CM and ICD–10 MS–DRGs. The Principal Diagnosis Is Its Own CC or MCC Lists were developed for the FY 2016 implementation of the ICD–10 version of the MS–DRGs to facilitate replication of the ICD–9–CM MS–DRGs. As part of our efforts to replicate the ICD–9–CM MS–DRGs, we implemented logic that may have increased the complexity of the MS–DRG assignment hierarchy and altered the format of the ICD–10 MS–DRG Definitions Manual. Two examples of workarounds used to facilitate replication are the proliferation of procedure clusters in the surgical MS–DRGs and the creation of the Principal Diagnosis Is Its Own CC or MCC Lists special logic.

The following paragraph was added to the Version 33 ICD–10 MS–DRG Definitions Manual to explain the use of the Principal Diagnosis Is Its Own CC or MCC Lists: ''A few ICD–10–CM diagnosis codes express conditions that are normally coded in ICD–9–CM using two or more ICD–9–CM diagnosis codes. In the interest of ensuring that the ICD–10 MS–DRGs Version 33 places a patient in the same DRG regardless whether the patient record were to be coded in ICD–9–CM or ICD–10–CM/PCS, whenever one of these ICD–10–CM combination codes is used as principal diagnosis, the cluster of ICD–9–CM codes that would be coded on an ICD–9–CM record is considered. If one of the ICD–9–CM codes in the cluster is a CC or MCC, then the single ICD–10–CM combination code used as a principal diagnosis must also imply the CC or MCC that the ICD–9–CM cluster would have presented. The ICD–10–CM diagnoses for which this implication must be made are listed here.'' Versions 34 and 35 of the ICD–10 MS–DRG Definitions Manual also include this special logic for the MS–DRGs.

The Principal Diagnosis Is Its Own CC or MCC Lists were developed in the absence of ICD–10 coded data by mapping the ICD–9–CM diagnosis codes to the new ICD–10–CM combination codes. CMS has historically used clinical judgment combined with data analysis to assign a principal diagnosis describing a complex or severe condition to the appropriate DRG or MS–DRG. The initial ICD–10 version of the MS–DRGs replicated from the ICD–9 version can now be evaluated using clinical judgment combined with ICD–10 coded data because it is no longer necessary to replicate MS–DRG assignment across the ICD–9 and ICD–10 versions of the MS–DRGs for purposes of calculating relative weights. Now that ICD–10 coded data are available, in addition to using the data for calculating relative weights, ICD–10 data can be used to evaluate the effectiveness of the special logic for assigning a severity level to a principal diagnosis, as an indicator of resource utilization. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20237), to evaluate the effectiveness of the special logic, we conducted analysis of the ICD–10 coded data combined with clinical review to determine whether to propose to keep the special logic for assigning a severity level to a principal diagnosis, or to propose to remove the special logic and use other available means of assigning a complex principal diagnosis to the appropriate MS–DRG.

In the proposed rule, using claims data from the September 2017 update of the FY 2017 MedPAR file, we employed the following method to determine the impact of removing the special logic used in the current Version 35 GROUPER to process claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists. Edits and cost estimations used for relative weight calculations were applied, resulting in 9,070,073 IPPS claims analyzed for this special logic impact evaluation. We refer readers to section II.G. of the preamble of this final rule for further information regarding the methodology for calculation of the relative weights.

First, we identified the number of cases potentially impacted by the special logic. We identified 310,184 cases reporting a principal diagnosis on the Principal Diagnosis Is Its Own CC or MCC lists. Of the 310,184 total cases that reported a principal diagnosis code on the Principal Diagnosis Is Its Own CC or MCC Lists, 204,749 cases also reported a secondary diagnosis code at the same severity level or higher severity level, and therefore the special logic had no impact on MS–DRG assignment. However, of the 310,184 total cases, there were 105,435 cases that did not report a secondary diagnosis code at the same severity level or higher severity level, and therefore the special logic could potentially impact MS–DRG assignment, depending on the specific severity leveling structure of the base DRG.

Next, we removed the special logic in the GROUPER that is used for processing claims reporting a principal diagnosis on the Principal Diagnosis Is Its Own CC or MCC Lists, thereby creating a Modified Version 35 GROUPER. Using this Modified Version 35 GROUPER, we reprocessed the 105,435 claims for which the principal diagnosis code was the sole source of a MCC or CC on the case, to obtain data for comparison showing the effect of removing the special logic.

After removing the special logic in the Version 35 GROUPER for processing claims containing diagnosis codes on the Principal Diagnosis Is Its Own CC or MCC Lists, and reprocessing the claims using the Modified Version 35 GROUPER software, we found that 18,596 (6 percent) of the 310,184 cases reporting a principal diagnosis on the Principal Diagnosis Is Its Own CC or MCC Lists resulted in a different MS–

DRG assignment. Overall, the number of claims impacted by removal of the special logic (18,596) represents 0.2 percent of the 9,070,073 IPPS claims analyzed.

Below we provide a summary of the steps that we followed for the analysis performed.

Step 1. We analyzed 9,070,073 claims to determine the number of cases impacted by the special logic.

WITH SPECIAL LOGIC—9,070,073 CLAIMS ANALYZED

Number of cases reporting a principal diagnosis from the Principal Diagnosis Is Its Own CC/MCC lists (special logic)	310,184
Number of cases reporting an additional CC/MCC secondary diagnosis code at or above the level of the designated severity level of the principal diagnosis	204,749
Number of cases not reporting an additional CC/MCC secondary diagnosis code	105,435

Step 2. We removed special logic from GROUPER and created a modified GROUPER.

Step 3. We reprocessed 105,435 claims with modified GROUPER.

WITHOUT SPECIAL LOGIC—105,435 CLAIMS ANALYZED

Number of cases reporting a principal diagnosis from the Principal Diagnosis Is Its Own CC/MCC lists	310,184
Number of cases resulting in different MS–DRG assignment	18,596

To estimate the overall financial impact of removing the special logic from the GROUPER, we calculated the aggregate change in estimated payment for the MS–DRGs by comparing average costs for each MS–DRG affected by the change, before and after removing the special logic. Before removing the special logic in the Version 35 GROUPER, the cases impacted by the special logic had an estimated average payment of $58 million above the average costs for all the MS–DRGs to which the claim was originally assigned. After removing the special logic in the Version 35 GROUPER, the 18,596 cases impacted by the special logic had an estimated average payment of $39 million below the average costs for the newly assigned MS–DRGs.

We performed regression analysis to compare the proportion of variance in the MS–DRGs with and without the special logic. The results of the regression analysis showed a slight decrease in variance when the logic was removed. While the decrease itself was not statistically significant (an R-squared of 36.2603 percent after the special logic was removed, compared with an R-squared of 36.2501 percent in the current version 35 GROUPER), we note that the proportion of variance across the MS–DRGs essentially stayed the same, and certainly did not increase, when the special logic was removed.

We further examined the 18,596 claims that were impacted by the special logic in the GROUPER for processing claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists. The 18,596 claims were analyzed by the principal diagnosis code and the MS–DRG assigned, resulting in 588 principal diagnosis and MS–DRG combinations or subsets. Of the 588 subsets of cases that utilized the special logic, 556 of the 588 subsets (95 percent) had fewer than 100 cases, 529 of the 588 subsets (90 percent) had fewer than 50 cases, and 489 of the 588 subsets (83 percent) had fewer than 25 cases.

We examined the 32 subsets of cases (5 percent of the 588 subsets) that utilized the special logic and had 100 or more cases. Of the 32 subsets of cases, 18 (56 percent) are similar in terms of average costs and length of stay to the MS–DRG assignment that results when the special logic is removed, and 14 of the 32 subsets of cases (44 percent) are similar in terms of average costs and length of stay to the MS–DRG assignment that results when the special logic is utilized.

The table below contains examples of four subsets of cases that utilize the special logic, comparing average length of stay and average costs between two MS–DRGs within a base DRG, corresponding to the MS–DRG assigned when the special logic is removed and the MS–DRG assigned when the special logic is utilized. All four subsets of cases involve the principal diagnosis code E11.52 (Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene). There are four subsets of cases in this example because the records involving the principal diagnosis code E11.52 are assigned to four different base DRGs, one medical MS–DRG and three surgical MS–DRGs, depending on the procedure code(s) reported on the claim. All subsets of cases contain more than 100 claims. In three of the four subsets, the cases are similar in terms of average length of stay and average costs to the MS–DRG assignment that results when the special logic is removed, and in one of the four subsets, the cases are similar in terms of average length of stay and average costs to the MS–DRG assignment that results when the special logic is utilized.

As shown in the following table, using ICD–10–CM diagnosis code E11.52 (Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene) as our example, the data findings show four different MS–DRG pairs for which code E11.52 was the principal diagnosis on the claim and where the special logic impacted MS–DRG assignment. For the first MS–DRG pair, we examined MS–DRGs 240 and 241 (Amputation for Circulatory System Disorders Except Upper Limb and Toe with CC and without CC/MCC, respectively). We found 436 cases reporting diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 5.5 days and average costs of $11,769. These 436 cases are assigned to MS–DRG 240 with the special logic utilized, and assigned to MS–DRG 241 with the special logic removed. The total number of cases reported in MS–DRG 240 was 7,675, with an average length of stay of 8.3 days and average costs of $17,876. The total number of cases reported in MS–DRG 241 was 778, with an average length of stay of 5.0 days and average costs of $10,882. The 436 cases are more similar to MS–DRG 241 in terms of length of stay and average cost and less similar to MS–DRG 240.

For the second MS–DRG pair, we examined MS–DRGs 256 and 257 (Upper Limb and Toe Amputation for Circulatory System Disorders with CC and without CC/MCC, respectively). We found 193 cases reporting ICD–10–CM

diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 4.2 days and average costs of $8,478. These 193 cases are assigned to MS–DRG 256 with the special logic utilized, and assigned to MS–DRG 257 with the special logic removed. The total number of cases reported in MS–DRG 256 was 2,251, with an average length of stay of 6.1 days and average costs of $11,987. The total number of cases reported in MS–DRG 257 was 115, with an average length of stay of 4.6 days and average costs of $7,794. These 193 cases are more similar to MS–DRG 257 in terms of average length of stay and average costs and less similar to MS–DRG 256.

For the third MS–DRG pair, we examined MS–DRGs 300 and 301 (Peripheral Vascular Disorders with CC and without CC/MCC, respectively). We found 185 cases reporting ICD–10–CM diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 3.6 days and average costs of $5,981. These 185 cases are assigned to MS–DRG 300 with the special logic utilized, and assigned to MS–DRG 301 with the special logic removed. The total number of cases reported in MS–DRG 300 was 29,327, with an average length of stay of 4.1 days and average costs of $7,272. The total number of cases reported in MS–DRG 301 was 9,611, with an average length of stay of 2.8 days and average costs of $5,263. These 185 cases are more similar to MS–DRG 301 in terms of average length of stay and average costs and less similar to MS–DRG 300.

For the fourth MS–DRG pair, we examined MS–DRGs 253 and 254 (Other Vascular Procedures with CC and without CC/MCC, respectively). We found 225 cases reporting diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 5.2 days and average costs of $17,901. These 225 cases are assigned to MS–DRG 253 with the special logic utilized, and assigned to MS–DRG 254 with the special logic removed. The total number of cases reported in MS–DRG 253 was 25,714, with an average length of stay of 5.4 days and average costs of $18,986. The total number of cases reported in MS–DRG 254 was 12,344, with an average length of stay of 2.8 days and average costs of $13,287. Unlike the previous three MS–DRG pairs, these 225 cases are more similar to MS–DRG 253 in terms of average length of stay and average costs and less similar to MS–DRG 254.

MS–DRG Pairs for Principal Diagnosis ICD–10–CM Code E11.52 With and Without Special MS–DRG Logic

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 240 and 241—Special logic impacted cases with ICD–10–CM code E11.52 as principal diagnosis	436	5.5	$11,769
MS–DRG 240—All cases	7,675	8.3	17,876
MS–DRG 241—All cases	778	5.0	10,882
MS–DRGs 253 and 254—Special logic impacted cases with ICD–10–CM E11.52 as principal diagnosis	225	5.2	17,901
MS–DRG 253—All cases	25,714	5.4	18,986
MS–DRG 254—All cases	12,344	2.8	13,287
MS–DRGs 256 and 257—Special logic impacted cases with ICD–10–CM E11.52 as principal diagnosis	193	4.2	8,478
MS–DRG 256—All cases	2,251	6.1	11,987
MS–DRG 257—All cases	115	4.6	7,794
MS–DRGs 300 and 301—Special logic impacted cases with ICD–10–CM E11.52 as principal diagnosis	185	3.6	5,981
MS–DRG 300—All cases	29,327	4.1	7,272
MS–DRG 301—All cases	9,611	2.8	5,263

Based on our analysis of the data, we stated that we believe that there may be more effective indicators of resource utilization than the Principal Diagnosis Is Its Own CC or MCC Lists and the special logic used to assign clinical severity to a principal diagnosis. As stated in the proposed rule and earlier in this discussion, it is no longer necessary to replicate MS–DRG assignment across the ICD–9 and ICD–10 versions of the MS–DRGs. The available ICD–10 data can now be used to evaluate other indicators of resource utilization.

Therefore, as an initial recommendation from the first phase in our comprehensive review of the CC and MCC lists, we proposed to remove the special logic in the GROUPER for processing claims containing a diagnosis code from the Principal Diagnosis Is Its Own CC or MCC Lists, and we proposed to delete the tables containing the lists of principal diagnosis codes, Table 6L.—Principal Diagnosis Is Its Own MCC List and Table 6M.—Principal Diagnosis Is Its Own CC List, from the ICD–10 MS–DRG Definitions Manual for FY 2019. We invited public comments on our proposals.

Comment: Commenters supported the proposed deletion of the Principal Diagnosis Is Its Own CC or MCC logic. One commenter stated that the lists were created to facilitate replication of the ICD–9 based MS–DRGs and are an artifact of the ICD–10 transitions. Another commenter recommended removing some of the conditions that are currently on the lists but expressed concern that eliminating the logic completely could impact the ability to measure a patient's severity of illness. One commenter noted that CMS described its internal comprehensive review and analysis that were conducted, which provided some level of insight for the proposal; however, the overarching comment was that CMS believed there were more effective indicators of resource utilization. Other commenters disagreed with CMS' proposal to ''globally'' remove the Principal Diagnosis Is Its Own CC or MCC logic. A few commenters stated that a more detailed analysis, consistent with the comprehensive CC/MCC analysis approach conducted for severity level changes, should occur. One commenter recommended that the logic described as part of the MS–DRG Conversion Project with the MCC and CC translations from ICD–9 to ICD–10 be considered. Another commenter acknowledged that CMS is no longer attempting to replicate the ICD–9 based MS–DRG GROUPER logic. However, this commenter noted that the conditions represented by the ICD–10–CM combination codes are clinically the

same conditions that were CCs or MCCs under ICD–9–CM.

Response: We appreciate the commenters' support. With regard to the commenter who recommended removing some of the conditions that are currently on the lists but expressed concern that eliminating the logic completely could impact the ability to measure a patient's severity of illness, we disagree because, in general, the description of a diagnosis code itself describes or implies a certain level of severity. In addition, there are other factors to consider besides the principal diagnosis when determining severity of illness and resource utilization. In response to the other commenters who disagreed with our proposal to remove the Principal Diagnosis Is Its Own CC or MCC logic and recommended that we perform an analysis consistent with the comprehensive CC/MCC analysis, we note that such an analysis would not be conclusive because the purpose of the comprehensive CC/MCC analysis is to evaluate the impact in resource use for patients with conditions reported as secondary diagnoses. We believe that the analysis that was performed and discussed in the proposed rule was appropriate for assessing if we should maintain the special logic that currently exists for assigning a severity level to a principal diagnosis, as well as to assess whether it would be appropriate to propose removing the special logic and utilize alternate methods to evaluate what should be considered a complex principal diagnosis for MS–DRG assignment purposes. As stated in the proposed rule (83 FR 20237), CMS has historically used clinical judgment combined with data analysis to assign a principal diagnosis describing a complex or severe condition to the appropriate MS–DRG. We also note that, as stated in the proposed rule (83 FR 20238), the findings from our analysis of the 18,596 claims that were impacted by the special logic in the GROUPER for processing claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists demonstrated that 556 of the 588 subsets had fewer than 100 cases. The low number of cases means that if the special logic had been proposed for the first time under ICD–10, 95 percent of the diagnosis codes that were responsible for 95 percent of the cases using the special logic would not have met the criteria for proposing a change to their severity level. With regard to the commenter who stated that the conditions represented by the ICD–10–CM combination codes are clinically the same conditions that were CCs or MCCs under ICD–9–CM, we note that combination diagnosis codes are a feature of the classification of both ICD–9–CM and ICD–10–CM. The majority of the combination diagnosis codes in ICD–9–CM are also combination codes in ICD–10–CM. The current list of ICD–10–CM codes that are included in the special logic is a result of the fact that the codes were classified differently in ICD–9–CM than in ICD–10–CM. Diagnoses represented as two separate codes under ICD–9–CM were represented in a combination code under ICD–10–CM. Codes that were combination codes in both ICD–9–CM and ICD–10–CM do not have any special severity logic applied, regardless of the clinical severity of the conditions described, or the increased use of resources that could be associated with a particular combination principal diagnosis. As a result, the categorization of ICD–10–CM codes into lists wherein the principal diagnosis is its own CC or MCC is based not on a systematic clinical evaluation of the severity of illness of patients with these combination diagnosis codes, or on a systematic evaluation of data containing these combination diagnosis codes used as principal diagnosis, but on a collection of codes selected exclusively because there were structural differences between the classification scheme in ICD–9–CM versus ICD–10–CM. Now that ICD–10 coded data are available, it can be used to evaluate other indicators of resource utilization, along with clinical judgment.

After consideration of the public comments we received, we are finalizing our proposal to remove the special logic in the GROUPER for processing claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists as an initial step in our first phase of the comprehensive review of the CC and MCC lists. We also are finalizing our proposal to delete the tables containing the lists of principal diagnosis codes, Table 6L.—Principal Diagnosis Is Its Own MCC List and Table 6M.—Principal Diagnosis Is Its Own CC List, from the ICD–10 MS–DRG Definitions Manual Version 36, effective October 1, 2018.

d. CC Exclusions List for FY 2019

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 35 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. If the code designated as a CC or MCC is allowed with all principal diagnoses, the phrase ''NoExcl'' (for no exclusions) follows the CC or MCC designation. For example, ICD–10–CM diagnosis code A17.83 (Tuberculous neuritis) has this ''NoExcl'' entry. For all other diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a non-CC. Part 2 is the list of diagnosis codes designated as a MCC only for

patients discharged alive; otherwise, they are assigned as a non-CC.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20239), for FY 2019, we proposed changes to the ICD–10 MS–DRGs Version 36 CC Exclusion List. Therefore, we developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2019; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2019; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2019; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2019. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with the proposed rule are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

To identify new, revised and deleted diagnosis and procedure codes, for FY 2019, we developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for the proposed rule and this final rule.

These tables are not published in the Addendum to the proposed rule or the final rule but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this final rule. As discussed in section II.F.18. of the preamble of this final rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

In the FY 2019 IPPS/LTCH PPS proposed rule, we invited public comments on the MDC and MS–DRG assignments for the new diagnosis and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, we invited public comments on the proposed severity level designations for the new diagnosis codes as set forth in Table 6A. and the proposed O.R. status for the new procedure codes as set forth in Table 6B.

Comment: One commenter addressed the proposed MS–DRG assignment for ICD–10–CM diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) that was included in Table 6A.—New Diagnosis Codes associated with the proposed rule. The commenter included the following codes that describe conditions involving appendicitis with peritonitis, abscess, perforation and gangrene.

ICD–10–CM code	Code description	Proposed MS–DRG
K35.20	Acute appendicitis with generalized peritonitis, without abscess	371, 372, 373
K35.21	Acute appendicitis with generalized peritonitis, with abscess	338, 339, 340 371, 372, 373
K35.30	Acute appendicitis with localized peritonitis, without perforation or gangrene	371, 372, 373
K35.31	Acute appendicitis with localized peritonitis and gangrene, without perforation	371, 372, 373
K35.32	Acute appendicitis with perforation and localized peritonitis, without abscess	338, 339, 340 371, 372, 373
K35.33	Acute appendicitis with perforation and localized peritonitis, with abscess	338, 339, 340 371, 372, 373
K35.890	Other acute appendicitis without perforation or gangrene	371, 372, 373
K35.891	Other acute appendicitis without perforation, with gangrene	371, 372, 373

The commenter stated that the proposed MS–DRG assignment for diagnosis code K35.20 is inappropriate and urged CMS to assign additional MS–DRGs and revise Table 6A. Specifically, the commenter expressed concern that MS–DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC, respectively) were the only MS–DRGs assigned to diagnosis code K35.20 and requested that MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) also be assigned. The commenter questioned why CMS only assigned MS–DRGs 371, 372, and 373 for diagnosis code K35.20 when diagnosis code K35.32 was assigned to MS–DRGs 338, 339, and 340 in addition to MS–DRGs 371, 372, and 373. The commenter stated that the FY 2019 ICD–10–CM Tabular List of Diseases and Injuries indicates that codes at the new subcategory K35.2 include a ruptured or perforated appendix, which is a complicating diagnosis and requires additional resources. The commenter expressed concern that the proposed MS–DRG assignment for diagnosis code K35.20 does not appropriately reflect the complications of the underlying disease or resources associated with acute appendicitis with generalized peritonitis. The commenter also noted that studies of patients admitted with appendicitis define complicated appendicitis as the presence of either generalized peritonitis due to perforated appendicitis or appendicular abscess. The commenter further noted that an appendix may perforate and cause generalized peritonitis without abscess if the perforation is walled off from the remainder of the peritoneal cavity because of its retroperitoneal location or by loops of small intestine or omentum.

Response: We note that the predecessor code for new diagnosis code K35.20 is diagnosis code K35.2 (Acute appendicitis with generalized peritonitis), which is currently assigned

to MS–DRGs 338, 339, 340, 371, 372, and 373. Diagnosis code K35.2 was subdivided into diagnosis codes K35.20 and K35.21. In assigning the proposed MS–DRGs for these new diagnosis codes, we considered the predecessor code MS–DRG assignment and the descriptions of the new diagnosis codes. Our clinical advisors determined that diagnosis code K35.21 ''with abscess'' was more appropriate to assign to MS–DRGs 338, 339, and 340 in addition to MS–DRGs 371, 372, and 373 versus diagnosis code K35.20 ''without abscess''. The degree and severity of the peritonitis in a patient with acute appendicitis can vary greatly. However, not all patients with peritonitis develop an abscess. While we agree that peritonitis is a serious condition when it develops in a patient with acute appendicitis, we also believe that, clinically, an abscess presents an even greater risk of complications that requires more resources as discussed in section II.F.15.b. of the preamble of this final rule with regard to the severity level designation.

We also consulted with the staff at the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for maintaining the ICD–10–CM diagnosis codes. The NCHS' staff acknowledged the clinical concerns of the commenter based on the manner in which diagnosis codes K35.2 and K35.3 were expanded and confirmed that they will consider further review of these newly expanded codes with respect to the clinical concepts.

Therefore, we maintain that the proposed MS–DRG assignment for diagnosis code K35.20 as shown in Table 6A is appropriate. Because the diagnosis codes that the commenter submitted in its comments are new, effective October 1, 2018, we do not yet have any claims data. We will continue to monitor these codes as data become available.

After consideration of the public comments we received, we are finalizing our proposal to assign diagnosis code K35.20 to MS–DRGs 371, 372, and 373 under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

Comment: One commenter recommended that the following new diagnosis codes that were included in Table 6A.—New Diagnosis Codes—FY 2019, be designated as a CC in the ICD–10–CM classification.

ICD–10–CM code	Code description
K61.31	Horseshoe abscess.
K61.39	Other ischiorectal abscess.
K61.5	Supralevator abscess.
K82.A1	Gangrene of gallbladder in cholecystitis.
O86.00	Infection of obstetric surgical wound, unspecified.
O86.01	Infection of obstetric surgical wound, superficial incisional site.
O86.02	Infection of obstetric surgical wound, deep incisional site.
O86.03	Infection of obstetric surgical wound, organ and space site.
O86.09	Infection of obstetric surgical wound, other surgical site.

According to the commenter, abscesses, postoperative infections, and gangrene of gallbladder warrant the CC designation because they are acute conditions and require antibiotics or surgical treatment and impact the length of stay. The commenter noted that, currently, diagnosis codes K61.3 (Ischiorectal abscess) and K61.4 (Intrasphincteric abscess) are designated as CCs. The commenter also noted that gangrene of gallbladder classifies to acute cholecystitis, which is a CC, and recommended that the codes listed in the above table all be designated as CCs.

Response: We appreciate the commenter's feedback on the proposed severity level designations of the diagnosis codes that were included in Table 6A.—New Diagnosis Codes—FY 2019. The commenter is correct that, currently, diagnosis codes K61.3 and K61.4 are designated as CCs. However, our clinical advisors reviewed diagnosis codes K61.31, K61.39, and K61.5 and continue to support maintaining the proposed non-CC designation because they do not agree from a clinical perspective that these conditions warrant a CC designation or significantly impact resource utilization as a secondary diagnosis. Specifically, our clinical advisors believe that these diagnosis codes described conditions that can range in severity and subsequently, the treatment that is rendered. With regard to the commenter's statement that abscesses, postoperative infections, and gangrene of gallbladder warrant the CC designation because they are acute conditions and require antibiotics or surgical treatment and impact the length of stay, we note that there are various types of abscesses and postoperative infections with varying levels of severity that do not always warrant surgical intervention.

With regard to the commenter's statement that gangrene of gallbladder classifies to acute cholecystitis which is a CC, we acknowledge that, currently, diagnosis code K81.0 (Acute cholecystitis) is a CC and has an inclusion term for gangrene of gallbladder. However, the new code description does not include the term ''acute''. Upon review of code K82.A1, our clinical advisors continue to support maintaining the proposed non-CC designation because they do not agree from a clinical perspective that this condition warrants a CC designation or significantly impacts resource utilization as a secondary diagnosis as the primary diagnosis likely is a more significant contributor to resource utilization. With regard to the codes describing infection of obstetrical wound of varying degrees and depths, the predecessor code O86.0 (Infection of obstetric wound) is currently classified as a non-CC and our clinical advisors agreed that, in the absence of data for the new codes, they are appropriately designated as non-CCs.

After consideration of the public comments we received, we are finalizing our proposed severity level assignments for the above listed diagnosis codes under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

We also are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following final tables associated with this final rule:

- Table 6A.—New Diagnosis Codes—FY 2019;
- Table 6B.—New Procedure Codes—FY 2019;
- Table 6C.—Invalid Diagnosis Codes—FY 2019;

- Table 6D.—Invalid Procedure Codes—FY 2019;
- Table 6E.—Revised Diagnosis Code Titles—FY 2019;
- Table 6F.—Revised Procedure Code Titles—FY 2019;
- Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2019;
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2019;
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2019;
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2019;
- Table 6I.1.—Additions to the MCC List—FY 2019;
- Table 6I.2.–Deletions to the MCC List—FY 2019;
- Table 6J.1.—Additions to the CC List—FY 2019; and
- Table 6J.2.—Deletions to the CC List—FY 2019.

We note that, as discussed in section II.F.15.c. of the preamble of this final rule, we proposed, and in this final rule are finalizing, to delete Table 6L. and Table 6M. from the ICD–10 MS–DRG Definitions Manual for FY 2019.

16. Comprehensive Review of CC List for FY 2019

a. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as an MCC, a CC, or a non-CC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since this comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when receiving requests to change the severity level of specific diagnosis codes. However, given the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since this review, we believe it is necessary to conduct a comprehensive analysis once again. We have begun this analysis and will discuss our findings in future rulemaking. We are currently using the same methodology utilized in FY 2008 and described below to conduct this analysis.

For each secondary diagnosis, we measured the impact in resource use for the following three subsets of patients:

(1) Patients with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs.

(2) Patients with at least one other secondary diagnosis that is a CC but none that is an MCC.

(3) Patients with at least one other secondary diagnosis that is an MCC.

Numerical resource impact values were assigned for each diagnosis as follows:

Value	Meaning
0	Significantly below expected value for the non-CC subgroup.
1	Approximately equal to expected value for the non-CC subgroup.
2	Approximately equal to expected value for the CC subgroup.
3	Approximately equal to expected value for the MCC subgroup.
4	Significantly above the expected value for the MCC subgroup.

Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset and C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a major CC. The C3 value reflects a patient with at least one other secondary diagnosis that is a major CC. A value close to 1.0 in the C1 field would suggest that the code produces the same expected value as a non-CC diagnosis. That is, average costs for the case are similar to the expected average costs for that subset and the diagnosis is not expected to increase resource usage. A higher value in the C1 (or C2 and C3) field suggests more resource usage is associated with the diagnosis and an increased likelihood that it is more like a CC or major CC than a non-CC. Thus, a value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For example, a C1 value of 1.8 for a secondary diagnosis means that for the subset of patients who have the secondary diagnosis and have either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs, the impact on resource use of the secondary diagnoses is greater than the expected value for a non-CC by an amount equal to 80 percent of the difference between the expected value of a CC and a non-CC (that is, the impact on resource use of the secondary diagnosis is closer to a CC than a non-CC).

These mathematical constructs are used as guides in conjunction with the judgment of our clinical advisors to classify each secondary diagnosis reviewed as an MCC, CC or non-CC. Our clinical panel reviews the resource use impact reports and suggests modifications to the initial CC subclass assignments when clinically appropriate.

b. Requested Changes to Severity Levels

(1) Human Immunodeficiency Virus [HIV] Disease

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20241), we received a request that we consider changing the severity level of ICD–10–CM diagnosis code B20 (Human immunodeficiency virus [HIV] disease) from an MCC to a CC. We used the approach outlined above to evaluate this request. The table below contains the data that were evaluated for this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
B20 (Human immunodeficiency virus [HIV] disease)	2,918	0.9946	8,938	2.1237	11,479	3.0960	MCC	CC

We stated in the proposed rule that while the data did not strongly suggest that the categorization of HIV as an MCC was inaccurate, our clinical advisors indicated that, for many patients with HIV disease, symptoms are well controlled by medications. Our clinical advisors stated that if these patients have an HIV-related complicating disease, that complicating disease would serve as a CC or an MCC. Therefore, they advised us that ICD–10–CM diagnosis code B20 is more similar to a CC than an MCC. Based on the data results and the advice of our clinical advisors, we proposed to change the severity level of ICD–10–CM diagnosis code B20 from an MCC to a CC.

Comment: Commenters opposed the proposal to change the severity level for ICD–10–CM diagnosis code B20 from an MCC to a CC. The commenters stated that the change should not be made without strong supporting empirical data, referencing the language in the proposed rule that indicated that the data did not strongly suggest that the categorization of HIV as an MCC was inaccurate. One commenter indicated that patients with CD4 counts of less than 100, or elevated viral loads, would need more laboratory tests, more imaging, and a higher level of care even if they are in the hospital for a non-HIV related condition. This commenter suggested that if diagnosis code B20 is changed to a CC, CMS develop distinct codes for patients with AIDS based on their level of CD4 and whether viral loads are suppressed.

Response: While we stated in the proposed rule that the data did not strongly suggest correlation of a secondary diagnosis code of B20 with a severity level of an MCC was inaccurate, the data also did not definitively support maintaining a severity level of an MCC. While we understand that HIV is a serious disease that causes significant chronic illness and can lead to serious complications, we note that when a patient is admitted for a non-HIV related condition, our clinical advisors do not believe that the secondary diagnosis of HIV would be expected to result in the additional resources associated with an MCC. As explained in the proposed rule, our clinical advisors believe that, for many patients with HIV disease, symptoms are well controlled by medications, and if these patients have an HIV-related complicating disease, that complicating disease would serve as a CC or an MCC. For these reasons, our clinical advisors continue to believe that ICD–10–CM diagnosis code B20 is more accurately characterized as a CC.

As discussed in section II.F.18. of the preamble of this final rule, requests for new ICD–10–CM diagnosis codes are discussed at the ICD–10 Coordination and Maintenance Committee meetings. We refer the commenter to the National Center for Health Statistics (NCHS) website at *https://www.cdc.gov/nchs/icd/icd10_maintenance.html* for further information regarding these meetings and the process for how to request code updates.

After consideration of the public comments we received, we are finalizing our proposal to change the severity level of diagnosis code of B20 from an MCC to a CC.

(2) Acute Respiratory Distress Syndrome

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20241), we also received a request to change the severity level for ICD–10–CM diagnosis code J80 (Acute respiratory distress syndrome) from a CC to a MCC. We used the approach outlined above to evaluate this request. The following table contains the data that were evaluated for this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
J80 (Acute respiratory distress syndrome)	1,840	1.7704	6,818	2.5596	18,376	3.3428	CC	MCC

We stated in the proposed rule that the data suggest that the resources involved in caring for a patient with this condition are 77 percent greater than expected when the patient has either no other secondary diagnosis present or all the other secondary diagnoses present are non-CCs. The resources are 56 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 34 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors agreed that the resources required to care for a patient with this secondary diagnosis are consistent with those of an MCC. Therefore, we proposed to change the severity level of ICD–10–CM diagnosis code J80 from a CC to an MCC.

Comment: Commenters supported the proposal to change the severity level of ICD–10–CM diagnosis code J80 from a CC to an MCC.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the severity level of ICD–10–CM diagnosis code J80 from a CC to an MCC.

(3) Encephalopathy

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20241), we also received a request to change the severity level for ICD–10–CM diagnosis code G93.40 (Encephalopathy, unspecified) from an MCC to a non-CC. The requestor pointed out that the nature of the encephalopathy or its underlying cause should be coded. The requestor also noted that unspecified heart failure is a non-CC. We used the approach outlined earlier to evaluate this request. The following table contains the data that were evaluated for this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
G93.40 (Encephalopathy, unspecified)	16,306	1.840	80,222	1.8471	139,066	2.4901	MCC	MCC

We stated in the proposed rule that the data suggest that the resources involved in caring for a patient with this condition are 84 percent greater than expected when the patient has either no other secondary diagnosis present or all the other secondary diagnoses present are non-CCs. We stated in the proposed rule that the resources are 15 percent lower than expected when reported in conjunction with another secondary diagnosis that is a CC, and 49 percent lower than expected when reported in conjunction with another secondary diagnosis code that is an MCC. The sentence should have read as follows: The resources are 15 percent lower than expected when reported in conjunction with another secondary diagnosis that is a CC, and 51 percent lower than expected when reported in conjunction with another secondary diagnosis code that is an MCC. We noted that the pattern observed in resource use for the condition of unspecified heart failure (ICD–10–CM diagnosis code I50.9) differs from that of unspecified encephalopathy. Our clinical advisors reviewed this request and agreed that, from a clinical standpoint, the resources involved in caring for a patient with this condition are aligned with those of an MCC. Therefore, we did not propose a change to the severity level for ICD–10–CM diagnosis code G93.40.

Comment: Several commenters supported the proposal to maintain the severity level for ICD–10–CM diagnosis code G93.40 as an MCC. One commenter opposed the proposal, stating that unspecified encephalopathy is poorly defined, not all specified encephalopathies are MCCs, and the MCC status creates an incentive for coding personnel to not pursue specificity of encephalopathy which could lead to a lower relative weight.

Response: We appreciate the commenters' support. After reviewing the rationale provided by the commenter who opposed our proposal, we concur with the commenter that unspecified encephalopathy is poorly defined, not all encephalopathies are MCCs, and the MCC status creates an incentive for coding personnel to not pursue specificity of encephalopathy. For these reason, our clinical advisors agree that it is appropriate to change the severity level from an MCC to a CC.

After consideration of the public comments we received, we are changing the severity level for ICD–10–CM diagnosis code G93.40 from an MCC to a CC.

(4) End-Stage Heart Failure and Hepatic Encephalopathy

Comment: One commenter stated that ICD–10–CM code I50.84 (End-stage heart failure) should be assigned the severity level of a CC and that hepatic encephalopathy should be assigned the severity level of an MCC. The commenter did not provide the specific ICD–10–CM diagnosis codes that describe hepatic encephalopathy.

Response: Because ICD–10–CM code I50.84 and the codes that describe hepatic encephalopathy referred to by the commenter are newly created codes, we do not yet have data with which to evaluate the commenter's request. We will consider these diagnosis codes during our ongoing comprehensive CC/MCC analysis once data become available.

After consideration of the public comment received, we are not changing the severity level of ICD–10–CM code I50.84 or the ICD–10–CM codes describing hepatic encephalopathy for FY 2019.

17. Review of Procedure Codes in MS DRGs 981 Through 983 and 987 Through 989

Each year, we review cases assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to change the procedures assigned among these MS–DRGs. MS–DRGs 981 through 983 and 987 through 989 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. Based on the results of our review of the claims data from the September 2017 update of the FY 2017 MedPAR file, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20242), we did not propose to move any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned.

Comment: One commenter identified two scenarios that involve some cases that are grouping to MS–DRGs 981 through 983 and MS–DRGs 987 through 989. The commenter stated that these grouping issues should be addressed by CMS and provided specific examples with a combination of several codes.

Response: We appreciate the commenter bringing these issues to our attention. However, we were unable to fully evaluate these scenarios for consideration in FY 2019. We intend to review and consider these items for FY 2020 as part of our ongoing analysis of the unrelated procedure MS–DRGs. As stated in section II.F.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classification issues to submit these comments no later than November 1 of each year so that they can be considered for possible inclusion in the annual proposed rule.

After consideration of the public comments we received, we are not

moving any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned for FY 2019.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983 and 987 Through 989

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

Based on the results of our review of the September 2017 update of the FY 2017 MedPAR file, we also proposed to maintain the current structure of MS–DRGs 981 through 983 and MS–DRGs 987 through 989.

Comment: One commenter recommended that CMS classify the insertion and revision of intracardiac pacemakers as discussed in section II.F.4.a. of the proposed rule (83 FR 20204) as extensive O.R. procedures (MS–DRG 981 through 983). The commenter performed its own analysis where the results demonstrated the average costs of the intracardiac pacemakers were higher than the average costs of cases in MS–DRGs 981 through 983.

Response: We are unclear as to the nature of the commenter's request, as the intracardiac pacemaker procedure codes are already designated as extensive O.R. procedures in the GROUPER logic, as discussed in section II.F.4.a. of the preamble of this final rule

After consideration of the public comments we received, we are finalizing our proposal to maintain the current structure of MS–DRGs 981 through 983 and MS–DRGs 987 through 989 under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

c. Adding Diagnosis or Procedure Codes to MDCs

We received a request recommending that CMS reassign cases for congenital pectus excavatum (congenital depression of the sternum or concave chest) when reported with a procedure describing repositioning of the sternum (the Nuss procedure) from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). ICD–10–CM diagnosis code Q67.6 (Pectus excavatum) is reported for this congenital condition and is currently assigned to MDC 4 (Diseases and Disorders of the Respiratory System). ICD–10–PCS procedure code 0PS044Z (Reposition sternum with internal fixation device, percutaneous endoscopic approach) may be reported to identify the Nuss procedure and is currently assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 515, 516, and 517. The requester noted that *acquired* pectus excavatum (ICD–10–CM diagnosis code M95.4) groups to MS–DRGs 515, 516, and 517 when reported with a ICD–10–PCS procedure code describing repositioning of the sternum and requested that cases involving diagnoses describing *congenital* pectus excavatum also group to those MS–DRGs when reported with a ICD–10–PCS procedure code describing repositioning of the sternum.

Our analysis of this grouping issue confirmed that, when pectus excavatum (ICD–10–CM diagnosis code Q67.6) is reported as a principal diagnosis with a procedure such as the Nuss procedure (ICD–10–PCS procedure code 0PS044Z), these cases group to MS–DRGs 981, 982, and 983. The reason for this grouping is because whenever there is a surgical procedure reported on a claim, which is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures.'' In the example provided, because the ICD–10–CM diagnosis code Q67.6 describing pectus excavatum is classified to MDC 4 and the ICD–10–PCS procedure code 0PS044Z is classified to MDC 8, the GROUPER logic assigns this case to the ''unrelated operating room procedures'' set of MS–DRGs.

During our review of ICD–10–CM diagnosis code Q67.6, we also reviewed additional ICD–10–CM diagnosis codes in the Q65 through Q79 code range to determine if there might be other conditions classified to MDC 4 that describe congenital malformations and deformities of the musculoskeletal system. We identified the following six ICD–10–CM diagnosis codes:

ICD–10–CM code	Code description
Q67.7	Pectus carinatum.
Q76.6	Other congenital malformations of ribs.
Q76.7	Congenital malformation of sternum.
Q76.8	Other congenital malformations of bony thorax.
Q76.9	Congenital malformation of bony thorax, unspecified.
Q77.2	Short rib syndrome.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20243), we proposed to reassign ICD–10–CM diagnosis code Q67.6, as well as the additional six ICD–10–CM diagnosis codes above describing congenital musculoskeletal conditions, from MDC 4 to MDC 8 where other related congenital conditions that correspond to the musculoskeletal system are classified, as discussed further below.

We identified other related ICD–10–CM diagnosis codes that are currently assigned to MDC 8 in categories Q67 (Congenital musculoskeletal deformities of head, face, spine and chest), Q76 (Congenital malformations of spine and bony thorax), and Q77 (Osteochondrodysplasia with defects of growth of tubular bones and spine) that are listed in the following table.

ICD–10–CM code	Code description
Q67.0	Congenital facial asymmetry.
Q67.1	Congenital compression facies.
Q67.2	Dolichocephaly.
Q67.3	Plagiocephaly.
Q67.4	Other congenital deformities of skull, face and jaw.
Q67.5	Congenital deformity of spine.
Q67.8	Other congenital deformities of chest.
Q76.1	Klippel-Feil syndrome.
Q76.2	Congenital spondylolisthesis.
Q76.3	Congenital scoliosis due to congenital bony malformation.
Q76.411	Congenital kyphosis, occipito-atlanto-axial region.
Q76.412	Congenital kyphosis, cervical region.
Q76.413	Congenital kyphosis, cervicothoracic region.
Q76.414	Congenital kyphosis, thoracic region.
Q76.415	Congenital kyphosis, thoracolumbar region.
Q76.419	Congenital kyphosis, unspecified region.
Q76.425	Congenital lordosis, thoracolumbar region.
Q76.426	Congenital lordosis, lumbar region.
Q76.427	Congenital lordosis, lumbosacral region.
Q76.428	Congenital lordosis, sacral and sacrococcygeal region.
Q76.429	Congenital lordosis, unspecified region.
Q76.49	Other congenital malformations of spine, not associated with scoliosis.
Q76.5	Cervical rib.
Q77.0	Achondrogenesis.
Q77.1	Thanatophoric short stature.
Q77.3	Chondrodysplasia punctate.
Q77.4	Achondroplasia.
Q77.5	Diastrophic dysplasia.
Q77.6	Chondroectodermal dysplasia.
Q77.7	Spondyloepiphyseal dysplasia.
Q77.8	Other osteochondrodysplasia with defects of growth of tubular bones and spine.
Q77.9	Osteochondrodysplasia with defects of growth of tubular bones and spine, unspecified.

Next, we analyzed the MS–DRG assignments for the related codes listed above and found that cases with the following conditions are assigned to MS–DRGs 551 and 552 (Medical Back Problems with and without MCC, respectively) under MDC 8.

ICD–10–CM code	Code description
Q76.2	Congenital spondylolisthesis.
Q76.411	Congenital kyphosis, occipito-atlanto-axial region.
Q76.412	Congenital kyphosis, cervical region.
Q76.413	Congenital kyphosis, cervicothoracic region.
Q76.414	Congenital kyphosis, thoracic region.
Q76.415	Congenital kyphosis, thoracolumbar region.
Q76.419	Congenital kyphosis, unspecified region.
Q76.49	Other congenital malformations of spine, not associated with scoliosis.

The remaining conditions shown below are assigned to MS–DRGs 564, 565, and 566 (Other Musculoskeletal System and Connective Tissue Diagnoses with MCC, with CC, and without CC/MCC, respectively) under MDC 8.

ICD–10–CM code	Code description
Q67.0	Congenital facial asymmetry.
Q67.1	Congenital compression facies.
Q67.2	Dolichocephaly.
Q67.3	Plagiocephaly.
Q67.4	Other congenital deformities of skull, face and jaw.
Q67.5	Congenital deformity of spine.
Q67.8	Other congenital deformities of chest.
Q76.1	Klippel-Feil syndrome.
Q76.3	Congenital scoliosis due to congenital bony malformation.
Q76.425	Congenital lordosis, thoracolumbar region.
Q76.426	Congenital lordosis, lumbar region.
Q76.427	Congenital lordosis, lumbosacral region.
Q76.428	Congenital lordosis, sacral and sacrococcygeal region.

ICD–10–CM code	Code description
Q76.429	Congenital lordosis, unspecified region.
Q76.5	Cervical rib.
Q77.0	Achondrogenesis.
Q77.1	Thanatophoric short stature.
Q77.3	Chondrodysplasia punctate.
Q77.4	Achondroplasia.
Q77.5	Diastrophic dysplasia.
Q77.6	Chondroectodermal dysplasia.
Q77.7	Spondyloepiphyseal dysplasia.
Q77.8	Other osteochondrodysplasia with defects of growth of tubular bones and spine.
Q77.9	Osteochondrodysplasia with defects of growth of tubular bones and spine, unspecified.

As a result of our review, we proposed to reassign ICD–10–CM diagnosis code Q67.6, as well as the additional six ICD–10–CM diagnosis codes above describing congenital musculoskeletal conditions, from MDC 4 to MDC 8 in MS–DRGs 564, 565, and 566. Our clinical advisors agreed with this proposed reassignment because it is clinically appropriate and consistent with the other related ICD–10–CM diagnosis codes grouped in the Q65 through Q79 range that describe congenital malformations and deformities of the musculoskeletal system that are classified under MDC 8 in MS–DRGs 564, 565, and 566. We stated in the propsed rule that by reassigning ICD–10–CM diagnosis code Q67.6 and the additional six ICD–10–CM diagnosis codes listed in the table above from MDC 4 to MDC 8, cases reporting these ICD–10–CM diagnosis codes in combination with the respective ICD–10–PCS procedure code will reflect a more appropriate grouping from a clinical perspective because they will now be classified under a surgical musculoskeletal system related MS–DRG and will no longer result in an MS–DRG assignment to the ''unrelated operating room procedures'' surgical class.

In summary, we proposed to reassign ICD–10–CM diagnosis codes Q67.6, Q67.7, Q76.6, Q76.7, Q76.8, Q76.9, and Q77.2 from MDC 4 to MDC 8 in MS–DRGs 564, 565, and 566 (Other Musculoskeletal System and Connective Tissue Diagnoses with MCC, with CC, and without CC/MCC, respectively).

Comment: Commenters supported the proposal to reassign the seven ICD–10–CM diagnosis codes describing congenital musculoskeletal conditions from MDC 4 to MDC 8 into MS–DRGs 564, 565 and 566. The commenters stated that the proposal was reasonable, given the ICD–10–CM codes and the information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposal to reassign ICD–10–CM diagnosis codes Q67.6, Q67.7, Q76.6, Q76.7, Q76.8, Q76.9, and Q77.2 from MDC 4 to MDC 8 in MS–DRGs 564, 565, and 566 under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

We also received a request recommending that CMS reassign cases for sternal fracture repair procedures from MS–DRGs 981, 982, and 983 and from MS–DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC and without CC/MCC, respectively) under MDC 4 to MS–DRGs 515, 516, and 517 under MDC 8. The requester noted that clavicle fracture repair procedures with an internal fixation device group to MS–DRGs 515, 516, and 517 when reported with an ICD–10–CM diagnosis code describing a fractured clavicle. However, sternal fracture repair procedures with an internal fixation device group to MS–DRGs 981, 982, and 983 or MS–DRGs 166, 167 and 168 when reported with an ICD–10–CM diagnosis code describing a fracture of the sternum. According to the requestor, because the clavicle and sternum are in the same anatomical region of the body, it would appear that assignment to MS–DRGs 515, 516, and 517 would be more appropriate for sternal fracture repair procedures.

The requestor provided the following list of ICD–10–PCS procedure codes in its request for consideration to reassign to MS–DRGs 515, 516 and 517 when reported with an ICD–10–CM diagnosis code for sternal fracture.

ICD–10–PCS code	Code description
0PS000Z	Reposition sternum with rigid plate internal fixation device, open approach.
0PS004Z	Reposition sternum with internal fixation device, open approach.
0PS00ZZ	Reposition sternum, open approach.
0PS030Z	Reposition sternum with rigid plate internal fixation device, percutaneous approach.
0PS034Z	Reposition sternum with internal fixation device, percutaneous approach.

We noted that the above five ICD–10–PCS procedure codes that may be reported to describe a sternal fracture repair are already assigned to MS–DRGs 515, 516, and 517 under MDC 8. In addition, ICD–10–PCS procedure codes 0PS000Z and 0PS030Z are assigned to MS–DRGs 166, 167 and 168 under MDC 4.

As noted in the previous discussion, whenever there is a surgical procedure reported on a claim, which is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures.'' In the examples provided by the requestor, when the ICD–10–CM diagnosis code describing a sternal fracture is classified under MDC 4 and the ICD–10–PCS procedure code describing a sternal fracture repair procedure is classified under MDC 8, the GROUPER logic assigns these cases to the ''unrelated operating room procedures'' group of MS–DRGs (981, 982, and 983) and when the ICD–10–CM diagnosis code describing a sternal fracture is classified under MDC 4 and the ICD–10–PCS procedure code

describing a sternal repair procedure is also classified under MDC 4, the GROUPER logic assigns these cases to MS–DRG 166, 167, or 168.

For our review of this grouping issue and the request to have procedures for sternal fracture repairs assigned to MDC 8, we analyzed the ICD–10–CM diagnosis codes describing a sternal fracture currently classified under MDC 4. We identified 10 ICD–10–CM diagnosis codes describing a sternal fracture with an ''initial encounter'' classified under MDC 4 that are listed in the following table.

ICD–10–CM code	Code description
S22.20XA	Unspecified fracture of sternum, initial encounter for closed fracture.
S22.20XB	Unspecified fracture of sternum, initial encounter for open fracture.
S22.21XA	Fracture of manubrium, initial encounter for closed fracture.
S22.21XB	Fracture of manubrium, initial encounter for open fracture.
S22.22XA	Fracture of body of sternum, initial encounter for closed fracture.
S22.22XB	Fracture of body of sternum, initial encounter for open fracture.
S22.23XA	Sternal manubrial dissociation, initial encounter for closed fracture.
S22.23XB	Sternal manubrial dissociation, initial encounter for open fracture.
S22.24XA	Fracture of xiphoid process, initial encounter for closed fracture.
S22.24XB	Fracture of xiphoid process, initial encounter for open fracture.

Our analysis of this grouping issue confirmed that when 1 of the 10 ICD–10–CM diagnosis codes describing a sternal fracture listed in the table above from MDC 4 is reported as a principal diagnosis with an ICD–10–PCS procedure code for a sternal repair procedure from MDC 8, these cases group to MS–DRG 981, 982, or 983. We also confirmed that when 1 of the 10 ICD–10–CM diagnosis codes describing a sternal fracture listed in the table above from MDC 4 is reported as a principal diagnosis with an ICD–10–PCS procedure code for a sternal repair procedure from MDC 4, these cases group to MS–DRG 166, 167 or 168.

Our clinical advisors agreed with the requested reclassification of ICD–10–CM diagnosis codes S22.20XA, S22.20XB, S22.21XA, S22.21XB, S22.22XA, S22.22XB, S22.23XA, S22.23XB, S22.24XA, and S22.24XB describing a sternal fracture with an initial encounter from MDC 4 to MDC 8. They advised that this requested reclassification is clinically appropriate because it is consistent with the other related ICD–10–CM diagnosis codes that describe fractures of the sternum and which are classified under MDC 8. The ICD–10–CM diagnosis codes describing a sternal fracture currently classified under MDC 8 to MS–DRGs 564, 565, and 566 are listed in the following table.

ICD–10–CM code	Code description
S22.20XD	Unspecified fracture of sternum, subsequent encounter for fracture with routine healing.
S22.20XG	Unspecified fracture of sternum, subsequent encounter for fracture with delayed healing.
S22.20XK	Unspecified fracture of sternum, subsequent encounter for fracture with nonunion.
S22.20XS	Unspecified fracture of sternum, sequela.
S22.21XD	Fracture of manubrium, subsequent encounter for fracture with routine healing.
S22.21XG	Fracture of manubrium, subsequent encounter for fracture with delayed healing.
S22.21XK	Fracture of manubrium, subsequent encounter for fracture with nonunion.
S22.21XS	Fracture of manubrium, sequela.
S22.22XD	Fracture of body of sternum, subsequent encounter for fracture with routine healing.
S22.22XG	Fracture of body of sternum, subsequent encounter for fracture with delayed healing.
S22.22XK	Fracture of body of sternum, subsequent encounter for fracture with nonunion.
S22.22XS	Fracture of body of sternum, sequela.
S22.23XD	Sternal manubrial dissociation, subsequent encounter for fracture with routine healing.
S22.23XG	Sternal manubrial dissociation, subsequent encounter for fracture with delayed healing.
S22.23XK	Sternal manubrial dissociation, subsequent encounter for fracture with nonunion.
S22.23XS	Sternal manubrial dissociation, sequela.
S22.24XD	Fracture of xiphoid process, subsequent encounter for fracture with routine healing.
S22.24XG	Fracture of xiphoid process, subsequent encounter for fracture with delayed healing.
S22.24XK	Fracture of xiphoid process, subsequent encounter for fracture with nonunion.
S22.24XS	Fracture of xiphoid process, sequela.

We stated in the proposed rule that by reclassifying the 10 ICD–10–CM diagnosis codes listed in the table earlier in this section describing sternal fracture codes with an ''initial encounter'' from MDC 4 to MDC 8, the cases reporting these ICD–10–CM diagnosis codes in combination with the respective ICD–10–PCS procedure codes will reflect a more appropriate grouping from a clinical perspective and will no longer result in an MS–DRG assignment to the ''unrelated operating room procedures'' surgical class when reported with a surgical procedure classified under MDC 8.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20245), we proposed to reassign ICD–10–CM diagnosis codes S22.20XA, S22.20XB, S22.21XA, S22.21XB, S22.22XA, S22.22XB, S22.23XA, S22.23XB, S22.24XA, and S22.24XB from under MDC 4 to MDC 8 to MS–DRGs 564, 565, and 566. We invited public comments on our proposals.

Comment: Commenters supported the proposal to reassign the 10 ICD–10–CM diagnosis codes describing sternal fractures with an initial encounter from MDC 4 to MDC 8 into MS–DRGs 564, 565 and 566. The commenters stated that the proposal was reasonable, given

the ICD–10–CM codes and the information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposal to reassign ICD–10–CM diagnosis codes S22.20XA, S22.20XB, S22.21XA, S22.21XB, S22.22XA, S22.22XB, S22.23XA, S22.23XB, S22.24XA, and S22.24XB from MDC 4 to MDC 8 to MS–DRGs 564, 565, and 566 under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

In addition, we received a request recommending that CMS reassign cases for rib fracture repair procedures from MS–DRGs 981, 982, and 983, and from MS–DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) under MDC 4 to MS–DRGs 515, 516, and 517 under MDC 8. The requestor noted that clavicle fracture repair procedures with an internal fixation device group to MS–DRGs 515, 516, and 517 when reported with an ICD–10–CM diagnosis code describing a fractured clavicle. However, rib fracture repair procedures with an internal fixation device group to MS–DRGs 981, 982, and 983 or to MS–DRGs 166, 167 and 168 when reported with an ICD–10–CM diagnosis code describing a rib fracture. According to the requestor, because the clavicle and ribs are in the same anatomical region of the body, it would appear that assignment to MS–DRGs 515, 516, and 517 would be more appropriate for rib fracture repair procedures.

The requestor provided the following list of 10 ICD–10–PCS procedure codes in its request for consideration for reassignment to MS–DRGs 515, 516 and 517 when reported with an ICD–10–CM diagnosis code for rib fracture.

ICD–10–PCS code	Code description
0PH104Z	Insertion of internal fixation device into 1 to 2 ribs, open approach.
0PH134Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous approach.
0PH144Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous endoscopic approach.
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach.
0PH234Z	Insertion of internal fixation device into 3 or more ribs, percutaneous approach.
0PH244Z	Insertion of internal fixation device into 3 or more ribs, percutaneous endoscopic approach.
0PS104Z	Reposition 1 to 2 ribs with internal fixation device, open approach.
0PS134Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous approach.
0PS204Z	Reposition 3 or more ribs with internal fixation, device, open approach.
0PS234Z	Reposition 3 or more ribs with internal fixation device, percutaneous approach.

We note that the above 10 ICD–10–PCS procedure codes that may be reported to describe a rib fracture repair are already assigned to MS–DRGs 515, 516, and 517 under MDC 8. In addition, 6 of the 10 ICD–10–PCS procedure codes listed above (0PH104Z, 0PH134Z, 0PH144Z, 0PH204Z, 0PH234Z and 0PH244Z) are also assigned to MS–DRGs 166, 167, and 168 under MDC 4.

As noted in the previous discussions above, whenever there is a surgical procedure reported on a claim, which is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures.'' In the examples provided by the requestor, when the ICD–10–CM diagnosis code describing a rib fracture is classified under MDC 4 and the ICD–10–PCS procedure code describing a rib fracture repair procedure is classified under MDC 8, the GROUPER logic assigns these cases to the ''unrelated operating room procedures'' group of MS–DRGs (981, 982, and 983) and when the ICD–10–CM diagnosis code describing a rib fracture is classified under MDC 4 and the ICD–10–PCS procedure code describing a rib repair procedure is also classified under MDC 4, the GROUPER logic assigns these cases to MS–DRG 166, 167, or 168.

For our review of this grouping issue and the request to have procedures for rib fracture repairs assigned to MDC 8, we analyzed the ICD–10–CM diagnosis codes describing a rib fracture and found that, while some rib fracture ICD–10–CM diagnosis codes are classified under MDC 8 (which would result in those cases grouping appropriately to MS–DRGs 515, 516, and 517), there are other ICD–10–CM diagnosis codes that are currently classified under MDC 4. We identified the following ICD–10–CM diagnosis codes describing a rib fracture with an initial encounter classified under MDC 4, as listed in the following table.

ICD–10–CM code	Code description
S2231XA	Fracture of one rib, right side, initial encounter for closed fracture.
S2231XB	Fracture of one rib, right side, initial encounter for open fracture.
S2232XA	Fracture of one rib, left side, initial encounter for closed fracture.
S2232XB	Fracture of one rib, left side, initial encounter for open fracture.
S2239XA	Fracture of one rib, unspecified side, initial encounter for closed fracture.
S2239XB	Fracture of one rib, unspecified side, initial encounter for open fracture.
S2241XA	Multiple fractures of ribs, right side, initial encounter for closed fracture.
S2241XB	Multiple fractures of ribs, right side, initial encounter for open fracture.
S2242XA	Multiple fractures of ribs, left side, initial encounter for closed fracture.
S2242XB	Multiple fractures of ribs, left side, initial encounter for open fracture.
S2243XA	Multiple fractures of ribs, bilateral, initial encounter for closed fracture.
S2243XB	Multiple fractures of ribs, bilateral, initial encounter for open fracture.
S2249XA	Multiple fractures of ribs, unspecified side, initial encounter for closed fracture.
S2249XB	Multiple fractures of ribs, unspecified side, initial encounter for open fracture.
S225XXA	Flail chest, initial encounter for closed fracture.
S225XXB	Flail chest, initial encounter for open fracture.

Our analysis of this grouping issue confirmed that, when one of the following four ICD–10–PCS procedure codes identified by the requestor (and listed in the table earlier in this section) from MDC 8 (0PS104Z, 0PS134Z, 0PS204Z, or 0PS234Z) is reported to describe a rib fracture repair procedure with a principal diagnosis code for a rib fracture with an initial encounter listed in the table above from MDC 4, these cases group to MS–DRG 981, 982, or 983.

During our review of those four repositioning of the rib procedure codes, we also identified the following four ICD–10–PCS procedure codes classified to MDC 8 that describe repositioning of the ribs.

ICD–10–PCS code	Code description
0PS10ZZ	Reposition 1 to 2 ribs, open approach.
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach.
0PS20ZZ	Reposition 3 or more ribs, open approach.
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach.

We confirmed that when one of the above four procedure codes is reported with a principal diagnosis code for a rib fracture listed in the table above from MDC 4, these cases also group to MS–DRG 981, 982, or 983.

Lastly, we confirmed that when one of the six ICD–10–PCS procedure codes describing a rib fracture repair listed in the previous table above from MDC 4 is reported with a principal diagnosis code for a rib fracture with an initial encounter from MDC 4, these cases group to MS–DRG 166, 167, or 168.

In response to the request to reassign the procedure codes that describe a rib fracture repair procedure from MS–DRGs 981, 982, and 983 and from MS–DRGs 166, 167, and 168 under MDC 4 to MS–DRGs 515, 516, and 517 under MDC 8, as discussed above, the 10 ICD–10–PCS procedure codes submitted by the requestor that may be reported to describe a rib fracture repair are already assigned to MS–DRGs 515, 516, and 517 under MDC 8 and 6 of those 10 procedure codes (0PH104Z, 0PH134Z, 0PH144Z, 0PH204Z, 0PH234Z, and 0PH244Z) are also assigned to MS–DRGs 166, 167, and 168 under MDC 4.

We analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting a principal diagnosis of a rib fracture (initial encounter) from the list of diagnosis codes shown in the table above with one of the six ICD–10–PCS procedure codes describing the insertion of an internal fixation device into the rib (0PH104Z, 0PH134Z, 0PH144Z, 0PH204Z, 0PH234Z, and 0PH244Z) in MS–DRGs 166, 167, and 168 under MDC 4. Our findings are shown in the table below.

MS–DRGs FOR OTHER RESPIRATORY SYSTEM O.R. PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 166–All cases	22,938	10.2	$24,299
MS–DRG 166–Cases with principal diagnosis of rib fracture(s) and insertion of internal fixation device for the rib(s)	40	11.4	43,094
MS–DRG 167–All cases	10,815	5.7	13,252
MS–DRG 167–Cases with principal diagnosis of rib fracture(s) and insertion of internal fixation device for the rib(s)	10	6.7	30,617
MS–DRG 168–All cases	3,242	3.1	9,708
MS–DRG 168–Cases with principal diagnosis of rib fracture(s) and insertion of internal fixation device for the rib(s)	4	2	21,501

As shown in this table, there were a total of 22,938 cases in MS–DRG 166, with an average length of stay of 10.2 days and average costs of $24,299. In MS–DRG 166, we found 40 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), with an average length of stay of 11.4 days and average costs of $43,094. There were a total of 10,815 cases in MS–DRG 167, with an average length of stay of 5.7 days and average costs of $13,252. In MS–DRG 167, we found 10 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), with an average length of stay of 6.7 days and average costs of $30,617. There were a total of 3,242 cases in MS–DRG 168, with an average length of stay of 3.1 days and average costs of $9,708. In MS–DRG 168, we found 4 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), with an average length of stay of 2 days and average costs of $21,501. Overall, for MS–DRGs 166, 167, and 168, there were a total of 54 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), demonstrating that while rib fractures may require treatment, they are not typically corrected surgically. Our clinical advisors agreed with the current assignment of procedure codes to MS–DRGs 166, 167, and 168 that may be reported to describe repair of a rib fracture under MDC 4, as well as the current assignment of procedure codes to MS–DRGs 515, 516, and 517 that may be reported to describe repair of a rib fracture under MDC 8. Our clinical advisors noted that initial, acute rib fractures can cause numerous respiratory related issues requiring various treatments and problems with the healing of a rib fracture are considered musculoskeletal issues.

We also noted that the procedure codes submitted by the requestor may be reported for other indications and they are not restricted to reporting for repair of a rib fracture. Therefore, assignment of these codes to the MDC 4 MS–DRGs and the MDC 8 MS–DRGs is clinically appropriate.

To address the cases reporting procedure codes describing the

repositioning of a rib(s) that are grouping to MS–DRGs 981, 982, and 983 when reported with a principal diagnosis of a rib fracture (initial encounter), in the FY 2019 IPPS/LTCH PPS proposed rule, we proposed to add the following eight ICD–10–PCS procedure codes currently assigned to MDC 8 into MDC 4, in MS–DRGs 166, 167 and 168.

ICD–10–PCS code	Code description
0PS104Z	Reposition 1 to 2 ribs with internal fixation device, open approach.
0PS10ZZ	Reposition 1 to 2 ribs, open approach.
0PS134Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous approach.
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach.
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach.
0PS20ZZ	Reposition 3 or more ribs, open approach.
0PS234Z	Reposition 3 or more ribs with internal fixation device, percutaneous approach.
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach.

Our clinical advisors agreed with this proposed addition to the classification structure because it is clinically appropriate and consistent with the other related ICD–10–PCS procedure codes that may be reported to describe rib fracture repair procedures with the insertion of an internal fixation device and are classified under MDC 4.

We stated in the proposed rule that by adding the eight ICD–10–PCS procedure codes describing repositioning of the rib(s) that may be reported to describe a rib fracture repair procedure under the classification structure for MDC 4, these cases will no longer result in an MS–DRG assignment to the ''unrelated operating room procedures'' surgical class when reported with a diagnosis code under MDC 4.

Comment: Commenters supported the proposal to add the eight ICD–10–PCS procedure codes describing repositioning of the ribs to MDC 4 in MS–DRGs 166, 167 and 168. The commenters stated that the proposal was reasonable, given the data, the ICD–10–PCS codes and the information provided.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposal to add ICD–10–PCS procedure codes 0PS104Z, 0PS10ZZ, 0PS134Z, 0PS144Z, 0PS204Z, 0PS20ZZ, 0PS234Z and 0PS244Z currently assigned to MDC 8 into MDC 4 in MS–DRGs 166, 167 and 168 under the ICD–10 MS–DRGs Version 36, effective October 1, 2018.

18. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention (CDC), and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2019 at a public meeting held on September 12–13, 2017, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 13, 2017.

The Committee held its 2018 meeting on March 6–7, 2018. The deadline for submitting comments on these code proposals was scheduled for April 6, 2018. It was announced at this meeting that any new ICD–10–CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2018 would be included in the October 1, 2018 update to ICD–10–CM/ICD–10–PCS. As discussed in earlier sections of the preamble of this final rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this final rule, which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* The code titles are adopted as part of the

ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they were not published in the Addendum to the proposed rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed rule.

Live Webcast recordings of the discussions of procedure codes at the Committee's September 12–13, 2017 meeting and March 6–7, 2018 meeting can be obtained from the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp*. The minutes of the discussions of diagnosis codes at the September 12–13, 2017 meeting and March 6–7, 2018 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were not any requests approved for an expedited April 1, 2018 implementation of a code at the September 12–13, 2017 Committee meeting. Therefore, there were not any new codes for implementation on April 1, 2018.

ICD–9–CM addendum and code title information is published on the CMS website at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC website at: *http://www.cdc.gov/nchs/icd/icd10.htm*. Additionally, information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is provided to the AHA for publication in the *Coding Clinic for ICD–10*. AHA also distributes coding update information to publishers and software vendors.

The following chart shows the number of ICD–10–CM and ICD–10–PCS codes and code changes since FY 2016 when ICD–10 was implemented.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR ICD–10–CM AND ICD–10–PCS CODES

Fiscal year	Number	Change
FY 2016:		
ICD–10–CM	69,823	
ICD–10–PCS	71,974	
FY 2017:		
ICD–10–CM	71,486	+1,663
ICD–10–PCS	75,789	+3,815
FY 2018:		
ICD–10–CM	71,704	+218
ICD–10–PCS	78,705	+2,916
FY 2019:.		
ICD–10–CM	71,932	+228
ICD–10–PCS	78,881	+176

As mentioned previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting.

At the September 12–13, 2017 and March 6–7, 2018 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that were to be implemented on October 1, 2018. We invited public comments on any code requests discussed at the September 12–13, 2017 and March 6–7, 2018 Committee meetings for implementation as part of the October 1, 2018 update. The deadline for commenting on code proposals discussed at the September 12–13, 2017 Committee meeting was November 13, 2017. The deadline for commenting on code proposals discussed at the March 6–7, 2018 Committee meeting was April 6, 2018.

19. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2019

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20250 through 20251), for FY 2019, we did not propose to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We proposed to continue to include the existing MS–DRGs currently subject to the policy as displayed in the table below.

MDC	MS–DRG	MS–DRG title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC.
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
1	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator.
1	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC.
1	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
1	026	Craniotomy & Endovascular Intracranial Procedures with CC.
1	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
1	040	Peripheral, Cranial Nerve & Other Nervous System Procedures with MCC.
1	041	Peripheral, Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulator.
1	042	Peripheral, Cranial Nerve & Other Nervous System Procedures without CC/MCC.
3	129	Major Head & Neck Procedures with CC/MCC or Major Device.
3	130	Major Head & Neck Procedures without CC/MCC.
5	215	Other Heart Assist System Implant.
5	216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.
5	217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC.
5	218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC.
5	219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.
5	220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.
5	221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC.
5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC.

MDC	MS–DRG	MS–DRG title
5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC.
5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC.
5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC.
5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC.
5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC.
5	242	Permanent Cardiac Pacemaker Implant with MCC.
5	243	Permanent Cardiac Pacemaker Implant with CC.
5	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
5	245	AICD Generator Procedures.
5	258	Cardiac Pacemaker Device Replacement with MCC.
5	259	Cardiac Pacemaker Device Replacement without MCC.
5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
5	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
5	265	AICD Lead Procedures.
5	266	Endovascular Cardiac Valve Replacement with MCC.
5	267	Endovascular Cardiac Valve Replacement without MCC.
5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
5	270	Other Major Cardiovascular Procedures with MCC.
5	271	Other Major Cardiovascular Procedures with CC.
5	272	Other Major Cardiovascular Procedures without CC/MCC.
8	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC.
8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
8	466	Revision of Hip or Knee Replacement with MCC.
8	467	Revision of Hip or Knee Replacement with CC.
8	468	Revision of Hip or Knee Replacement without CC/MCC.
8	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement.
8	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC.

We did not receive any public comments on our proposal to continue to include the existing MS–DRGs currently subject to the policy and to not add any additional MS–DRGs. Therefore, we are finalizing the list of MS–DRGs in the table included in the proposed rule and above that will be subject to the replaced devices offered without cost or with a credit policy, effective October 1, 2018.

20. Other Policy Changes: Other Operating Room (O.R.) and Non-O.R. Issues

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20251 through 20257), we addressed requests that we received regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures, or changing the designation from O.R. procedure to non-O.R. procedure. In cases where we proposed to change the designation of procedure codes from non-O.R. to O.R. procedures, we also proposed one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned. We generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures newly designated as O.R. procedures. We invited public comments on these proposed MS–DRG assignments.

We also noted that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion below. Instead, we only discussed MS–DRGs that require explicitly adding the relevant procedures codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended. In addition, cases that contain O.R. procedures will map to MS–DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, if requestors included some or all of MS–DRGs 981 through 989 in their request or included MS–DRGs that require the presence of any O.R. procedure, we did not specifically address that aspect in summarizing their request or our response to the request in the section below.

(a) Percutaneous and Percutaneous Endoscopic Excision of Brain and Cerebral Ventricle

One requestor identified 22 ICD–10–PCS procedure codes that describe procedures involving transcranial brain and cerebral ventricle excision that the requestor stated would generally require the resources of an operating room. The 22 procedure codes are listed in the following table.

ICD–10–PCS procedure code	Code description
00B03ZX	Excision of brain, percutaneous approach, diagnostic.

ICD–10–PCS procedure code	Code description
00B13ZX	Excision of cerebral meninges, percutaneous approach, diagnostic.
00B23ZX	Excision of dura mater, percutaneous approach, diagnostic.
00B63ZX	Excision of cerebral ventricle, percutaneous approach, diagnostic.
00B73ZX	Excision of cerebral hemisphere, percutaneous approach, diagnostic.
00B83ZX	Excision of basal ganglia, percutaneous approach, diagnostic.
00B93ZX	Excision of thalamus, percutaneous approach, diagnostic.
00BA3ZX	Excision of hypothalamus, percutaneous approach, diagnostic.
00BB3ZX	Excision of pons, percutaneous approach, diagnostic.
00BC3ZX	Excision of cerebellum, percutaneous approach, diagnostic.
00BD3ZX	Excision of medulla oblongata, percutaneous approach, diagnostic.
00B04ZX	Excision of brain, percutaneous endoscopic approach, diagnostic.
00B14ZX	Excision of cerebral meninges, percutaneous endoscopic approach, diagnostic.
00B24ZX	Excision of dura mater, percutaneous endoscopic approach, diagnostic.
00B64ZX	Excision of cerebral ventricle, percutaneous endoscopic approach, diagnostic.
00B74ZX	Excision of cerebral hemisphere, percutaneous endoscopic approach, diagnostic.
00B84ZX	Excision of basal ganglia, percutaneous endoscopic approach, diagnostic.
00B94ZX	Excision of thalamus, percutaneous endoscopic approach, diagnostic.
00BA4ZX	Excision of hypothalamus, percutaneous endoscopic approach, diagnostic.
00BB4ZX	Excision of pons, percutaneous endoscopic approach, diagnostic.
00BC4ZX	Excision of cerebellum, percutaneous endoscopic approach, diagnostic.
00BD4ZX	Excision of medulla oblongata, percutaneous endoscopic approach, diagnostic.

The requestor stated that, although percutaneous burr hole biopsies are performed through smaller openings in the skull than open burr hole biopsies, these procedures require drilling or cutting through the skull using sterile technique with anesthesia for pain control. The requestor also noted that similar procedures involving percutaneous drainage of the subdural space are currently classified as O.R. procedures in Version 35 of the ICD–10 MS–DRGs. However, these 22 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that the 22 ICD–10–PCS codes be designated as O.R. procedures and assigned to MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively).

In the proposed rule, we stated that we agreed with the requestor that these procedures typically require the resources of an operating room. Therefore, we proposed to add these 22 ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 25, 26, and 27 in MDC 1 (Diseases and Disorders of the Nervous System).

Comment: One commenter supported the proposal to change the designation of the 22 procedure codes listed in the table above to O.R. procedures.

Response: We appreciate the commenter's support.

After consideration of the public comment we received, we are finalizing our proposal to change the designation of the 22 ICD–10–PCS procedure codes shown in the table above from non-O.R. procedures to O.R. procedures, effective October 1, 2018.

b. Open Extirpation of Subcutaneous Tissue and Fascia

One requestor identified 22 ICD–10–PCS procedure codes that describe procedures involving open extirpation of subcutaneous tissue and fascia that the requestor stated would generally require the resources of an operating room. The 22 procedure codes are listed in the following table.

ICD–10–PCS procedure code	Code description
0JC00ZZ	Extirpation of matter from scalp subcutaneous tissue and fascia, open approach.
0JC10ZZ	Extirpation of matter from face subcutaneous tissue and fascia, open approach.
0JC40ZZ	Extirpation of matter from right neck subcutaneous tissue and fascia, open approach.
0JC50ZZ	Extirpation of matter from left neck subcutaneous tissue and fascia, open approach.
0JC60ZZ	Extirpation of matter from chest subcutaneous tissue and fascia, open approach.
0JC70ZZ	Extirpation of matter from back subcutaneous tissue and fascia, open approach.
0JC80ZZ	Extirpation of matter from abdomen subcutaneous tissue and fascia, open approach.
0JC90ZZ	Extirpation of matter from buttock subcutaneous tissue and fascia, open approach.
0JCB0ZZ	Extirpation of matter from perineum subcutaneous tissue and fascia, open approach.
0JCC0ZZ	Extirpation of matter from pelvic region subcutaneous tissue and fascia, open approach.
0JCD0ZZ	Extirpation of matter from right upper arm subcutaneous tissue and fascia, open approach.
0JCF0ZZ	Extirpation of matter from left upper arm subcutaneous tissue and fascia, open approach.
0JCG0ZZ	Extirpation of matter from right lower arm subcutaneous tissue and fascia, open approach.
0JCH0ZZ	Extirpation of matter from left lower arm subcutaneous tissue and fascia, open approach.
0JCJ0ZZ	Extirpation of matter from right hand subcutaneous tissue and fascia, open approach.
0JCK0ZZ	Extirpation of matter from left hand subcutaneous tissue and fascia, open approach.
0JCL0ZZ	Extirpation of matter from right upper leg subcutaneous tissue and fascia, open approach.
0JCM0ZZ	Extirpation of matter from left upper leg subcutaneous tissue and fascia, open approach.
0JCN0ZZ	Extirpation of matter from right lower leg subcutaneous tissue and fascia, open approach.
0JCP0ZZ	Extirpation of matter from left lower leg subcutaneous tissue and fascia, open approach.
0JCQ0ZZ	Extirpation of matter from right foot subcutaneous tissue and fascia, open approach.
0JCR0ZZ	Extirpation of matter from left foot subcutaneous tissue and fascia, open approach.

The requestor stated that these procedures involve making an open incision deeper than the skin under general anesthesia, and that irrigation and/or excision of devitalized tissue or cavity are often required and are considered inherent to the procedure. The requestor also stated that open drainage of subcutaneous tissue and fascia, open excisional debridement of subcutaneous tissue and fascia, and open nonexcisional debridement/extraction of subcutaneous tissue and fascia are designated as O.R. procedures, and that these 22 procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these 22 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that the 22 ICD–10–PCS procedure codes listed in the table be assigned to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, CC, and without CC/MCC, respectively).

In the proposed rule, we stated that we disagreed with the requestor that these procedures typically require the resources of an operating room. Our clinical advisors indicated that these open extirpation procedures are minor procedures that can be performed outside of an operating room, such as in a radiology suite with CT or MRI guidance. We disagreed that these procedures are similar to open drainage procedures. Therefore, we proposed to maintain the status of these 22 ICD–10–PCS procedure codes as non-O.R. procedures.

Comment: Some commenters supported the proposal to maintain the designation of the 22 identified procedure codes as non-O.R. procedures. One commenter opposed the proposal, stating that open extirpation procedures typically require the use of anesthesia and an operating room. This commenter stated that the 22 procedures are similar to open drainage, excisional debridement, and non-excisional debridement/extraction of subcutaneous tissue and fascia, which are designated as O.R. procedures.

Response: We appreciate the commenters' support. In response to the commenter who opposed the proposal, our clinical advisors continue to believe that these open extirpation procedures are minor procedures that can be performed outside of an operating room, such as in a radiology suite with CT or MRI guidance, and therefore do not require the use of an operating room. Our clinical advisors further noted that the use of anesthesia frequently occurs in a CT or MRI suite. In addition, our clinical advisors continue to disagree with the assertion that these procedures are similar to open drainage procedures because fewer resources are required for open extirpation procedures relative to open drainage procedures and the open extirpation procedures are not usually performed in the operating room.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. status of the 22 identified open extirpation procedures.

c. Open Scrotum and Breast Procedures

One requestor identified 13 ICD–10–PCS procedure codes that describe procedures involving open drainage, open extirpation, and open debridement/excision of the scrotum and breast. The requestor stated that the 13 procedures listed in the following table involve making an open incision deeper than the skin under general anesthesia, and that irrigation and/or excision of devitalized tissue or cavity are often required and are considered inherent to the procedure. The requestor also stated that open drainage of subcutaneous tissue and fascia, open excisional debridement of subcutaneous tissue and fascia, open non-excisional debridement/extraction of subcutaneous tissue and fascia, and open excision of breast are designated as O.R. procedures, and that these 13 procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these 13 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment.

ICD–10–PCS procedure code	Code description
0V950ZZ	Drainage of scrotum, open approach.
0VB50ZZ	Excision of scrotum, open approach.
0VC50ZZ	Extirpation of matter from scrotum, open approach.
0H9U0ZZ	Drainage of left breast, open approach.
0H9T0ZZ	Drainage of right breast, open approach.
0H9V0ZZ	Drainage of bilateral breast, open approach.
0H9W0ZZ	Drainage of right nipple, open approach.
0H9X0ZZ	Drainage of left nipple, open approach.
0HCT0ZZ	Extirpation of matter from right breast, open approach.
0HCU0ZZ	Extirpation of matter from left breast, open approach.
0HCV0ZZ	Extirpation of matter from bilateral breast, open approach.
0HCW0ZZ	Extirpation of matter from right nipple, open approach.
0HCX0ZZ	Extirpation of matter from left nipple, open approach.

The requestor recommended that the 3 ICD–10–PCS scrotal procedure codes be assigned to MS–DRGs 717 and 718 (Other Male Reproductive System O.R. Procedures Except Malignancy with CC/MCC and without CC/MCC, respectively) and the 10 breast procedure codes be assigned to MS–DRGs 584 and 585 (Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC and without CC/MCC, respectively).

In the proposed rule, we stated that we agreed with the requestor that these procedures typically require the resources of an operating room due to the nature of breast and scrotal tissue, as well as with the MS–DRG assignments recommended by the requestor. In addition, we stated that we believe that the scrotal codes should also be assigned to MS–DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy with CC/MCC and without CC/MCC, respectively). Therefore, we proposed to add these 13 ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 715, 716, 717, and 718 in MDC 12 (Diseases and Disorders of the Male Reproductive System) for the scrotal procedure codes and assigned to MS–DRGs 584 and 585 in MDC 9 (Diseases and Disorders of the Skin,

Subcutaneous Tissue & Breast) for the breast procedure codes.

Comment: Commenters supported the proposal to change the designation of the 13 identified procedure codes to O.R. procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 13 ICD–10–PCS procedure codes shown in the table above from non-O.R. procedures to O.R. procedures, effective October 1, 2018.

d. Open Parotid Gland and Submaxillary Gland Procedures

One requestor identified eight ICD–10–PCS procedure codes that describe procedures involving open drainage and open extirpation of the parotid or submaxillary glands, shown in the following table.

ICD–10–PCS procedure code	Code description
0C980ZZ	Drainage of right parotid gland, open approach.
0C990ZZ	Drainage of left parotid gland, open approach.
0C9G0ZZ	Drainage of right submaxillary gland, open approach.
0C9H0ZZ	Drainage of left submaxillary gland, open approach.
0CC80ZZ	Extirpation of matter from right parotid gland, open approach.
0CC90ZZ	Extirpation of matter from left parotid gland, open approach.
0CCG0ZZ	Extirpation of matter from right submaxillary gland, open approach.
0CCH0ZZ	Extirpation of matter from left submaxillary gland, open approach.

The requestor stated that these procedures involve making an open incision through subcutaneous tissue, fascia, and potentially muscle, to reach and incise the parotid or submaxillary gland under general anesthesia, and that irrigation and/or excision of devitalized tissue or cavity may be required and are considered inherent to the procedure. The requestor also stated that open drainage of subcutaneous tissue and fascia, open excisional debridement of subcutaneous tissue and fascia, and open non-excisional debridement/extraction of subcutaneous tissue and fascia are designated as O.R. procedures, and that these eight procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these eight ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor requested that these procedures be assigned to MS–DRG 139 (Salivary Gland Procedures).

In the proposed rule, we stated that we agreed with the requestor that these eight procedures typically require the resources of an operating room. Therefore, we proposed to add these ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRG 139 in MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth and Throat).

Comment: One commenter supported the proposal to change the designation of the 8 identified procedure codes to O.R. procedures.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 8 ICD–10–PCS procedure codes shown in the table above from non-O.R. procedures to O.R. procedures, effective October 1, 2018.

e. Removal and Reinsertion of Spacer; Knee Joint and Hip Joint

One requestor identified four sets of ICD–10–PCS procedure code combinations (eight ICD–10–PCS codes) that describe procedures involving open removal and insertion of spacers into the knee or hip joints, shown in the following table. The requestor stated that these are invasive procedures involving removal and reinsertion of devices into major joints and are performed in the operating room under general anesthesia. In the ICD–10 MS–DRGs Version 35, these four ICD–10–PCS procedure code combinations are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that CMS determine the most appropriate surgical DRGs for these procedures.

ICD–10–PCS procedure code	Code description
0SPC08Z	Removal of spacer from right knee joint, open approach.
0SHC08Z	Insertion of spacer into right knee joint, open approach.
0SPD08Z	Removal of spacer from left knee joint, open approach.
0SHD08Z	Insertion of spacer into left knee joint, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.
0SH908Z	Insertion of spacer into right hip joint, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.
0SHB08Z	Insertion of spacer into left hip joint, open approach.

In the proposed rule, we stated that we agreed with the requestor that these procedures typically require the resources of an operating room. However, our clinical advisors indicated that these codes should be designated as O.R. procedures even when reported as stand-alone procedures. Therefore, for the knee procedures, we proposed to add these four ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 488 and 489 (Knee Procedures without Principal diagnosis of Infection with CC/MCC and without CC/MCC, respectively), both in MDC 8 (Diseases and Disorders of the Musculoskeletal

System and Connective Tissue). For the hip procedures, we proposed to add these four ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue).

Comment: Commenters supported the proposal to change the designation of the eight identified procedure codes to O.R. procedures. Several commenters who supported the proposal also requested that CMS ensure that changing the designation to O.R. procedures not have the unintended impact of reducing payment for these procedures. These commenters also requested that CMS clarify that the proposed MS–DRG assignments only apply when the eight codes are reported as stand-alone procedures and not, for example, when a spacer is removed and a permanent joint implant is inserted. One commenter stated that additional cost data would be useful in determining whether the payment for the proposed MS–DRGs fully reflect the O.R. resources used in these procedures.

Response: We appreciate the commenters' support. With regard to the MS–DRG assignment, we are clarifying that, in all cases, the GROUPER logic would consider all of the procedures reported, the principal diagnosis, the surgical hierarchy, and the MS–DRG assignments for those procedures to determine the appropriate MS–DRG assignment. In cases where there is a procedure that is used for MS–DRG assignment that is higher in the surgical hierarchy, that procedure code would determine the MS–DRG assignment. In cases where the other procedure(s) are lower in the surgical hierarchy, the case would be assigned to the MS–DRGs listed above. With regard to the comments about the implications for payment and the cost data, we note that the goals of changing the designation of procedures from non-O.R. to O.R., or vice versa, are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system. Therefore, decisions to change an O.R. designation are based on whether such a change would accomplish those goals and not whether the change in designation would impact the payment in a particular direction.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the eight ICD–10–PCS procedure codes shown in the table above from non-O.R. procedures to O.R. procedures, effective October 1, 2018.

f. Endoscopic Dilation of Ureter(s) With Intraluminal Device

One requestor identified the following three ICD–10–PCS procedure codes that describe procedures involving endoscopic dilation of ureter(s) with intraluminal device.

ICD–10–PCS procedure code	Code description
0T778DZ	Dilation of left ureter with intraluminal device, via natural or artificial opening endoscopic.
0T768DZ	Dilation of right ureter with intraluminal device, via natural or artificial opening endoscopic.
0T788DZ	Dilation of bilateral ureters with intraluminal device, via natural or artificial opening endoscopic.

The requestor stated that these procedures involve the use of cystoureteroscopy to view the bladder and ureter and dilation under visualization, which are often followed by placement of a ureteral stent. The requestor also stated that endoscopic extirpation of matter from ureter, endoscopic biopsy of bladder, endoscopic dilation of bladder, endoscopic dilation of renal pelvis, and endoscopic dilation of the ureter without insertion of intraluminal device are all assigned to surgical DRGs, and that these three procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these three ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that these procedures be assigned to MS–DRGs 656, 657, and 658 (Kidney and Ureter Procedures for Neoplasm with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 659, 660, and 661 (Kidney and Ureter Procedures for Non-Neoplasm with MCC, with CC, and without CC/MCC, respectively).

In the proposed rule, we stated that we agreed with the requestor that these procedures typically require the resources of an operating room. In addition to the MS–DRGs recommended by the requestor, we further stated that we believe that these procedure codes should also be assigned to other MS–DRGs, consistent with the assignment of other dilation of ureter procedures: MS–DRG 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively). Therefore, we proposed to add the three ICD–10–PCS procedure codes identified by the requestor to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 656, 657, and 658 in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), MS–DRGs 659, 660, and 661 in MDC 11, MS–DRGs 907, 908, and 909 in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs), and MS–DRGs 957, 958, and 959 in MDC 24 (Multiple Significant Trauma).

Comment: One commenter supported the proposal to change the designation of the three identified procedure codes to O.R. procedures.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the three ICD–10–PCS procedure codes shown in the table above from non-O.R. procedures to O.R. procedures, effective October 1, 2018.

g. Thoracoscopic Procedures of Pericardium and Pleura

One requestor identified seven ICD–10–PCS procedure codes that describe procedures involving thoracoscopic drainage of the pericardial cavity or pleural cavity, or extirpation of matter from the pleura, as shown in the following table.

ICD–10–PCS procedure code	Code description
0W9D4ZZ	Drainage of pericardial cavity, percutaneous endoscopic approach.
0W9D40Z	Drainage of pericardial cavity with drainage device, percutaneous endoscopic approach.
0W9D4ZX	Drainage of pericardial cavity, percutaneous endoscopic approach, diagnostic.
0W994ZX	Drainage of right pleural cavity, percutaneous endoscopic approach, diagnostic.
0W9B4ZX	Drainage of left pleural cavity, percutaneous endoscopic approach, diagnostic.
0BCP4ZZ	Extirpation of matter from left pleura, percutaneous endoscopic approach.
0BCN4ZZ	Extirpation of matter from right pleura, percutaneous endoscopic approach.

The requestor stated that these procedures involve making an incision through the chest wall and inserting a thoracoscope for visualization of thoracic structures during the procedure. The requestor also stated that some thoracoscopic procedures are assigned to surgical MS–DRGs, while other procedures are assigned to medical MS–DRGs. In the ICD–10 MS–DRGs Version 35, these seven ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment.

In the proposed rule, we stated that we agreed with the requestor that these procedures typically require the resources of an operating room, as well as significant time and skill. During our review, we noted that the following two related procedures using the open approach also were not currently recognized as O.R. procedures:

ICD–10–PCS procedure code	Code description
0BCP0ZZ	Extirpation of matter from left pleura, open approach.
0BCN0ZZ	Extirpation of matter from right pleura, open approach.

Therefore, to be consistent with the MS–DRGs to which other approaches for procedures involving drainage or extirpation of matter from the pleura are assigned, we proposed to add these nine ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to one of the following MS–DRGs: MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 4 (Diseases and Disorders of the Respiratory System); MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 5 (Diseases and Disorders of the Circulatory System); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17; MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma). We invited public comments on our proposal.

Comment: One commenter supported the proposal to change the designation of the nine identified procedure codes to O.R. procedures.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the nine ICD–10–PCS procedure codes shown in the tables above from non-O.R. procedures to O.R. procedures, effective October 1, 2018.

h. Open Insertion of Totally Implantable and Tunneled Vascular Access Devices

One requestor identified 20 ICD–10–PCS procedure codes that describe procedures involving open insertion of totally implantable and tunneled vascular access devices. The codes are identified in the following table.

ICD–10–PCS procedure code	Code description
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach.
0JH60XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, open approach.
0JH80WZ	Insertion of totally implantable vascular access device into abdomen subcutaneous tissue and fascia, open approach.
0JH80XZ	Insertion of tunneled vascular access device into abdomen subcutaneous tissue and fascia, open approach.
0JHD0WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, open approach.
0JHD0XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, open approach.
0JHF0WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, open approach.
0JHF0XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, open approach.
0JHG0WZ	Insertion of totally implantable vascular access device into right lower arm subcutaneous tissue and fascia, open approach.
0JHG0XZ	Insertion of tunneled vascular access device into right lower arm subcutaneous tissue and fascia, open approach.
0JHH0WZ	Insertion of totally implantable vascular access device into left lower arm subcutaneous tissue and fascia, open approach.
0JHH0XZ	Insertion of tunneled vascular access device into left lower arm subcutaneous tissue and fascia, open approach.
0JHL0WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, open approach.
0JHL0XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, open approach.
0JHM0WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, open approach.
0JHM0XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, open approach.
0JHN0WZ	Insertion of totally implantable vascular access device into right lower leg subcutaneous tissue and fascia, open approach.

ICD–10–PCS procedure code	Code description
0JHN0XZ	Insertion of tunneled vascular access device into right lower leg subcutaneous tissue and fascia, open approach.
0JHP0WZ	Insertion of totally implantable vascular access device into left lower leg subcutaneous tissue and fascia, open approach.
0JHP0XZ	Insertion of tunneled vascular access device into left lower leg subcutaneous tissue and fascia, open approach.

The requestor stated that open procedures to insert totally implantable vascular access devices (VAD) involve implantation of a port by open approach, cutting through subcutaneous tissue/fascia, placing the device, and then closing tissues so that none of the device is exposed. The requestor explained that open procedures to insert tunneled VADs involve insertion of the catheter into central vasculature, and then open incision of subcutaneous tissue and fascia through which the device is tunneled. The requestor also indicated that these procedures require two ICD–10–PCS codes: One for the insertion of the VAD or port within the subcutaneous tissue; and one for percutaneous insertion of the central venous catheter that is connected to the device. The requestor further noted that, in MDC 11, cases with these procedure codes are assigned to surgical MS–DRGs and that insertion of infusion pumps by open approach groups to surgical MS–DRGs. The requestor recommended that these procedures be assigned to surgical MS–DRGs in MDC 09 as well. We examined the O.R. designations for this group of procedures and determined that they currently are designated as non-O.R. procedures for MDC 09 and MDC 11.

In the proposed rule, we stated that we agreed with the requestor that procedures involving open insertion of totally implantable VAD procedures typically require the resources of an operating room. However, we stated that we disagreed that the tunneled VAD procedures typically require the resources of an operating room. Therefore, we proposed to update the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index to designate the 10 ICD–10–PCS procedure codes describing the totally implantable VAD procedures as O.R. procedures, which will continue to be assigned to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures, with CC, with MCC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). We noted that these procedures already affect MS–DRG assignment to these MS–DRGs. However, we stated that if the procedure is unrelated to the principal diagnosis, it will be assigned to MS–DRGs 981, 982, and 983 instead of a medical MS–DRG.

Comment: Commenters supported the proposal to change the designation of the open insertion of totally implantable VAD procedures to O.R. procedures. One commenter requested that CMS reconsider the GROUPER logic to add totally implantable VADs to additional MDCs, and not just MDCs 9 and 11.

Response: We appreciate the commenters' support. With regard to the GROUPER logic, we will consider whether procedures should be added to additional MDCs during our annual assessment of the codes that group to the unrelated procedure MS–DRGs, which is discussed later in this section of the preamble of this final rule.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the 10 ICD–10–PCS procedure codes describing open insertion of totally implantable VAD procedures shown in the table above from non-O.R. procedures to O.R. procedures, effective October 1, 2018.

Comment: Some commenters supported the proposal to maintain the non-O.R. assignment of the tunneled VAD procedures listed in the table above, while others opposed this proposal. The commenters who opposed the proposal stated that tunneled VAD procedures involve significantly more resources than non-tunneled catheters because of the significant subcutaneous tunneling required. The commenters also noted that the procedures require the specialized setting of an operating room or interventional radiology suite. The commenters explained the following aspects of the technique that they believe indicate that the procedures should be designated as O.R. procedures: A small incision is typically made and one end of the catheter is advanced into the internal jugular vein, and threaded into the superior/inferior vena cava, or right atrium under fluoroscopic guidance. The other end of the catheter is tunneled beneath the skin and subcutaneous tissue and a small incision is made at the exit site on the chest. A small cuff is sometimes anchored to the skin to stabilize and prevent infection. While the tunneled VADs are typically performed with small incisions, the subcutaneous tunneling is the most complex portion of the procedure. In addition, one commenter listed additional tunneled VAD codes (performed on other body parts, such as the arms and legs) that should also be considered for a change to the O.R. designation.

Response: Our clinical advisors continue to believe that tunneled VAD procedures do not typically require the use of an operating room. As the commenter stated, these procedures are frequently performed under image guidance, which our clinical advisors believe would typically take place in a radiology suite. Our clinical advisors believe that the list of other VAD procedures cited by the commenter would also typically take place in the radiology suite and, therefore, would not typically require the use of an operating room. Therefore, we are not making a change to the O.R. designation of the codes suggested by the commenter.

After consideration of the public comments we received, we are finalizing our proposals to change the designation of the totally implantable VAD procedures to O.R. procedures and to maintain the non-O.R. designation of the tunneled VAD procedures.

i. Percutaneous Joint Reposition With Internal Fixation Device

One requestor identified 20 ICD–10–PCS procedure codes that describe procedures involving percutaneous joint reposition with internal fixation device, shown in the following table.

ICD–10–PCS procedure code	Code description
0SS034Z	Reposition lumbar vertebral joint with internal fixation device, percutaneous approach.
0SS334Z	Reposition lumbosacral joint with internal fixation device, percutaneous approach.
0SS534Z	Reposition sacrococcygeal joint with internal fixation device, percutaneous approach.
0SS634Z	Reposition coccygeal joint with internal fixation device, percutaneous approach.
0SS734Z	Reposition right sacroiliac joint with internal fixation device, percutaneous approach.
0SS834Z	Reposition left sacroiliac joint with internal fixation device, percutaneous approach.
0SS934Z	Reposition right hip joint with internal fixation device, percutaneous approach.
0SSB34Z	Reposition left hip joint with internal fixation device, percutaneous approach.
0SSC34Z	Reposition right knee joint with internal fixation device, percutaneous approach.
0SSD34Z	Reposition left knee joint with internal fixation device, percutaneous approach.
0SSF34Z	Reposition right ankle joint with internal fixation device, percutaneous approach.
0SSG34Z	Reposition left ankle joint with internal fixation device, percutaneous approach.
0SSH34Z	Reposition right tarsal joint with internal fixation device, percutaneous approach.
0SSJ34Z	Reposition left tarsal joint with internal fixation device, percutaneous approach.
0SSK34Z	Reposition right tarsometatarsal joint with internal fixation device, percutaneous approach.
0SSL34Z	Reposition left tarsometatarsal joint with internal fixation device, percutaneous approach.
0SSM34Z	Reposition right metatarsal-phalangeal joint with internal fixation device, percutaneous approach.
0SSN34Z	Reposition left metatarsal-phalangeal joint with internal fixation device, percutaneous approach.
0SSP34Z	Reposition right toe phalangeal joint with internal fixation device, percutaneous approach.
0SSQ34Z	Reposition left toe phalangeal joint with internal fixation device, percutaneous approach.

The requestor stated that reposition of the sacrum, femur, tibia, fibula, and other fractures of bone with internal fixation device by percutaneous approach are assigned to surgical DRGs, and that reposition of sacroiliac, hip, knee, and other joint locations with internal fixation should therefore also be assigned to surgical DRGs. In the ICD–10 MS–DRGs Version 35, these 20 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment.

In the proposed rule, we stated that we disagreed with the requestor that these procedures typically require the resources of an operating room, as these procedures are not as invasive as the bone reposition procedures referenced by the requestor. Our clinical advisors advised that these procedures are typically performed in a radiology suite. Therefore, we proposed to maintain the status of these 20 ICD–10–PCS procedure codes as non-O.R. procedures.

Comment: Some commenters supported the proposal to maintain the status of the 20 ICD–10–PCS procedure codes that describe procedures involving percutaneous joint reposition with internal fixation device listed in the table above, while one commenter opposed our proposal. The commenter who opposed the proposal stated that these procedures are often done under image guidance, but that they are typically done in the operating room because they require anesthesia. The commenter stated that these procedures involving dislocated joints are even more resource intensive than fracture treatment involving a single bone, which are classified as O.R. procedures.

Response: Our clinical advisors continue to believe that the resources involved in furnishing these procedures are consistent with non-O.R. procedures, given that they are typically done with imaging guidance. Our clinical advisors noted that it is not uncommon for anesthesia to be used in the radiology suite, and that the nature of the resources used in repositioning displaced joints do not require the use of an operating room.

After consideration of the public comments we received, we are finalizing our proposal to maintain the non-O.R. status of the 20 ICD–10–PCS procedure codes that describe procedures involving percutaneous joint reposition with internal fixation device listed in the table above.

j. Endoscopic Destruction of Intestine

One requestor identified four ICD–10–PCS procedure codes that describe procedures involving endoscopic destruction of the intestine, as shown in the following table.

ICD–10–PCS procedure code	Code description
0D5A8ZZ	Destruction of jejunum, via natural or artificial opening endoscopic.
0D5B8ZZ	Destruction of ileum, via natural or artificial opening endoscopic.
0D5C8ZZ	Destruction of ileocecal valve, via natural or artificial opening endoscopic.
0D588ZZ	Destruction of small intestine, via natural or artificial opening endoscopic.

The requestor stated that these procedures are rarely performed in the operating room. In the ICD–10 MS–DRGs Version 35, these four ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment.

In the proposed rule, we stated that we agreed with the requestor that these procedures do not typically require the resources of an operating room. Therefore, we proposed to remove these four procedure codes from the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures.

Comment: One commenter supported the proposal to change the designation of the four identified procedure codes to non-O.R. procedures.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the four ICD–10–PCS procedure codes shown in the table above from O.R. procedures to non-O.R. procedures, effective October 1, 2018.

k. Drainage of Lower Lung Via Natural or Artificial Opening Endoscopic, Diagnostic

One requestor identified the following ICD–10–PCS procedure codes that describe procedures involving endoscopic drainage of the lung via natural or artificial opening for diagnostic purposes.

ICD–10–PCS procedure code	Code description
0B9J8ZX	Drainage of left lower lung lobe, via natural or artificial opening endoscopic, diagnostic.
0B9F8ZX	Drainage of right lower lung lobe, via natural or artificial opening endoscopic, diagnostic.

The requestor stated that these procedures are rarely performed in the operating room.

In the proposed rule, we stated that we agreed with the requestor that these procedures do not require the resources of an operating room. In addition, while we were reviewing this comment, we identified three additional related codes:

ICD–10–PCS procedure code	Code description
0B9D8ZX	Drainage of right middle lung lobe, via natural or artificial opening endoscopic, diagnostic.
0B9C8ZX	Drainage of right upper lung lobe, via natural or artificial opening endoscopic, diagnostic.
0B9G8ZX	Drainage of left upper lung lobe, via natural or artificial opening endoscopic, diagnostic.

In the ICD–10 MS–DRGs Version 35, these ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment.

We proposed to remove ICD–10–PCS procedure codes 0B9J8ZX, 0B9F8ZX, 0B9D8ZX, 0B9C8ZX, and 0B9G8ZX from the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures.

Comment: One commenter supported the proposal to change the designation of the five identified procedure codes to non-O.R. procedures.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of the five ICD–10–PCS procedure codes shown in the tables above from O.R. procedures to non-O.R. procedures, effective October 1, 2018.

l. Endobronchial Valve Procedures

One commenter responding to the FY 2019 IPPS/LTCH PPS proposed rule identified eight ICD–10–PCS procedure codes that describe endobronchial valve procedures that the commenter believed should be designated as O.R. procedures. The codes are identified in the following table.

ICD–10–PCS procedure code	Code description
0BH38GZ	Insertion of endobronchial valve into right main bronchus, via natural or artificial opening endoscopic.
0BH48GZ	Insertion of endobronchial valve into right upper lobe bronchus, via natural or artificial opening endoscopic.
0BH58GZ	Insertion of endobronchial valve into right middle lobe bronchus, via natural or artificial opening endoscopic.
0BH68GZ	Insertion of endobronchial valve into right lower lobe bronchus, via natural or artificial opening endoscopic.
0BH78GZ	Insertion of endobronchial valve into left main bronchus, via natural or artificial opening endoscopic.
0BH88GZ	Insertion of endobronchial valve into left upper lobe bronchus, via natural or artificial opening endoscopic.
0BH98GZ	Insertion of endobronchial valve into lingula bronchus, via natural or artificial opening endoscopic.
0BHB8GZ	Insertion of endobronchial valve into left lower lobe bronchus, via natural or artificial opening endoscopic.

The commenter stated that these procedures are most commonly performed in the O.R., given the need for better monitoring and support through the process of identifying and occluding a prolonged air leak using endobronchial valve technology. The commenter also noted that other endobronchial valve procedures have an O.R. designation. In the ICD–10 MS–DRGs Version 35, these eight ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The commenter requested that these eight codes be assigned to MS–DRG 163 (Major Chest Procedures with MCC) due to similar cost and resource use.

Our clinical advisors disagree with the commenter that the eight identified procedures typically require the use of an operating room. Our clinical advisors believe that these procedures would typically be performed in an endoscopy suite. Therefore, we are not changing the non-O.R. designation of the eight identified ICD–10–PCS codes listed in the table above.

21. Out of Scope Public Comments Received

We received public comments regarding a number of MS–DRG and related issues that were outside the scope of the proposals included in the FY 2019 IPPS/LTCH PPS proposed rule. These comments were as follows:

- One commenter requested that CMS evaluate the MS–DRG assignment for Face Transplant procedures and its designation as an extensive versus nonextensive O.R. procedure.
- One commenter requested that a new ICD–10–CM diagnosis code be created for a Kennedy terminal ulcer.
- One commenter requested that CMS examine the MS–DRG assignment and/or payment of patients who are admitted to the hospital for initiation or titration of certain antiarrhythmic drugs.
- One commenter requested that diagnosis codes in category O9A.2- and

O9A.3- for obstetrical patients be considered as a principal diagnosis for MDC 24 (Multiple Significant Trauma).

- One commenter requested that new MS–DRGs be created for endovascular cardiac valve replacements with and without a cardiac catheterization.
- One commenter recommended that CMS analyze claims data for cases reporting renal replacement therapy and issue guidance to facilities on the use of the ICD–10–PCS procedure codes.
- One commenter requested specific MS–DRG assignments for ICD–10–PCS codes that were not yet approved at the time of issuance of the proposed rule.
- One commenter recommended changes to the severity level designation for diagnosis codes that appear in Table 6E.—Revised Diagnosis Code Titles associated with the proposed rule.

Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.F.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classification to submit these comments no later than November 1 of each year so that they can be considered for possible inclusion in the annual proposed rule and, if included, may be subjected to public review and comment. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

G. Recalibration of the FY 2019 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

In developing the FY 2019 system of weights, we proposed to use two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2017 MedPAR data used in this final rule include discharges occurring on October 1, 2016, through September 30, 2017, based on bills received by CMS through March 31, 2018, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2017 MedPAR file used in calculating the relative weights includes data for approximately 9,689,743 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 31, 2018 update of the FY 2017 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2019 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2019 relative weights are based on the ICD–10–CM diagnoses and ICD–10–PCS procedure codes from the FY 2017 MedPAR claims data, grouped through the ICD–10 version of the FY 2019 GROUPER (Version 36).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the March 31, 2018 update of the FY 2016 HCRIS for calculating the final FY 2019 cost-based relative weights.

2. Methodology for Calculation of the Relative Weights

As we explain in section II.E.2. of the preamble of this final rule, we calculated the FY 2019 relative weights based on 19 CCRs, as we did for FY 2018. The methodology we used to calculate the FY 2019 MS–DRG cost-based relative weights based on claims data in the FY 2017 MedPAR file and data from the FY 2016 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2019 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2017 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.5 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI Initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI Initiative in our ratesetting process.

The participation of hospitals in the BPCI initiative is set to conclude on September 30, 2018. The participation of hospitals in the Bundled Payments for Care Improvement (BPCI) Advanced model is set to start on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*. As we stated in the proposed rule, for FY 2019, consistent with how we have treated hospitals that participated in the BPCI Initiative, we believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted above and in the proposed rule, these hospitals are still receiving IPPS payments under section 1886(d) of the Act.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2016 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20259), we stated that if stakeholders have comments about the groupings in this table, we may consider those comments as we finalize our policy. However, we did not receive any comments on the groupings in this table, and therefore, we are finalizing the groupings as proposed.

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Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X					
	Ward Charges	015X					
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Burn Intensive Care Unit	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
				Surgical Intensive Care Unit	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
				Other Special Care Unit	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64
						C_1_C7_64	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Drugs Charged To Patient	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_73	
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623		Medical Supplies Charged to Patients	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_71	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_96	C_1_C6_96	D3_HOS_C2_96
						C_1_C7_96	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_97	C_1_C6_97	D3_HOS_C2_97
						C_1_C7_97	
Implantable Devices		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_72	
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_66	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68
						C_1_C7_68	
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_65	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
						C_1_C7_50	
		071X		Recovery Room	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51
						C_1_C7_51	
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52
						C_1_C7_52	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_53	
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69
						C_1_C7_69	
Cardiac Catheteri-zation		0481		Cardiac Catheterization	C_1_C5_59	C_1_C6_59	D3_HOS_C2_59
						C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_60	
				PBP Clinic Laboratory Services	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61
						C_1_C7_61	
		074X, 086X		Electro-Encephalography	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70
						C_1_C7_70	
Radiology	Radiology Charges	032X, 040X		Radiology – Diagnostic	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_54	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
		028x, 0331, 0332, 0333, 0335, 0339, 0342		Radiology – Therapeutic	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344		Radioisotope	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
						C_1_C7_56	
Computed Tomography (CT) Scan	CT Scan Charges	035X		Computed Tomography (CT) Scan	C_1_C5_57	C_1_C6_57	D3_HOS_C2_57
						C_1_C7_57	
Magnetic Resonance Imaging (MRI)	MRI Charges	061X		Magnetic Resonance Imaging (MRI)	C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
						C_1_C7_58	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91
						C_1_C7_91	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_62	
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63
						C_1_C7_63	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X,052X, 053X					
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X					
	Renal Dialysis	0800X		Renal Dialysis	C_1_C5_74	C_1_C6_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges	080X and 082X-088X				C_1_C7_74	
				Home Program Dialysis	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_94	
	Outpatient Service Charges	049X		ASC (Non Distinct Part)	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
	Lithotripsy Charge	079X				C_1_C7_75	
				Other Ancillary	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
						C_1_C7_76	
	Clinic Visit Charges	051X		Clinic	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90
						C_1_C7_90	
				Observation beds	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_92.01	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Professional Fees Charges	096X, 097X, and 098X		Other Outpatient Services	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_93	
	Ambulance Charges	054X		Ambulance	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_95	
				Rural Health Clinic	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88
						C_1_C7_88	
				FQHC	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_89	

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In the FY 2019 IPPS/LTCH PPS proposed rule, we also invited public comments on our proposals related to recalibration of the proposed FY 2019 relative weights and the changes in the relative weights from FY 2018.

Comment: Several commenters expressed concern about significant reductions in the relative weights for certain MS–DRGs, typically citing reductions of greater than 20 percent from FY 2018. Some commenters specifically addressed the significant reductions to MS–DRG 215. Commenters stated that the proposed payment rate for MS–DRG 215 is less than the cost of the medical devices used in these procedures, and suggested that the reduced payments resulting from the reduction in the relative weight could limit access to the procedures that map to this MS–DRG. Some commenters suggested that CMS maintain the relative weight for MS–DRG 215 at the FY 2018 level until the claims data reflects the changes in coding advice for

procedures that map to this MS–DRG. Other commenters suggested a 1-year policy for FY 2019 to ensure that the 2-year decrease in payment rates for any MS–DRG from FY 2017 does not exceed 20 percent. Yet other commenters suggested a phase-in for MS–DRGs with significant reductions to their weights to give hospitals time to modify their operations to adapt to the new rates. Commenters referenced prior rulemaking in which CMS delayed or transitioned changes impacting payment rates to limit the impact on providers.

Response: As we indicated in the FY 2018 IPPS/LTCH final rule (82 FR 38103), we do not believe it is normally appropriate to address relative weight fluctuations that appear to be driven by changes in the underlying data. Nevertheless, after reviewing the comments received and the data used in our ratesetting calculations, we acknowledge an outlier circumstance where the weight for an MS–DRG is seeing a significant reduction of at least 20 percent for each of the 2 years since CMS began using the ICD–10 data in calculating the relative weights. While we would ordinarily consider this weight change to be appropriately driven by the underlying data, given the comments received and the potential for these declines to be related to the ongoing implementation of ICD–10, we are adopting a temporary one-time measure for FY 2019 for an MS–DRG where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2019 relative weight would have declined by 20 percent or more from the FY 2018 relative weight. (We note that no FY 2018 weight declined by more than 20 percent from FY 2017 due to our FY 2018 policy.) Specifically, for an MS–DRG meeting this criterion, the FY 2019 relative weight will be set equal to the FY 2018 final relative weight. We believe this policy is consistent with our general authority to assign and update appropriate weighting factors under sections 1886(d)(4)(B) and (C) of the Act. We also believe that it appropriately addresses the situation in which the reduction to the FY 2019 relative weights may still be potentially related to the implementation of ICD–10. We continue to believe that changes in relative weights that are not of this outlier magnitude over the 2 years since we first incorporated the ICD–10 data in our ratesetting are appropriately being driven by the underlying data and not the implementation of ICD–10. There is a significant approximately 10-percentage point outlier gap between this type of reduction and any other reduction that has occurred over the 2-year period.

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2016 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

Comment: Several commenters noted that the CCRs used in the calculation of the relative weights did not match those calculated using the FY 2016 HCRIS.

Response: We appreciate the commenters bringing this issue to our attention. The commenters are correct that there was an error in the calculation of the national average CCRs in the FY 2019 proposed rule, in that we inadvertently used the FY 2015 HCRIS data rather than the FY 2016 HCRIS data. The CCRs used in the calculation of the relative weights in this final rule correctly reflect the described methodology and the FY 2016 HCRIS data.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. We calculated the transfer-adjusted discharges for use in the calculation of the Version 36 MS–DRG relative weights using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program discussed in section IV.A.2.b. of the preamble of this final rule. For the purposes of calculating the normalization factor, we used the transfer-adjusted discharges with the expanded postacute care transfer policy for Version 35 as well. (When we calculate the normalization factor, we calculate the transfer-adjusted case count for the prior GROUPER version (in this case Version 35) and multiply by the weights of that GROUPER. We then compare that pool to the transfer-adjusted case count using the new GROUPER version.) The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The FY 2019 cost-based relative weights were then normalized by an adjustment factor of 1.761194774 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 19 national average CCRs for FY 2019 are as follows:

Group	CCR
Routine Days	0.442
Intensive Days	0.368
Drugs	0.191
Supplies & Equipment	0.299
Implantable Devices	0.309
Therapy Services	0.304
Laboratory	0.113
Operating Room	0.179
Cardiology	0.103
Cardiac Catheterization	0.11
Radiology	0.145
MRIs	0.074
CT Scans	0.035
Emergency Room	0.159
Blood and Blood Products	0.296
Other Services	0.345
Labor & Delivery	0.382
Inhalation Therapy	0.156
Anesthesia	0.078

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a

threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We proposed to use that same case threshold in recalibrating the MS–DRG relative weights for FY 2019. Using data from the FY 2017 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2019, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we proposed to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2018 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown:

Low–volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS DRGs).
795	Normal Newborn	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

After consideration of the comments we received, we are finalizing our proposals, with the modification for recalibrating the relative weights for FY 2019 at the same level as the FY 2018 relative weights for MS–DRGs where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2019 relative weight would have declined by 20 percent or more from the FY 2018 relative weight.

H. Add-On Payments for New Services and Technologies for FY 2019

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs. The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to a technology that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2018 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate applications for new medical service or technology add-

on payments for FY 2019. We refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Tables.html* to download and view Table 10.

As previously stated, Table 10 that is released with each proposed and final rule contains the thresholds that we use to evaluate applications for new medical service and technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. For example, the thresholds in Table 10 released with the FY 2018 IPPS/LTCH PPS final rule are applicable to FY 2019 new technology applications. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20276), we proposed, beginning with the thresholds for FY 2020 and future years, to provide the thresholds that we previously included in Table 10 as one of our data files posted via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, which is the same URL where the impact data files associated with the rulemaking for the applicable fiscal year are posted. We stated that we believed this proposed change in the presentation of this information, specifically in the data files rather than in a Table 10, will clarify for the public that the listed thresholds will be used for new technology add-on payment applications for the next fiscal year (in this case, for FY 2020) rather than for the fiscal year that is otherwise the subject of the rulemaking (in this case, for FY 2019), while continuing to furnish the same information on the new technology add-on payment thresholds for applications for the next fiscal year as has been provided in previous fiscal years. Accordingly, we would no longer include Table 10 as one of our IPPS tables, but would instead include the thresholds applicable to the next fiscal year (beginning with FY 2020) in the data files associated with the prior fiscal year (in this case, FY 2019).

We did not receive any public comments on this proposal. Therefore, we are finalizing the proposal, without modification, and presenting the MS–DRG threshold amounts (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) that will be used in evaluating new technology add-on payment applications for FY 2020 in a data file that is available, along with the other data files associated with this FY 2019 IPPS/LTCH PPS final rule, on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or medical service.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of the year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local Medicare Administrative Contractors (MACs) (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline

and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS website, in a user friendly format. This guide was published in 2010 and is available on the CMS website at: *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf*.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov*.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20277), we noted that applicants for add-on payments for new medical services or technologies for FY 2020 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2020, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA; it is currently approved under OMB control number 0938–1347, which expires on December 31, 2020.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2019 prior to publication of the FY 2019 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on December 4, 2017 (82 FR 57275), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 13, 2018. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2019 new medical service and technology add-on payment applications before the publication of the FY 2019 IPPS/LTCH PPS proposed rule.

As stated in the proposed rule, approximately 150 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the town hall on the CMS YouTube web page at: *https://www.youtube.com/watch?v=9niqfxXe4oA&t=217s*. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of February 23, 2018, in our evaluation of the new technology add-on payment applications for FY 2019 in the FY 2019 IPPS/LTCH PPS proposed rule.

In response to the published notice and the February 13, 2018 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2019 new technology add-on payments. (We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule for summaries of the comments received in response to the published notice and the New Technology Town Hall meeting and our responses (83 FR 20278 through 20280).) We also noted in the proposed rule that we do not summarize comments that are unrelated to the ''substantial clinical improvement'' criterion. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (82 FR 57275 through 57277), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2019. Therefore, we did not summarize those written comments in the proposed rule. In section II.H.5. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule, we summarized comments regarding individual applications, or, if applicable, indicated that there were no comments received in response to the New Technology Town Hall meeting

notice, at the end of each discussion of the individual applications.

Public commenters stated opinions and made suggestions relating to the mapping of new technologies to the appropriate MS–DRG, deeming a new technology a substantial clinical improvement if it receives HDE approval from the FDA, and the use of external data in determining the cost threshold that CMS considers to be outside of the scope of the proposed rule. Because we did not request public comments nor propose to make any changes to any of the issues above, we are not summarizing these public comments, nor responding to them in this final rule. As noted below in section II.H.5.a. of the preamble of this final rule, we refer readers to section II.F.2.d. of the preamble of this final rule for a summary of and our responses to the public comments we received in response to our solicitation regarding the most appropriate mechanism to provide payment to hospitals for new technologies, such as CAR T-cell therapy drugs, including through the use of new technology add-on payments (82 FR 20294), as well as a summary of the public comments we received in response to the solicitation for public comment on our concerns with the payment alternatives that we considered for CAR T-cell therapy drugs and therapies and our responses to those comments (83 FR 20190).

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html,* including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. FY 2019 Status of Technologies Approved for FY 2018 Add-On Payments

a. Defitelio® (Defibrotide)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for FY 2017 for Defitelio® (defibrotide), a treatment for patients diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multiorgan dysfunction. VOD, also known as sinusoidal obstruction syndrome (SOS), is a potentially life-threatening complication of hematopoietic stem cell transplantation (HSCT), with an incidence rate of 8 percent to 15 percent. Diagnoses of VOD range in severity from what has been classically defined as a disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure and death. Patients treated with HSCT who develop VOD with multi-organ failure face an immediate risk of death, with a mortality rate of more than 80 percent when only supportive care is used. The applicant asserted that Defitelio® improves the survival rate of patients diagnosed with VOD with multi-organ failure by 23 percent.

Defitelio® received Orphan Drug Designation for the treatment of VOD in 2003 and for the prevention of VOD in 2007. It has been available to patients as an investigational drug through an expanded access program since 2006. The applicant's New Drug Application (NDA) for Defitelio® received FDA approval on March 30, 2016. The applicant confirmed that Defitelio® was not available on the U.S. market as of the FDA NDA approval date of March 30, 2016. According to the applicant, commercial packaging could not be completed until the label for Defitelio® was finalized with FDA approval, and that commercial shipments of Defitelio® to hospitals and treatment centers began on April 4, 2016. Therefore, we agreed that, based on this information, the newness period for Defitelio® begins on April 4, 2016, the date of its first commercial availability.

The applicant received approval to use unique ICD–10–PCS procedure codes to describe the use of Defitelio®, with an effective date of October 1, 2016. The approved ICD–10PCS procedure codes are: XW03392 (Introduction of defibrotide sodium anticoagulant into peripheral vein, percutaneous approach); and XW04392 (Introduction of defibrotide sodium anticoagulant into central vein, percutaneous approach).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Defitelio® and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Defitelio® for new technology add-on payments for FY 2017 (81 FR 56906). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 25 mg/kg/day for a minimum of 21 days of treatment. The recommended dose is 6.25 mg/kg given as a 2-hour intravenous infusion every 6 hours. Dosing should be based on a patient's baseline body weight, which is assumed to be 70 kg for an average adult patient. All vials contain 200 mg at a cost of $825 per vial. Therefore, we determined that cases involving the use of the Defitelio® technology would incur an average cost per case of $151,800 (70 kg adult × 25 mg/kg/day × 21 days = 36,750 mg per patient/200 mg vial = 184 vials per patient × $825 per vial = $151,800). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Defitelio® is $75,900.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for Defitelio®, we considered the beginning of the newness period to commence on the first day Defitelio® was commercially available (April 4, 2016). Because the 3-year anniversary date of the entry of the Defitelio® onto the U.S. market (April 4, 2019) will

occur in the latter half of FY 2019, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20280 through 20281), we proposed to continue new technology add-on payments for this technology for FY 2019. We proposed that the maximum payment for a case involving Defitelio® would remain at $75,900 for FY 2019. We invited public comments on our proposal to continue new technology add-on payments for Defitelio® for FY 2019.

Comment: A few commenters agreed with CMS' proposal to continue new technology add-on payments for Defitelio® for FY 2019. In addition, the applicant provided updated cost information that indicated, as of April 4, 2018, the current Wholesale Acquisition Cost (WAC) for Defitelio® is $875.24 per vial, which changes the average cost per case from $151,800 to $161,000 (70 kg adult × 25 mg/kg/day × 21 days = 36,750 mg per patient/200 mg vial = 184 vials per patient × $875 per vial = $161,000). As such, the applicant requested that CMS revise the maximum new technology add-on payment for Defitelio® for FY 2019 to $80,500, or increase the maximum new technology add-on payment for cases involving the use of Defitelio® to 50 percent of the revised WAC of the technology per case.

Response: We appreciate the commenters' support and the updated cost information submitted by the applicant.

After consideration of the public comments we received, we are finalizing our proposal, with modification, to continue new technology add-on payments for Defitelio® for FY 2019. Based on the applicant's updated cost information, the maximum new technology add-on payment for a case involving the use of Defitelio® is $80,500 for FY 2019.

b. EDWARDS INTUITY Elite™ Valve System (INTUITY) and LivaNova Perceval Valve (Perceval)

Two manufacturers, Edwards Lifesciences and LivaNova, submitted applications for new technology add-on payments for FY 2018 for the INTUITY Elite™ Valve System (INTUITY) and the Perceval Valve (Perceval), respectively. Both of these technologies are prosthetic aortic valves inserted using surgical aortic valve replacement (AVR). The applicant for the INTUITY valve stated that it has a unique design, which utilizes features that were not previously included in conventional aortic valves. The deployment mechanism allows for rapid deployment. The expandable frame can reshape the native valve's orifice, creating a larger and more efficiently shaped effective orifice area. In addition, the expandable skirt allows for structural differentiation upon fixation of the valve requiring 3 permanent, guiding sutures rather than the 12 to 18 permanent sutures used to fasten standard prosthetic aortic valves. The applicant for the Perceval valve described the Perceval valve as including: (a) No permanent sutures; (b) a dedicated delivery system that increases the surgeon's visibility; (c) an enabler of a minimally invasive approach; (d) a capability to promote complexity reduction and reproducibility of the procedure; and (e) a unique device assembly and delivery system.

Aortic valvular disease is relatively common, primarily manifested by aortic stenosis. Most aortic stenosis is due to calcification of the valve, either on a normal tri-leaflet valve or on a congenitally bicuspid valve. The resistance to outflow of blood is progressive over time, and as the size of the aortic orifice narrows, the heart must generate increasingly elevated pressures to maintain blood flow. Symptoms such as angina, heart failure, and syncope eventually develop, and portend a very serious prognosis. There is no effective medical therapy for aortic stenosis, so the diseased valve must be replaced or, less commonly, repaired.

According to both applicants, the INTUITY valve and the Perceval valve are the first sutureless, rapid deployment aortic valves that can be used for the treatment of patients who are candidates for surgical AVR. Because potential cases representing patients who are eligible for treatment using the INTUITY and the Perceval aortic valve devices would group to the same MS–DRGs, and we believe that these devices are intended to treat the same or similar disease in the same or similar patient population, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, we determined these two devices are substantially similar to each other and that it was appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS.

With respect to the newness criterion, the INTUITY valve received FDA approval on August 12, 2016, and was commercially available on the U.S. market on August 19, 2016. The Perceval valve received FDA approval on January 8, 2016, and was commercially available on the U.S. market on February 29, 2016. In accordance with our policy, we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38120) that we believe it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Accordingly, for both devices, we stated that the beginning of the newness period is February 29, 2016, when the Perceval valve became commercially available. The ICD–10–PCS code approved to identify procedures involving the use of both devices when surgically implanted is ICD–10–PCS code X2RF032 (Replacement of aortic valve using zooplastic tissue, rapid deployment technique, open approach, new technology group 2).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the INTUITY and Perceval valves and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved the INTUITY and Perceval valves for new technology add-on payments for FY 2018 (82 FR 38125). We stated that we believed that the use of a weighted-average of the cost of the standard valves based on the projected number of cases involving each technology to determine the maximum new technology add-on payment was most appropriate. To compute the weighted-cost average, we summed the total number of projected cases for each of the applicants, which equaled 2,429 cases (1,750 plus 679). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 72 percent for the INTUITY and 28 percent for the Perceval valve. We then multiplied the cost per case for the manufacturer specific valve by the case-weighted percentage (0.72 * $12,500 = $9,005.76 for INTUITY and 0.28 * $11,500 = $3,214.70 for the Perceval valve). This resulted in a case-weighted average cost of $12,220.46 for the valves. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the INTUITY or Perceval valves is $6,110.23 for FY 2018.

With regard to the newness criterion for the INTUITY and Perceval valves, we considered the newness period for the INTUITY and Perceval valves to begin February 29, 2016. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market

occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the technology onto the U.S. market (February 29, 2019) will occur in the first half of FY 2019, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20281), we proposed to discontinue new technology add-on payments for the INTUITY and Perceval valves for FY 2019. We invited public comments on our proposal to discontinue new technology add-on payments for the INTUITY and Perceval valves.

Comment: Some commenters supported CMS' proposal to discontinue new technology add-on payments for the INTUITY and Perceval valves and stated that the consideration of these two applications together demonstrated CMS' commitment to efficiency and optimization of the new technology add-on payment application process. Most commenters agreed that it is appropriate for the newness period to be based on the earliest anniversary date of the product's entry onto the U.S. market, given that the two technologies were evaluated and approved as one application. Other commenters disagreed with CMS' proposal to discontinue new technology add-on payments for the INTUITY and Perceval valves for reasons including the following: (1) There is no precedent for CMS to determine the 3-year anniversary date of a product's entry onto the U.S. market for two technologies that have been jointly awarded new technology add-on payments with different market availability dates; (2) it is inappropriate to choose the earliest market availability date for this class of technologies because it does not acknowledge the disparate newness periods for the two applicants; and (3) Medicare claims data and MS–DRG payment rates do not adequately reflect the additional costs of these technologies. Instead, some of these commenters suggested that the mid-point of the two commercial market availability dates for the Perceval and INTUITY valves be used as the beginning of the newness period, which would be May 25, 2016. These commenters believed that, by using the May 25, 2016 mid-point commercial market availability date, the newness period would conclude on May 25, 2019, which occurs in the second half of the fiscal year and, therefore, would allow new technology add-on payments for the Perceval and INTUITY valves to continue through FY 2019. Another commenter also disagreed with CMS' proposal to discontinue new technology add-on payments for the Perceval and INTUITY valves because the commenter believed that the commercial market availability date of February 29, 2016, is an inappropriate beginning for the newness period for the Perceval valve due to the thorough training and education process that was implemented by LivaNova, which impacted the market availability of the Perceval valve prior to April 1, 2016, and noted there were fewer than 30 Medicare patients who received implants involving the use of the Perceval valve prior to April 1, 2016.

Response: We appreciate the commenters' input. With regard to the beginning of the technology's newness period, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data begin to become available. Therefore, the precedent the commenter mentions regarding two technologies that have been jointly awarded new technology add-on payments with different commercial market availability dates is not relevant. Section 412.87(b)(2) states that a medical service or technology may be considered ''new'' within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Section 412.87(b)(2) also specifies that after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of the section. Additionally, as stated above, we have determined that the Perceval and INTUITY valves are substantially similar to each other and, therefore, we used the earliest date when data became available for the technology to determine the beginning of the newness period. Therefore, the newness period began February 29, 2016.

In addition, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute and our implementing regulations, a technology is no longer considered as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). As such, in this case, because the Perceval and INTUITY valves have been available on the U.S. market for more than 2 to 3 years, we consider the costs to have been included in the MS–DRG relative weights regardless of whether the technologies' use in the Medicare population has been frequent or infrequent.

Based on all of the reasons stated above, the Perceval and INTUITY valves are no longer considered ''new'' for purposes of new technology add-on payments for FY 2019. Therefore, after consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the Perceval and INTUITY valves for FY 2019.

c. GORE® EXCLUDER® Iliac Branch Endoprosthesis (Gore IBE Device)

W. L. Gore and Associates, Inc. submitted an application for new technology add-on payments for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (GORE IBE device) for FY 2017. The device consists of two components: The Iliac Branch Component (IBC) and the Internal Iliac Component (IIC). The applicant indicated that each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access. According to the applicant, the device is designed to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries.

With regard to the newness criterion, the applicant received FDA pre-market approval of the GORE IBE device on February 29, 2016. The following procedure codes describe the use of this technology: 04VC0EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VC3EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VC4EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VD0EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VD3EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VD4EZ (Restriction of left common iliac artery

with branched or fenestrated intraluminal device, one or two arteries, percutaneous endoscopic approach).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the GORE IBE device and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved the GORE IBE device for new technology add-on payments for FY 2017 (81 FR 56909). With the new technology add-on payment application, the applicant indicated that the total operating cost of the GORE IBE device is $10,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the GORE IBE device is $5,250.

With regard to the newness criterion for the GORE IBE device, we considered the beginning of the newness period to commence when the GORE IBE device received FDA approval on February 29, 2016. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the GORE IBE device onto the U.S. market (February 28, 2019) will occur in the first half of FY 2019, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20282), we proposed to discontinue new technology add-on payments for this technology for FY 2019. We invited public comments on our proposal to discontinue new technology add-on payments for the GORE IBE device.

Comment: The applicant (manufacturer) disagreed with CMS' proposal to discontinue new technology add-on payments for the GORE IBE device, and recommended that CMS continue new technology add-on payments for an additional year until sufficient claims data are available to reflect the cost of the technology. The applicant indicated that the FDA approval date is the date that the manufacturer may begin commercialization and actual manufacturing and marketing takes several months. As such, the applicant believed that it would be more appropriate to use the date of first sale or the date of the first procedure as the beginning of the newness period because it would more appropriately align with the point at which claims and costs data would begin to become available.

With regard to the GORE IBE device, the applicant noted that there was a deletion of ICD–10–PCS procedure codes in FY 2018 used for the coding of procedures identifying the GORE IBE implant, which created confusion for hospital billing departments that were reporting these codes. As a result, the applicant believed that the GORE IBE implant procedures may have been under-reported and the claims data has not captured the utilization and cost data for these implant procedures. Additionally, the applicant stated that MACs, as a general practice, do not include Category III CPT codes in their internal processes and, specifically, do not include 0254T for the identification of the GORE IBE procedure. The applicant believed that this lack of alignment between the new technology add-on payment policy and the MACs' treatment of Category III CPT codes for the identification of GORE IBE procedures likely contributed to the severe under-reporting of procedures involving the GORE IBE implant. Therefore, the applicant recommended that CMS maintain consistent ICD–10 coding practices, encourage the MACs to include procedures involving devices for which new technology add-on payments are effective in their internal processes, and extend new technology add-on payments for the GORE IBE technology through FY 2019 to allow assessment of sufficient claims data that reflect the costs of the GORE IBE device.

Response: We appreciate the applicant's input. As stated above, while CMS may consider a documented delay in a technology's availability on the U.S. market in determining when the newness period begins, its policy for determining whether to extend new technology add-on payments for an additional year generally applies regardless of the volume of claims for the technology after the beginning of the newness period. Similar to our discussion earlier and in the FY 2006 IPPS final rule (70 FR 47349), we do not believe that case volume is a relevant consideration for making the determination as to whether a product is considered ''new'' for purposes of new technology add-on payments. Consistent with the statute and our implementing regulations, a technology is no longer considered ''new'' once it is more than 2 to 3 years old, and the costs of the procedures are considered to be included in the relative weights irrespective of how frequently the technology has been used in the Medicare population. Additionally, since the technology is on the market coding changes or local coverage determinations typically do not delay the beginning of the newness period. Therefore, in this case, because the GORE IBE device has been available on the U.S. market for more than 2 to 3 years, we consider claims and costs data to be available for DRG recalibration of the relative weights, and the costs of the technology to have been included in the MS–DRG relative weights regardless of whether the technology's use in the Medicare population has been frequent or infrequent.

Based on the reasons stated above, the GORE IBE device is no longer considered ''new'' for purposes of new technology add-on payments for FY 2019. Therefore, after consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the GORE IBE device for FY 2019.

d. PRAXBIND (Idarucizumab)

Boehringer Ingelheim Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2017 for idarucizumab (also known as PRAXBIND), a product developed as an antidote to reverse the effects of PRADAXA (dabigatran), which is also manufactured by Boehringer Ingelheim Pharmaceuticals, Inc.

Dabigatran is an oral direct thrombin inhibitor currently indicated: (1) To reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAF); (2) for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; (3) to reduce the risk of recurrence of DVT and PE in patients who have been previously treated; and (4) for the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery. Currently, unlike the anticoagulant warfarin, there is no specific way to reverse the anticoagulant effect of dabigatran in the event of a major bleeding episode. Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of dabigatran in emergency situations.

PRAXBIND was approved by the FDA on October 16, 2015. PRAXBIND is indicated for the use in the treatment of

patients who have been administered PRADAXA when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery or urgent medical procedures or in life-threatening or uncontrolled bleeding.

The applicant was granted approval to use unique ICD–10–PCS procedure codes that became effective October 1, 2016, to describe the use of this technology. The approved ICD–10–PCS procedure codes are: XW03331 (Introduction of idarucizumab, dabigatran reversal agent into peripheral vein, percutaneous approach, new technology group 1); and XW04331 (Introduction of idarucizumab, dabigatran reversal agent into central vein, percutaneous approach, new technology group 1).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for idarucizumab and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved idarucizumab for new technology add-on payments for FY 2017 (81 FR 56897). With the new technology add-on payment application, the applicant indicated that the total operating cost of idarucizumab is $3,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving idarucizumab is $1,750.

With regard to the newness criterion for idarucizumab, we considered the beginning of the newness period to commence when PRAXBIND was approved by the FDA on October 16, 2015. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of PRAXBIND onto the U.S. market will occur in the first half of FY 2019 (October 15, 2018), in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20282), we proposed to discontinue new technology add-on payments for this technology for FY 2019. We invited public comments on our proposal to discontinue new technology add-on payments for idarucizumab.

Comment: A few commenters supported CMS' proposal to discontinue new technology add-on payments for FY 2019 for idarucizumab.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for idarucizumab for FY 2019.

e. Stelara® (Ustekinumab)

Janssen Biotech submitted an application for new technology add-on payments for the Stelara® induction therapy for FY 2018. Stelara® received FDA approval as an intravenous (IV) infusion treatment for adult patients with moderately to severe active Crohn's disease (CD) who have failed or were intolerant to treatment using immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker, or failed or were intolerant to treatment using one or more TNF blockers. The FDA approved Stelara® on September 23, 2016. Stelara® IV is intended for induction—subcutaneous prefilled syringes are intended for maintenance dosing. Stelara® must be administered intravenously by a health care professional in either an inpatient hospital setting or an outpatient hospital setting.

Stelara® for IV infusion is packaged in single 130 mg vials. Induction therapy consists of a single IV infusion dose using the following weight-based dosing regimen: Patients weighing less than (<)55 kg are administered 260 mg of Stelara® (2 vials); patients weighing more than (>)55 kg, but less than (<)85 kg are administered 390 mg of Stelara® (3 vials); and patients weighing more than (>)85 kg are administered 520 mg of Stelara® (4 vials). An average dose of Stelara® administered through IV infusion is 390 mg (3 vials). Maintenance doses of Stelara® are administered at 90 mg, subcutaneously, at 8-week intervals and may occur in the outpatient hospital setting.

CD is an inflammatory bowel disease of unknown etiology, characterized by transmural inflammation of the gastrointestinal (GI) tract. Symptoms of CD may include fatigue, prolonged diarrhea with or without bleeding, abdominal pain, weight loss and fever. CD can affect any part of the GI tract including the mouth, esophagus, stomach, small intestine, and large intestine. Conventional pharmacologic treatments of CD include antibiotics, mesalamines, corticosteroids, immunomodulators, tumor necrosis alpha (TNFα) inhibitors, and anti-integrin agents. Surgery may be necessary for some patients diagnosed with CD in which conventional therapies have failed.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Stelara® and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved Stelara® for new technology add-on payments for FY 2018 (82 FR 38129). Cases involving Stelara® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW033F3 (Introduction of other New Technology therapeutic substance into peripheral vein, percutaneous approach, new technology group 3). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 390 mg (3 vials) at a hospital acquisition cost of $1,600 per vial (for a total of $4,800). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Stelara® is $2,400.

With regard to the newness criterion for Stelara®, we considered the beginning of the newness period to commence when Stelara® received FDA approval as an IV infusion treatment of Crohn's disease (CD) on September 23, 2016. Because the 3-year anniversary date of the entry of Stelara® onto the U.S. market (September 23, 2019) will occur after FY 2019, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20282 through 20283) we proposed to continue new technology add-on payments for this technology for FY 2019. We proposed that the maximum payment for a case involving Stelara® would remain at $2,400 for FY 2019. We invited public comments on our proposal to continue new technology add-on payments for Stelara® for FY 2019.

Comment: A few commenters supported CMS' proposal to continue new technology add-on payments for Stelara® for FY 2019. In addition, the applicant (manufacturer) also agreed with CMS' proposal to continue new technology add-on payments for the Stelara® for FY 2019, and noted that because the technology's 3-year anniversary date of the product's entry onto the U.S. market would not occur until September 23, 2019, it is appropriate to continue new technology add-on payments for FY 2019.

Response: We appreciate the commenters' support. After consideration of the public comments

we received, we are finalizing our proposal to continue new technology add-on payments for Stelara® for FY 2019. The maximum payment for a case involving Stelara® will remain at $2,400 for FY 2019.

f. Vistogard™ (Uridine Triacetate)

BTG International Inc. submitted an application for new technology add-on payments for the Vistogard™ for FY 2017. Vistogard™ was developed as an emergency treatment for fluorouracil or capecitabine overdose regardless of the presence of symptoms and for those who exhibit early-onset, severe, or life-threatening toxicity.

Chemotherapeutic agent 5-fluorouracil (5-FU) is used to treat specific solid tumors. It acts upon deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in the body, as uracil is a naturally occurring building block for genetic material. Fluorouracil is a fluorinated pyrimidine. As a chemotherapy agent, fluorouracil is absorbed by cells and causes the cell to metabolize into byproducts that are toxic and used to destroy cancerous cells. According to the applicant, the byproducts fluorodoxyuridine monophosphate (F-dUMP) and floxuridine triphosphate (FUTP) are believed to do the following: (1) Reduce DNA synthesis; (2) lead to DNA fragmentation; and (3) disrupt RNA synthesis. Fluorouracil is used to treat a variety of solid tumors such as colorectal, head and neck, breast, and ovarian cancer. With different tumor treatments, different dosages, and different dosing schedules, there is a risk for toxicity in these patients. Patients may suffer from fluorouracil toxicity/death if 5-FU is delivered in slight excess or at faster infusion rates than prescribed. The cause of overdose can happen for a variety of reasons including: Pump malfunction, incorrect pump programming or miscalculated doses, and accidental or intentional ingestion.

Vistogard™ is an antidote to fluorouracil toxicity and is a prodrug of uridine. Once the drug is metabolized into uridine, it competes with the toxic byproduct FUTP in binding to RNA, thereby reducing the impact FUTP has on cell death.

With regard to the newness criterion, Vistogard™ received FDA approval on December 11, 2015. However, as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56910), due to the delay in Vistogard™'s commercial availability, we considered the newness period to begin March 2, 2016, instead of December 11, 2015. The applicant noted that the Vistogard™ is the first FDA-approved antidote used to reverse fluorouracil toxicity. The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure code: XW0DX82 (Introduction of Uridine Triacetate into Mouth and Pharynx, External Approach, new technology group 2). The new code became effective on October 1, 2016.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Vistogard™ and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Vistogard™ for new technology add-on payments for FY 2017 (81 FR 56912). With the new technology add-on payment application, the applicant stated that the total operating cost of Vistogard™ is $75,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving Vistogard™ is $37,500.

With regard to the newness criterion for the Vistogard™, we considered the beginning of the newness period to commence upon the entry of Vistogard™ onto the U.S. market on March 2, 2016. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the Vistogard™ onto the U.S. market (March 2, 2019) will occur in the first half of FY 2019, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20283), we proposed to discontinue new technology add-on payments for this technology for FY 2019. We invited public comments on our proposal to discontinue new technology add-on payments for the Vistogard™.

Comment: A few commenters supported CMS' proposal to discontinue new technology add-on payments for FY 2019 for Vistogard™.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for Vistogard™ for FY 2019.

g. ZINPLAVA™ (Bezlotoxumab)

Merck & Co., Inc. submitted an application for new technology add-on payments for ZINPLAVA™ for FY 2018. ZINPLAVA™ is indicated to reduce recurrence of *Clostridium difficile* infection (CDI) in adult patients who are receiving antibacterial drug treatment for a diagnosis of CDI who are at high risk for CDI recurrence. ZINPLAVA™ is not indicated for the treatment of the presenting episode of CDI and is not an antibacterial drug.

Clostridium difficile (*C-diff*) is a disease-causing anaerobic, spore forming bacteria that can affect the gastrointestinal (GI) tract. Some people carry the *C-diff* bacterium in their intestines, but never develop symptoms of an infection. The difference between asymptomatic colonization and pathogenicity is caused primarily by the production of an enterotoxin (Toxin A) and/or a cytotoxin (Toxin B). The presence of either or both toxins can lead to symptomatic CDI, which is defined as the acute onset of diarrhea with a documented infection with toxigenic *C-diff,* or the presence of either toxin A or B. The GI tract contains millions of bacteria, commonly referred to as ''normal flora'' or ''good bacteria,'' which play a role in protecting the body from infection. Antibiotics can kill these good bacteria and allow the *C-diff* bacteria to multiply and release toxins that damage the cells lining the intestinal wall, resulting in a CDI. CDI is a leading cause of hospital-associated gastrointestinal illnesses. Persons at increased risk for CDI include people who are treated with current or recent antibiotic use, people who have encountered current or recent hospitalization, people who are older than 65 years, immunocompromised patients, and people who have recently had a diagnosis of CDI. CDI symptoms include, but are not limited to, diarrhea, abdominal pain, and fever. CDI symptoms range in severity from mild (abdominal discomfort, loose stools) to severe (profuse, watery diarrhea, severe pain, and high fevers). Severe CDI can be life-threatening and, in rare cases, can cause bowel rupture, sepsis and organ failure. CDI is responsible for 14,000 deaths per year in the United States.

C-diff produces two virulent, pro-inflammatory toxins, Toxin A and Toxin B, which target host colonocytes (that is, large intestine endothelial cells) by binding to endothelial cell surface receptors via combined repetitive oligopeptide (CROP) domains. These toxins cause the release of inflammatory cytokines leading to intestinal fluid secretion and intestinal inflammation. The applicant asserted that ZINPLAVA™ targets Toxin B sites within the CROP domain rather than the

C-diff organism itself. According to the applicant, by targeting *C-diff* Toxin B, ZINPLAVA™ neutralizes Toxin B, prevents large intestine endothelial cell inflammation, symptoms associated with CDI, and reduces the recurrence of CDI.

ZINPLAVA™ received FDA approval on October 21, 2016, for reduction of recurrence of CDI in adult patients receiving antibacterial drug treatment for CDI and who are at high risk of CDI recurrence. ZINPLAVA™ became commercially available on February 10, 2017. Therefore, the newness period for ZINPLAVA™ began on February 10, 2017. The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure codes: XW033A3 (Introduction of bezlotoxumab monoclonal antibody, into peripheral vein, percutaneous approach, new technology group 3) and XW043A3 (Introduction of bezlotoxumab monoclonal antibody, into central vein, percutaneous approach, new technology group 3).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for ZINPLAVA™ and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved ZINPLAVA™ for new technology add-on payments for FY 2018 (82 FR 38119). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 10mg/kg of ZINPLAVA™ administered as an IV infusion over 60 minutes as a single dose. According to the applicant, the WAC for one dose is $3,800. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of ZINPLAVA™ is $1,900.

With regard to the newness criterion for ZINPLAVA™, we considered the beginning of the newness period to commence on February 10, 2017. Because the 3-year anniversary date of the entry of ZINPLAVA™ onto the U.S. market (February 10, 2020) will occur after FY 2019, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20283 through 20284), we proposed to continue new technology add-on payments for this technology for FY 2019. We proposed that the maximum payment for a case involving ZINPLAVA™ would remain at $1,900 for FY 2019. We invited public comments on our proposal to continue new technology add-on payments for ZINPLAVA™ for FY 2019.

Comment: A few commenters supported CMS' proposal to continue new technology add-on payments for ZINPLAVA™ for FY 2019.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for ZINPLAVA™ for FY 2019. The maximum new technology add-on payment for a case involving ZINPLAVA™ will remain at $1,900 for FY 2019.

5. FY 2019 Applications for New Technology Add-On Payments

We received 15 applications for new technology add-on payments for FY 2019. In accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year that the application is being considered. Since the issuance of the FY 2019 IPPS/LTCH PPS proposed rule, three applicants, Progenics Pharmaceuticals, Inc. (the applicant for AZEDRA®), Somahlution, Inc. (the applicant for DURAGRAFT®), and TherOx, Inc. (the applicant for Supersaturated Oxygen (SSO_2) Therapy), withdrew their applications. One applicant, Isoray Medical, Inc. and GT Medical Technologies, Inc. (the applicant for GammaTile™), did not meet the deadline of July 1 for FDA approval or clearance of the technology and, therefore, the technology is not eligible for consideration for new technology add-on payments for FY 2019. A discussion of the remaining 11 applications is presented below.

a. KYMRIAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel)

Two manufacturers, Novartis Pharmaceuticals Corporation and Kite Pharma, Inc. submitted separate applications for new technology add-on payments for FY 2019 for KYMRIAH (tisagenlecleucel) and YESCARTA (axicabtagene ciloleucel), respectively. Both of these technologies are CD–19-directed T-cell immunotherapies used for the purposes of treating patients with aggressive variants of non-Hodgkin lymphoma (NHL). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20284), we noted that KYMRIAH was approved by the FDA on August 30, 2017, for use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse, which is a different indication and patient population than the new indication and targeted patient population for which the applicant submitted a request for approval of new technology add-on payments for FY 2019. Specifically, and as summarized in a table presented in the proposed rule and updated in the following table presented in this final rule, the new indication for which Novartis Pharmaceuticals Corporation is requesting approval for new technology add-on payments for KYMRIAH is as an autologous T-cell immune therapy indicated for use in the treatment of patients with relapsed/refractory (r/r) diffuse large B-Cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not eligible for autologous stem cell transplant (ASCT). In addition, we indicated that as of the time of the development of the proposed rule, Novartis Pharmaceuticals Corporation had been granted Breakthrough Therapy designation by the FDA, and was awaiting FDA approval for the use of KYMRIAH under this new indication. The updated table that follows reflects that Novartis Pharmaceuticals Corporation received FDA approval for the use of KYMRIAH under this new indication on May 1, 2018. We also noted that Kite Pharma, Inc. previously submitted an application for approval for new technology add-on payments for FY 2018 for KTE–C19 for use as an autologous T-cell immune therapy in the treatment of adult patients with r/r aggressive B-cell NHL who are ineligible for ASCT. However, Kite Pharma, Inc. withdrew its application for KTE–C19 prior to publication of the FY 2018 IPPS/LTCH PPS final rule. Kite Pharma, Inc. resubmitted an application for approval for new technology add-on payments for FY 2019 for KTE–C19 under a new name, YESCARTA, for the same indication. Kite Pharma, Inc. received FDA approval for this original indication and treatment use of YESCARTA on October 18, 2017. (We refer readers to the following updated table for a comparison of the indications and FDA approvals for KYMRIAH and YESCARTA).

COMPARISON OF INDICATION AND FDA APPROVAL FOR KYMRIAH AND YESCARTA

FY 2019 applicant technology name	Description of indication for which new technology add-on payments are being requested	FDA approval status
KYMRIAH (Novartis Pharmaceuticals Corporation).	KYMRIAH: Autologous T-cell immune therapy indicated for use in the treatment of patients with relapsed/refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B cell lymphoma (DLBCL) not eligible for autologous stem cell transplant (ASCT).	FDA approval received 5/1/2018.
YESCARTA (Kite Pharma, Inc.).	YESCARTA: Autologous T-cell immune therapy indicated for use in the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.	FDA approval received 10/18/2017.
Technology approved for other indications	Description of other indication	FDA approval of other indication
KYMRIAH (Novartis Pharmaceuticals Corporation).	KYMRIAH: CD–19-directed T-cell immunotherapy indicated for the use in the treatment of patients up to 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse.	FDA approval received 8/30/2017.
YESCARTA (Kite Pharma, Inc.).	None	N/A.

We note that procedures involving the KYMRIAH and YESCARTA therapies are both reported using the following ICD–10–PCS procedure codes: XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3); and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3). We further note that, in section II.F.2.d. of the preamble of this final rule, we are finalizing our proposal to assign cases reporting these ICD–10–PCS procedure codes to Pre-MDC MS–DRG 016 for FY 2019 and to revise the title of this MS–DRG to (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy). We refer readers to section II.F.2.d. of the preamble of this final rule for a complete discussion of these final policies.

According to the applicants, patients with NHL represent a heterogeneous group of B-cell malignancies with varying patterns of behavior and response to treatment. B-cell NHL can be classified as either an aggressive, or indolent disease, with aggressive variants including DLBCL; primary mediastinal large B-cell lymphoma (PMBCL); and transformed follicular lymphoma (TFL). Within diagnoses of NHL, DLBCL is the most common subtype of NHL, accounting for approximately 30 percent of patients who have been diagnosed with NHL, and survival without treatment is measured in months.[6] Despite improved therapies, only 50 to 70 percent of newly diagnosed patients are cured by standard first-line therapy alone. Furthermore, r/r disease continues to carry a poor prognosis because only 50 percent of patients are eligible for autologous stem cell transplantation (ASCT) due to advanced age, poor functional status, comorbidities, inadequate social support for recovery after ASCT, and provider or patient choice.[7] [8] [9] [10] Of the roughly 50 percent of patients that are eligible for ASCT, nearly 50 percent fail to respond to prerequisite salvage chemotherapy and cannot undergo ASCT.[11] [12] [13] [14] Second-line chemotherapy regimens studied to date include rituximab, ifosfamide, carboplatin and etoposide (R–ICE), and rituximab, dexamethasone, cytarabine, and cisplatin (R–DHAP), followed by consolidative high-dose therapy (HDT)/ASCT. Both regimens offer similar overall response rates (ORR) of 51 percent with 1 in 4 patients achieving long-term complete response (CR) at the expense of increased toxicity.[15] Second-line treatment with dexamethasone, high-dose cytarabine, and cisplatin (DHAP) is considered a standard chemotherapy regimen, but is associated with substantial treatment-related toxicity.[16] For patients who experience disease progression during or after primary treatment, the combination of HDT/ASCT remains the only curative option.[17] According to the applicants, given the modest response to second-line therapy and/or HDT/ASCT, the population of patients with the highest unmet need is those with chemorefractory disease, which include DLBCL, PMBCL, and TFL. These

[6] Chaganti, S., et al., ''Guidelines for the management of diffuse large B-cell lymphoma,'' BJH Guideline, 2016. Available at: *www.bit.do/bsh-guidelines*.

[7] Matasar, M., et al., ''Ofatumumab in combination with ICE or DHAP chemotherapy in relapsed or refractory intermediate grade B-cell lymphoma,'' *Blood,* 25 July 2013, vol. 122, No 4.

[8] Hitz, F., et al., ''Outcome of patients with chemotherapy refractory and early progressive diffuse large B cell lymphoma after R–CHOP treatment,'' *Blood* (American Society of Hematology (ASH) annual meeting abstracts, poster session), 2010, pp. 116 (abstract #1751).

[9] Telio, D., et al., ''Salvage chemotherapy and autologous stem cell transplant in primary refractory diffuse large B-cell lymphoma: outcomes and prognostic factors,'' *Leukemia & Lymphoma,* 2012, vol. 53(5), pp. 836–41.

[10] Moskowitz, C.H., et al., ''Ifosfamide, carboplatin, and etoposide: a highly effective cytoreduction and peripheral-blood progenitor-cell mobilization regimen for transplant-eligible patients with non-Hodgkin's lymphoma,'' *Journal of Clinical Oncology,* 1999, vol. 17(12), pp. 3776–85.

[11] Crump, M., et al., ''Outcomes in patients with refractory aggressive diffuse large B-cell lymphoma (DLBCL): results from the international scholar-1 study,'' Abstract and poster presented at Pan Pacific Lymphoma Conference (PPLC), July 2016.

[12] Gisselbrecht, C., et al., ''Results from SCHOLAR–1: outcomes in patients with refractory aggressive diffuse large B-cell lymphoma (DLBCL),'' Oral presentation at European Hematology Association conference, July 2016.

[13] Iams, W., Reddy, N., ''Consolidative autologous hematopoietic stem-cell transplantation in first remission for non-Hodgkin lymphoma: current indications and future perspective,'' *Ther Adv Hematol,* 2014, vol. 5(5), pp. 153–67.

[14] Kantoff, P.W., et al., ''Sipuleucel-T immunotherapy for castration-resistant prostate cancer,'' *N Engl J Med,* 2010, vol. 363, pp. 411–422.

[15] Rovira, J., Valera, A., Colomo, L., et al., ''Prognosis of patients with diffuse large B cell lymphoma not reaching complete response or relapsing after frontline chemotherapy or immunochemotherapy,'' *Ann Hematol,* 2015, vol. 94(5), pp. 803–812.

[16] Swerdlow, S.H., Campo, E., Pileri, S.A., et al., ''The 2016 revision of the World Health Organization classification of lymphoid neoplasms,'' *Blood,* 2016, vol. 127(20), pp. 2375–2390.

[17] Koristka, S., Cartellieri, M., Arndt, C., et al., ''Tregs activated by bispecific antibodies: killers or suppressors?,'' *OncoImmunology,* 2015, vol. (3):e994441, DOI: 10.4161/2162402X.2014.994441.

patients are defined as either progressive disease (PD) as best response to chemotherapy, stable disease as best response following greater than or equal to 4 cycles of first-line or 2 cycles of later-line therapy, or relapse within less than or equal to 12 months of ASCT.[18] Based on these definitions and available data from a multi-center retrospective study (SCHOLAR–1), chemorefractory disease treated with current and historical standards of care has consistently poor outcomes with an ORR of 26 percent and median overall survival (OS) of 6.3 months.[19]

According to Novartis Pharmaceuticals Corporation, the recent FDA approval (on May 1, 2018) for the additional indication allows KYMRIAH to be used for the treatment of patients with R/R DLBCL who are not eligible for ASCT. Novartis Pharmaceuticals Corporation describes KYMRIAH as a CD–19-directed genetically modified autologous T-cell immunotherapy which utilizes peripheral blood T-cells, which have been reprogrammed with a transgene encoding, a chimeric antigen receptor (CAR), to identify and eliminate CD–19-expressing malignant and normal cells. Upon binding to CD–19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination, and persistence of KYMRIAH cells. The transduced T-cells expand in vivo to engage and eliminate CD–19-expressing cells and may exhibit immunological endurance to help support long-lasting remission.[20] [21] [22] [23] At the time the applicant submitted its application for new technology add-on payments, the applicant conveyed that no other agent currently used in the treatment of patients with r/r DLBCL employs gene modified autologous cells to target and eliminate malignant cells.

According to Kite Pharma, Inc., YESCARTA is indicated for the use in the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, PMBCL, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. YESCARTA is not indicated for the treatment of patients with primary central nervous system lymphoma. The applicant for YESCARTA described the technology as a CD–19-directed genetically modified autologous T-cell immunotherapy that binds to CD–19-expressing cancer cells and normal B-cells. These normal B-cells are considered to be non-essential tissue, as they are not required for patient survival. According to the applicant, studies demonstrated that following anti-CD–19 CAR T-cell engagement with CD–19-expressing target cells, the CD–28 and CD–3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines. This sequence of events leads to the elimination of CD–19-expressing tumor cells.

Both applicants expressed that their technology is the first treatment of its kind for the targeted adult population. In addition, both applicants asserted that their technology is new and does not use a substantially similar mechanism of action or involve the same treatment indication as any other currently FDA-approved technology. In the FY 2019 IPPS/LTCH PPS proposed rule, we noted that, at the time each applicant submitted its new technology add-on payment application, neither technology had received FDA approval for the indication for which the applicant requested approval for the new technology add-on payment. We indicated that KYMRIAH had been granted Breakthrough Therapy designation for the use in the treatment of patients for the additional indication that is the subject of its new technology add-on application and, as of the time of the development of the proposed rule, was awaiting FDA approval. As noted previously, the applicant for KYMRIAH received approval for this additional indication on May 1, 2018. We further noted in the proposed rule that, YESCARTA received FDA approval for use in the treatment of patients and the indication stated in its application on October 18, 2017, after each applicant submitted its new technology add-on payment application.

As noted, according to both applicants, KYMRIAH and YESCARTA are the first CAR T-cell immunotherapies of their kind. Because potential cases representing patients who may be eligible for treatment using KYMRIAH and YESCARTA would group to the same MS–DRGs (because the same ICD–10–CM diagnosis codes and ICD–10–PCS procedures codes are used to report treatment using either KYMRIAH or YESCARTA), and we believed that these technologies are intended to treat the same or similar disease in the same or similar patient population, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, we disagreed with the applicants and believed these two technologies are substantially similar to each other and that it was appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. For these reasons, and as discussed further below, we stated that we intended to make one determination regarding approval for new technology add-on payments that would apply to both applications, and in accordance with our policy, would use the earliest market availability date submitted as the beginning of the newness period for both KYMRIAH and YESCARTA. Several public commenters submitted comments regarding whether the technologies are substantially similar to each other in response to the proposed rule and we summarize and respond to the public comments below.

With respect to the newness criterion, as previously stated, YESCARTA received FDA approval on October 18, 2017. According to the applicant, prior to FDA approval, YESCARTA had been available in the U.S. only on an investigational basis under an investigational new drug (IND) application. For the same IND patient population, and until commercial availability, YESCARTA was available under an Expanded Access Program (EAP) which started on May 17, 2017. The applicant stated that it did not recover any costs associated with the EAP. According to the applicant, the first commercial shipment of YESCARTA was received by a certified treatment center on November 22, 2017. As discussed previously, KYMRIAH received FDA approval May 1, 2018, for use in the treatment of patients diagnosed with r/r DLBCL that are not eligible for ASCT. Additionally, as noted in the proposed rule, KYMRIAH was previously granted Breakthrough Therapy designation by the FDA. We stated in the proposed rule that we believe that, in accordance with our policy, if these technologies are substantially similar to each other, it is appropriate to use the earliest market

[18] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood-2017–03–769620.

[19] Ibid.

[20] KYMRIAH™ [prescribing information], East Hanover, NJ: Novartis Pharmaceuticals Corp, 2017.

[21] Kalos, M., Levine, B.L., Porter, D.L., et al., ''T-cells with chimeric antigen receptors have potent antitumor effects and can establish memory in patients with advanced leukemia,'' *Sci Transl M*ed, 2011, vol. 3(95), pp, 95ra73.

[22] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[23] Wang, X., Riviere, I., ''Clinical manufacturing of CART cells: foundation of a promising therapy,'' *Mol Ther Oncolytics,* 2016, vol. 3, pp. 16015.

availability date submitted as the beginning of the newness period for both technologies. Therefore, based on our policy, with regard to both technologies, if the technologies are approved for new technology add-on payments, we stated that we believe that the beginning of the newness period would be November 22, 2017.

We stated in the proposed rule that, because we believe these two technologies are substantially similar to each other, we believe it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discussed each set of data separately. However, we stated that we intended to make one determination regarding new technology add-on payments that would apply to both applications. We stated that we believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and we believe that continuing our current practice of extending new technology add-on payments without a further application from the manufacturer of the competing product, or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products to submit separate new technology add-on payment applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

We stated that, if substantially similar technologies are submitted for review in different (and subsequent) years, rather than the same year, we would evaluate and make a determination on the first application and apply that same determination to the second application. However, we stated that, because the technologies have been submitted for review in the same year and we believe they are substantially similar to each other, we believe that it is appropriate to consider both sets of cost data and clinical data in making a determination, and we do not believe that it is possible to choose one set of data over another set of data in an objective manner. We received public comments regarding our proposal to evaluate KYMRIAH and YESCARTA as one application for new technology add-on payments under the IPPS and we summarize and respond to these public comments below.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20284), we stated that we believe that KYMRIAH and YESCARTA are substantially similar to each other for purposes of analyzing these two applications as one application. As discussed in the proposed rule, we stated that we also need to determine whether KYMRIAH and YESCARTA are substantially similar to existing technologies prior to their approval by the FDA and their release onto the U.S. market. As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant for KYMRIAH asserted that its unique design, which utilizes features that were not previously included in traditional cytotoxic chemotherapeutic or immunotherapeutic agents, constitutes a new mechanism of action. The deployment mechanism allows for identification and elimination of CD–19-expressing malignant and non-malignant cells, as well as possible immunological endurance to help support long-lasting remission.[24] [25] [26] [27] The applicant provided context regarding how KYMRIAH's unique design contributes to a new mechanism of action by explaining that peripheral blood T-cells, which have been reprogrammed with a transgene encoding, a CAR, identify and eliminate CD–19-expressing malignant and nonmalignant cells. As explained by the applicant, upon binding to CD–19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination, and persistence of KYMRIAH cells.[28] [29] [30] According to the applicant, transduced T-cells expand in vivo to engage and eliminate CD–19-expressing cells and may exhibit immunological endurance to help support long-lasting remission.[31] [32] [33]

The applicant for YESCARTA stated that YESCARTA is the first engineered autologous cellular immunotherapy comprised of CAR T-cells that recognizes CD–19 express cancer cells and normal B-cells with efficacy in patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, PMBCL, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma as demonstrated in a multi-centered clinical trial. Therefore, the applicant believed that YESCARTA's mechanism of action is distinct and unique from any other cancer drug or biologic that is currently approved for use in the treatment of patients who have been diagnosed with aggressive B-cell NHL, namely single-agent or combination chemotherapy regimens. At the time of the development of the proposed rule, the applicant also pointed out that YESCARTA was the only available therapy that has been granted FDA approval for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, PMBCL, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

With respect to the second and third criteria, whether a product is assigned to the same or a different MS–DRG and whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant

[24] KYMRIAH [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2017.

[25] Kalos, M., Levine, B.L., Porter, D.L., et al., ''T cells with chimeric antigen receptors have potent antitumor effects and can establish memory in patients with advanced leukemia,'' *Sci Transl Med,* 2011, vol. 3(95), pp. 95ra73.

[26] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[27] Maude, S.L., Frey, N., Shaw, P.A., et al., ''Chimeric antigen receptor T cells for sustained remissions in leukemia,'' *N Engl J Med,* 2014, vol. 371(16), pp. 1507–1517.

[28] KYMRIAH™ [prescribing information], East Hanover, NJ: Novartis Pharmaceuticals Corp, 2017.

[29] Kalos, M., Levine, B.L., Porter, D.L., et al., ''T-cells with chimeric antigen receptors have potent antitumor effects and can establish memory in patients with advanced leukemia,'' *Sci Transl Med,* 2011, 3(95), pp, 95ra73.

[30] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[31] Kalos, M., Levine, B.L., Porter, D.L., et al., ''T cells with chimeric antigen receptors have potent antitumor effects and can establish memory in patients with advanced leukemia,'' *Sci Transl Med,* 2011, vol. 3(95), pp. 95rs73.

[32] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[33] Maude, S.L., Frey, N., Shaw, P.A., et al., ''Chimeric antigen receptor T-cells for sustained remissions in leukemia,'' *N Engl J Med,* 2014, vol. 371(16) pp. 1507–1517.

for KYMRIAH indicated that the technology is used in the treatment of the same patient population, and potential cases representing patients that may be eligible for treatment using KYMRIAH would be assigned to the same MS–DRGs as cases involving patients with a DLBCL diagnosis. Potential cases representing patients that may be eligible for treatment using KYMRIAH map to 437 separate MS–DRGs, with the top 20 MS–DRGs covering approximately 68 percent of all patients who have been diagnosed with DLBCL. For patients with DLBCL and who have received chemotherapy during their hospital stay, the target population mapped to 8 separate MS–DRGs, with the top 2 MS–DRGs covering over 95 percent of this population: MS–DRGs 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC), and 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC). The applicant for YESCARTA submitted findings that potential cases representing patients that may be eligible for treatment using YESCARTA span 15 unique MS–DRGs, 8 of which contain more than 10 cases. The most common MS–DRGs were: MS–DRGs 840 (Lymphoma and Non-Acute Leukemia with MCC), 841 (Lymphoma and Non-Acute Leukemia with CC), and 823 (Lymphoma and Non-Acute Leukemia with other O.R. Procedures with MCC). These 3 MS–DRGs accounted for 628 (76 percent) of the 827 cases. While the applicants for KYMRIAH and YESCARTA submitted different findings regarding the most common MS–DRGs to which potential cases representing patients who may be eligible for treatment involving their technology would map, we stated in the proposed rule that we believe that, under the current MS–DRGs (FY 2018), potential cases representing patients who may be eligible for treatment involving either KYMRIAH or YESCARTA would map to the same MS–DRGs because the same ICD–10–CM diagnosis codes and ICD–10–PCS procedures codes will be used to report cases for patients who may be eligible for treatment involving KYMRIAH and YESCARTA. Furthermore, as noted above, we proposed, and are finalizing, that cases reporting these ICD–10–PCS procedure codes would be assigned to MS–DRG 016 for FY 2019. Therefore, under this proposal (and our finalized policy), for FY 2019, cases involving the utilization of KYMRIAH and YESCARTA would continue to map to the same MS–DRGs.

The applicant for YESCARTA also addressed the concern expressed by CMS in the FY 2018 IPPS/LTCH PPS proposed rule regarding Kite Pharma Inc.'s FY 2018 new technology add-on payment application for the KTE–C19 technology (82 FR 19888). At the time, CMS expressed concern that KTE–C19 may use the same or similar mechanism of action as the Bi-Specific T-Cell engagers (BiTE) technology. The applicant for YESCARTA explained that YESCARTA has a unique and distinct mechanism of action that is substantially different from BiTE's or any other drug or biologic currently assigned to any MS–DRG in the FY 2016 MedPAR Hospital Limited Data Set. In providing more detail regarding how YESCARTA is different from the BiTE technology, the applicant explained that the BiTE technology is not an engineered autologous T-cell immunotherapy derived from a patient's own T-cells. Instead, it is a bi-specific T-cell engager that recognizes CD–19 and CD–3 cancer cells. Unlike engineered T-cell therapy, BiTE does not have the ability to enhance the proliferative and cytolytic capacity of T-cells through ex-vivo engineering. Further, BiTE is approved for the treatment of patients who have been diagnosed with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and is not approved for patients with relapsed or refractory large B-cell lymphoma, whereas YESCARTA is indicated for use in the treatment of adult patients with r/r aggressive B-cell NHL who are ineligible for ASCT.

The applicant for YESCARTA also indicated that its mechanism of action is not the same or similar to the mechanism of action used by KYMRIAH's currently available FDA-approved CD–19-directed genetically modified autologous T-cell immunotherapy indicated for use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.[34] The applicant for YESCARTA stated that the mechanism of action is different from KYMRIAH's FDA-approved therapy because the spacer, transmembrane and co-stimulatory domains of YESCARTA are different from those of KYMRIAH. The applicant explained that YESCARTA is comprised of a CD–28 co-stimulatory domain and KYMRIAH has 4–1BB co-stimulatory domain. Further, the applicant stated the manufacturing processes of the two immunotherapies are also different, which may result in cell composition differences leading to possible efficacy and safety differences.

We stated in the proposed rule that while the applicant for YESCARTA stated how its technology is different from KYMRIAH, because both technologies are CD–19-directed T-cell immunotherapies used for the purpose of treating patients with aggressive variants of NHL, we believe that YESCARTA and KYMRIAH are substantially similar treatment options. Furthermore, in the FY 2019 IPPS/LTCH PPS proposed rule, we also stated that we were concerned there may be an age overlap (18 to 25) between the two different patient populations for the currently approved KYMRIAH technology and YESCARTA technology. We stated in the proposed rule, which was issued prior to the approval for a second indication (adult patients), that the indication for the KYMRIAH technology is for use in the treatment of patients who are up to 25 years of age and the YESCARTA technology is indicated for use in the treatment of adult patients.

We noted in the proposed rule that the applicant asserted that YESCARTA is not substantially similar to KYMRIAH. We stated that under this scenario, if both YESCARTA and KYMRIAH meet all of the new technology add-on payment criteria and are approved for new technology add-on payments for FY 2019, for purposes of making the new technology add-on payment, because procedures utilizing either YESCARTA or KYMRIAH CAR T-cell therapy drugs are reported using the same ICD–10–PCS procedure codes, in order to accurately pay the new technology add-on payment to hospitals that perform procedures utilizing either technology, it may be necessary to use alternative coding mechanisms to make the new technology add-on payments. In the FY 2019 IPPS/LTCH PPS proposed rule, CMS invited comments on alternative coding mechanisms to make the new technology add-on payments, if necessary.

We also invited public comments on whether KYMRIAH and YESCARTA are substantially similar to existing technologies and whether the technologies meet the newness criterion.

Comment: The applicants for KYMRIAH and YESCARTA each provided comments regarding whether KYMRIAH and YESCARTA were substantially similar to the other, or to any existing technology. Additional commenters also submitted comments.

[34] Food and Drug Administration. Available at: *www.accessdata.fda.gov/scripts/opdlisting/oopd/.*

The applicant for YESCARTA stated that it continued to believe each technology consists of notable differences in the construction, as well as manufacturing processes and successes that may lead to differences in activity. The applicant encouraged CMS to evaluate YESCARTA as a separate new technology add-on payment application and approve separate new technology add-on payments for YESCARTA, effective October 1, 2018, and to not move forward with a single new technology add-on payment evaluation determination that covers both CAR T-cell therapies, YESCARTA and KYMRIAH. The applicant stated that the transmembrane domain of YESCARTA is comprised of a fragment of CD–28 co-stimulatory molecule, including an extracellular hinge domain, which provides structural flexibility for optimal binding of the target antigen by the scFV target binding region. The applicant further stated that, in contrast, KYMRIAH consists of a spacer and a transmembrane domain, which are derived from CD8-a. The applicant for YESCARTA believed that, the spacer provides a flexible link between the scFv and the transmembrane domain, which then accommodates different orientations of the antigen binding domain upon CD19 antigen recognition. The applicant stated that these differences in the origin of the transmembrane component between the YESCARTA and KYMRIAH may be one of the differences which lead to differentiation in CAR function and resulting activity between the two CAR constructs, which will be described later in this section.

The applicant for YESCARTA believed perhaps the most critical difference between the two technologies, YESCARTA and KYMRIAH, may be that of the co-stimulatory domains, which connect the extracellular scFv antigen binding domain to the cytoplasmic CD3-zeta downstream signaling domain. The applicant explained that, for YESCARTA, the technology is derived from the intracellular domains of co-stimulatory protein CD–28. However, for KYMRIAH, in contrast, the technology is derived from the co-stimulatory protein 4–1BB (CD137). The applicant believed that, although clear mechanisms are unknown, it is surmised that the difference in co-stimulatory region of the two CAR products may be responsible for differences in activity. The applicant stated that the ongoing hypothesis for these differences are based on differentially affecting CAR T-cell cytokine production, expansion, cytotoxicity and persistence after administration.

The applicant for YESCARTA also described an additional concept regarding the manufacturing process that it believed supported why the two technologies were different. The applicant explained that both, YESCARTA and KYMRIAH, are prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. However, the applicant stated that, with YESCARTA, the mononuclear cells are then enriched for T-cells and activated with anti-CD–3 antibody in the presence of IL–2 then transduced with the replication incompetent y-retroviral vector containing the anti-CD–19 CAR transgene. The applicant further explained that the transduced T-cells are expanded in cell culture, washed, formulated into a suspension, and cryopreserved. The applicant for YESCARTA believed that, in contrast, KYMRIAH uses anti CD–3/anti CD–28 coated magnetic beads for T-cell enrichment and activation, rather than anti-CD–3 antibody and IL–2, which are removed after CAR T-cell expansion and prior to harvest. The applicant explained that a further difference in the manufacturing of KYMRIAH is the use of lentiviral vector in the anti-CD–19 CAR gene transduction rather than a y-retroviral vector, as used for YESCARTA in manufacturing. The applicant stated that both y-retroviral or lentiviral vectors can permanently insert DNA into the genome. However, lentiviral vectors are capable of transducing quiescent cells, while y-retroviral vectors require cells in mitosis. According to the applicant, the manufacturing success in clinical trials is also different with results showing median turnaround time of 17 days for YESCARTA, with 99 percent success rate versus median turnaround time of 113 days, with 93 percent success rate for KYMRIAH.

The applicant for YESCARTA further stated that, if CMS decides to establish one new technology add-on payment determination and approval for both CAR T-cell therapies, the add-on payments should be structured to ensure that payment does not hinder access in any way for patients to receive the most appropriate cell therapy and use of YESCARTA and KYMRIAH can be uniquely and individually identified in the Medicare inpatient data.

Other commenters believed that the two CAR T-cell technologies should be considered as separate new technology add-on payment applications because the technologies' indications are approved for two different patient populations and diagnoses. The commenters stated that, while the approval for one of the diagnoses for adults is the same for KYMRIAH and YESCARTA, KYMRIAH has also been approved for treating children and, therefore, that should be reasoning to consider the application separately. Additionally, commenters stated that the pricing of both medications varies based on the patient population, and encouraged CMS to recognize this discrepancy when determining approval of new technology add-on payment and establishing adequate payments rates. Commenters agreed with CMS' conclusion that it is appropriate to consider both sets of cost and clinical data when determining whether the standard criteria for new technology add-on payments for KYMRIAH and YESCARTA were met, but also encouraged CMS to consider evaluation and determination of both technologies as separate applications.

Some commenters disagreed with CMS' views of the YESCARTA and KYMRIAH with respect to substantial similarity and expressed concerns with CMS' conclusion that the two CAR T-cell therapies are substantially similar to each other. The commenters believed that, because each therapy has received separate FDA Breakthrough designations, is approved based on separate Biological License Applications, and may likely be used in the treatment of different patient populations in different sites of care, consideration for approval of new technology add-on payments should be based on separate applications. Commenters further believed that, for purposes of meeting the newness criterion, each new technology add-on payment application must be treated as being unique. Despite these concerns, commenters supported CMS creating a new MS–DRG for procedures and cases representing patients receiving treatment involving CAR T-cell therapies, and recognized that each of the CAR T-cell therapies would be used in the treatment of cases representing patients that would be assigned to the same MS–DRG.

Several commenters disagreed with CMS' determination that the applications for KYMRIAH and YESCARTA are similar enough to warrant consideration as a single new technology add-on payment application, and recommended CMS consider the applications separately. Commenters believed that because KYMRIAH received FDA approval for the use in the treatment of patients diagnosed with

r/r DLBCL on May 1, 2018, the beginning of the newness period for KYMRIAH for cases reporting the ICD–10–PCS procedure codes representing patients diagnosed with r/r DLBCL should not be the same as YESCARTA, which began November 22, 2017. Commenters stated that equating the two beginning dates for the start of the newness periods will prematurely shorten the new technology add-on payment period for KYMRIAH's new patient population, which commenters believed would wrongfully withhold anticipated payments from hospitals. Commenters also recommended that, if CMS finalized its position to consider KYMRIAH and YESCARTA as one application, to use the approval date for KYMRIAH as the beginning of the newness period to avoid any inappropriate shortening of the new technology add-on payment length.

Other commenters further cautioned CMS that combining the new technology add-on payment applications' evaluation and determination for these two therapies would create precedent that may make it unlikely for future CAR T-cell therapies to be considered distinct from existing CAR T-cell therapies, or substantially similar. As a result, the commenters believed that, if CMS finalized its proposal to make a combined decision for KYMRIAH and YESCARTA, it is more likely that future CAR T-cell therapies will not qualify for new technology add-on payments. The commenters noted that, to mitigate any potential negative impact if CMS combines both the applications and makes its determination, it would be important for CMS to leave open the option for future CAR T-cell therapies to apply for and receive approval of new technology add-on payments, regardless of the decision made for the current applications under consideration.

Some commenters believed that section 1886(d)(5)(K) of the Act does not appear to clearly authorize CMS to jointly evaluate KYMRIAH and YESCARTA, which were submitted by separate manufacturers, as separate new technology add-on payment applications for two different products approved by FDA under two separate Biologics License Applications with distinct clinical and cost data submissions. The commenters believed that CMS' assessment appeared concentrated on a handful of perceived similarities in the mechanism of action and the patient and disease categories between the two newly approved CAR T-cell products. Commenters stated that this focused approach appeared to give little weight to the distinctions in the manufacturing process and co-stimulatory domains between the two CAR T-cell therapies, which obscures the important distinctions in how the different CAR T-cell technologies have been refined and optimized. The commenters further stated that CMS' evaluation also does not fully account for the difference in clinical profiles of these two agents.

Other commenters believed that failure to recognize the legitimate distinctions and technological innovations reflected by CAR T-cell therapy—and inherent across different CAR T-cell treatments, such as KYMRIAH and YESCARTA, could artificially restrict access to new technology add-on payments for these new and promising technologies. Commenters recommended CMS encourage development of medical innovation by applying the new technology add-on payment ''newness'' criterion in a way that recognizes the unique, novel, and distinct nature of the CAR T-cell technology.

In evaluating the new technology add-on payment applications for KYMRIAH and YESCARTA, some commenters believed that CMS may be overlooking the significant ways these two technologies represent a substantial medical advancement compared to existing therapies, most of which patients have already failed, before they go on to receive treatment involving CAR T-cell therapy. The commenters stated that CMS appeared to be unduly focusing on the perceived similarities between the two newly approved CAR T-cell therapies versus the advancement the technologies represent over existing therapies. The commenters encouraged CMS to recognize the ways in which KYMRIAH and YESCARTA significantly differ from existing technologies and to further apply the ''newness'' eligibility requirement for new technology add-on payments in a manner that does not unnecessarily discourage the availability of new technology add-on payments for these newly approved CAR T-cell therapies that represent significant clinical advantages over existing treatments.

The applicant for KYMRIAH stated that, at the time it submitted its new technology add-on payment application and as summarized in the FY 2019 IPPS/LTCH PPS proposed rule, similar to the applicant for YESCARTA, it believed the two technologies were not substantially similar to the other, or to other cancer drugs or biologics currently approved for use in the treatment of aggressive B-cell NHL and, therefore, met the newness criterion. However, the applicant acknowledged that, since the date it submitted its new technology add-on payment application both technologies, YESCARTA and KYMRIAH, have received FDA approval for the technologies' intended indications. The applicant for KYMRIAH further indicated that, based on FDA's recent approval, it agreed with CMS that KYMRIAH is substantially similar to YESCARTA, as defined by the new technology add-on payment application evaluation criteria.

The applicant for KYMRIAH detailed how it believed the technology is substantially similar to YESCARTA with respect to each criterion pertaining to substantial similarity.

With regard to the first criterion, whether YESCARTA and KYMRIAH use the same or a similar mechanism of action to achieve a therapeutic action, the applicant stated that, although KYMRIAH's and YESCARTA's mechanisms of actions are distinct and unique from any other cancer drug or biologic that is currently FDA-approved, namely single-agent or combination chemotherapy regimens, the applicant believed KYMRIAH and YESCARTA use the same or similar mechanisms of action to achieve the therapeutic outcome. To further support the assertion that the two technologies are substantially similar to one another, the applicant for KYMRIAH also provided the FDA-approved prescribing information (''12.1 Mechanism of Action'') issued for KYMRIAH and YESCARTA describing the mechanisms of actions as being the same or similar for both technologies in the following manner:

- KYMRIAH: *KYMRIAH is a CD19-directed genetically modified autologous T cell immunotherapy which involves reprogramming a patient's own T cells with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate CD–19-expressing malignant and normal cells. The CAR is comprised of a murine single-chain antibody fragment which recognizes CD–19 and is fused to intracellular signaling domains from 4–1BB (CD137) and CD3 zeta. The CD3 zeta component is critical for initiating T-cell activation and antitumor activity, while 4–1BB enhances the expansion and persistence of KYMRIAH. Upon binding to CD–19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination, and persistence of the KYMRIAH cells.*
- YESCARTA: *YESCARTA, a CD–19-directed genetically modified autologous T-cell immunotherapy, binds to CD–19-expressing cancer cells and normal B cells. Studies*

demonstrated that following anti-CD–19 CAR T cell engagement with CD–19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD–19-expressing cells.

In a summary of the FDA-approved prescribing information, the applicant further noted that, within the FDA-approved prescribing information, both KYMRIAH and YESCARTA are CD–19-directed genetically modified autologous T-cell immunotherapies that bind to CD–19-expressing cancer cells and normal B cells. Upon binding to CD–19-expressing cells, the respective CARs transmit a signal to promote T cell expansion, activation, and target cell elimination.

In response to the differences between KYMRIAH and YESCARTA related to spacer, transmembrane and co-stimulatory domains, which were stated by the applicant for YESCARTA, the applicant for KYMRIAH believed that, although there are structural differences that impact aspects of how the treatment effect is achieved, the overall mechanisms of actions of the two CAR T-cell therapy products are similar. The applicant explained that in defining drug classes, the FDA provided guidance that a class defined by mechanism of action would include drugs that have similar pharmacologic action at the receptor, membrane or tissue level. The applicant indicated that KYMRIAH is a cellular immunotherapy generated by gene modification of autologous donor T-cells. Further, the applicant for KYMRIAH stated that through the process of apheresis, leukocytes are harvested from the patient and undergo a process of ex-vivo gene transfer in which a CAR is introduced by lentiviral transduction. The applicant further explained that the CAR construct contains an antigen binding region designed to target CD–19, a co-stimulatory domain known as 4–1BB and a signaling domain called CD–3-zeta. The applicant stated that once transferred, the patient's T-cells will express the CAR construct anti-CD–19 4–1BB/CD–3-zeta, and undergo ex-vivo expansion. The applicant for KYMRIAH stated that both, KYMRIAH and YESCARTA, utilize a gene transfer process to modify autologous patient immune cells with a chimeric antigen receptor capable of directing immune mediated killing at a pre-specified target. The applicant further explained that both technologies accomplish their pharmacological effect through the use of three specialized domains, which are structurally different, but achieve similar environmental interactions. The applicant indicated that, in both agents, the antigen binding domain identifies CD–19 and, therefore, the interaction between the agent and its environment begins with the same receptor target interaction. Additionally, the applicant noted that both KYMRIAH and YESCARTA induce T-cell mediated cell death of the bound tumor cell by activating the T-cell expressing the CAR through the signaling domain, which is common to both agents and, therefore, at the tissue level, both generate a pharmacological impact by producing T-cell mediated apoptosis. The applicant for KYMRIAH stated that the pharmacological effect of these two agents is attained through tumor directed expansion of CAR T-cells and the development of memory T-cells that allow for potential long-term persistence and immunosurveillance. The applicant believed that, in both agents, this is achieved through the use of a co-stimulatory domain, which leads to the secretion of inflammatory substances such as cytokines, chemokines and growth factors, which induce T-cell proliferation and differentiation. The applicant for KYMRIAH stated that, although it agreed with the applicant for YESCARTA's assertion that 41BB and CD–28 are both structurally and functionally different and that at a micro level they generate a different metabolic profile and stimulate different types of memory T-cell, on a macroscopic level the general impact is ''substantially similar'' in that the mechanisms of actions allow for expansion and memory, which yield tumor-directed killing of the target tissue and memory T-cell generation for longer duration response that can be expected with a traditional biologic agent. The applicant further believed that, while the manufacturing process, safety and efficacy outcomes of any two members of a class of drugs may differ, these factors do not impact the mechanism of action.

With regard to the second criterion, whether YESCARTA and KYMRIAH will be assigned to the same or a different MS–DRG, the applicant stated that this criterion is met because cases representing patients eligible for treatment involving both, KYMRIAH and YESCARTA, will be reported using the same ICD–10–PCS procedure codes (XW033C3 and XW043C3) and will be assigned to the same MS–DRG—Pre-MDC MS–DRG 016 (as discussed in section II.F.2.d. of the preamble of this final rule).

With regard to the third criterion, whether YESCARTA® and KYMRIAH® will be used to treat the same or similar patient population, the applicant stated that both, KYMRIAH and YESCARTA, are FDA approved to treat adult patients diagnosed with r/r aggressive B-cell NHL in the same or similar patient population. The applicant, in summary, agreed with CMS' conclusion that KYMRIAH is ''substantially similar'' to YESCARTA, as defined by CMS, because both technologies are: (1) Intended to treat the same or similar disease in the same or similar patient population; (2) purposed to achieve the same therapeutic outcome using the same or similar mechanism of action; and (3) would be assigned to the same MS–DRGs. However, the applicant stated that, despite being ''substantially similar'' technologies, KYMRIAH and YESCARTA are not ''substantially similar'' to any other existing technology and, therefore, it believed KYMRIAH met the newness criterion.

Other commenters, generally, agreed that both, KYMRIAH and YESCARTA, are substantially similar technologies. One commenter stated that it agreed with CMS' approach on both clinical and policy grounds because given the promises and perils of both therapies, the surrounding coverage and payment issues present to be the same and that will also be the case for the successor drugs expected to soon achieve FDA approval and enter the U.S. market. The commenter explained that consideration of KYMRIAH and YESCARTA as one new technology add-on payment application simplifies the newness test because both technologies were assigned an ICD–10–PCS procedure code in 2017, and cases involving the utilization of the technologies and procedures reporting the ICD–10–PCS procedure codes will be assigned to the same MS–DRG, effective with the beginning of FY 2019 on October 1, 2018. The commenter also noted that, CMS indicated that November 22, 2017, would be the beginning date for the ''newness'' period because it marks the first delivery of YESCARTA to eligible treatment centers. The commenter believed this date was somewhat arbitrary, but did not provide an alternative date for consideration and, therefore, agreed that KYMRIAH and YESCARTA should be considered together as one new technology add-on payment application, both technologies met the criterion for newness, and the newness period appropriately begins on November 22, 2017. The commenter stated that, if approved for new

technology add-on payments, this newness period should grant CMS and the public sufficient time under the MS–DRG recalibration and the new technology add-on payment policies to determine whether MS–DRG 016 is an appropriate MS–DRG assignment for payment of CAR T-cell therapies.

Response: We appreciate all the commenters' input and the additional detail regarding whether KYMRIAH and YESCARTA are substantially similar to each other and existing technologies.

After consideration of the public comments we received, although we recognize the technologies are not completely the same in terms of their manufacturing process, co-stimulatory domains, and clinical profiles, we and also as the commenters expressed, are not convinced that these differences result in the use of a different mechanism of action and, therefore, infer that the two technologies' mechanisms of action are the same. Furthermore, we believe that KYMRIAH and YESCARTA are substantially similar to one another because potential cases representing patients who may be eligible for treatment using KYMRIAH and YESCARTA would group to the same MS–DRGs (because the same ICD–10–CM diagnosis codes and ICD–10–PCS procedures codes are used to report treatment using either KYMRIAH or YESCARTA). We also believe, as we and other commenters describe throughout this section, that these technologies are intended to treat the same or similar disease in the same or similar patient population—patients with r/r DLBCL who are ineligible for, or who have failed ASCT, and are purposed to achieve the same therapeutic outcome—ORR, CR, OS using the same or similar mechanism of action using genetically modified autologous T-cell immunotherapies. The respective CAR T-cells transmit a signal to promote T-cell expansion, activation, and ultimately cancer cell elimination to produce a targeted cellular therapy that may persist in the body even after the malignancy is eradicated.

We also believe that KYMRIAH and YESCARTA are not substantially similar to any other existing technologies because, as both applicants asserted in their FY 2019 new technology add-on payment applications and as stated by the other commenters, the technologies do not use the same or similar mechanism of action to achieve a therapeutic outcome as any other existing drug or therapy assigned to the same or different MS–DRG and represent the only FDA-approved technologies for this treatment population.

With regard to the commenter that indicated pricing of both products varies based on the patient population, and encouraged CMS to recognize this discrepancy when determining approval of new technology add-on payment and establishing adequate payments rates, we note that the applicants for both, KYMRIAH and YESCARTA, estimate that the average cost for an administered dose of KYMRIAH or YESCARTA is $373,000. We refer readers to the end of this discussion for complete details on the pricing of KYMRIAH and YESCARTA.

With respect to CMS' policy for evaluating substantially similar technologies, we believe our current policy is consistent with the authority and criteria in section 1886(d)(5)(K) of the Act. We note that CMS is authorized by the Act to develop criteria for the purposes of evaluating new technology add-on payment applications. For the purposes of new technology add-on payments, when technologies are substantially similar to each other, we believe it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS, for the reasons we discussed above and consistent with our evaluation of substantially similar technologies in prior rulemaking (82 FR 38120).

Finally, we note that for FY 2019, there is no payment impact regarding the determination that the two technologies are substantially similar to each other because the cost of the technologies is the same. However, we welcome additional comments in future rulemaking regarding whether KYMRIAH and YESCARTA are substantially similar and intend to revisit this issue in next year's proposed rule.

As we stated in the proposed rule and above, each applicant submitted separate analysis regarding the cost criterion for each of their products, and both applicants maintained that their product meets the cost criterion. We summarize each analysis below.

With regard to the cost criterion, the applicant for KYMRIAH searched the FY 2016 MedPAR claims data file to identify potential cases representing patients who may be eligible for treatment using KYMRIAH. The applicant identified claims that reported an ICD–10–CM diagnosis code of: C83.30 (DLBCL, unspecified site); C83.31 (DLBCL, lymph nodes of head, face and neck); C83.32 (DLBCL, intrathoracic lymph nodes); C83.33 (DLBCL, intra-abdominal lymph nodes); C83.34 (DLBCL, lymph nodes of axilla and upper limb); C83.35 (DLBCL, lymph nodes of inquinal region and lower limb); C83.36 (DLBCL, intrapelvic lymph nodes); C83.37 (DLBCL, spleen); C83.38 (DLBCL, lymph nodes of multiple sites); or C83.39 (DLBCL, extranodal and solid organ sites). The applicant also identified potential cases where patients received chemotherapy using two encounter codes, Z51.11 (Antineoplastic chemotherapy) and Z51.12 (Antineoplastic immunotherapy), in conjunction with DLBCL diagnosis codes.

Applying the parameters above, the applicant for KYMRIAH identified a total of 22,589 DLBCL potential cases that mapped to 437 MS–DRGs. The applicant chose the top 20 MS–DRGs which made up a total of 15,451 potential cases at 68 percent of total cases. Of the 22,589 total DLBCL potential cases, the applicant also provided a breakdown of DLBCL potential cases where chemotherapy was used, and DLBCL potential cases where chemotherapy was not used. Of the 6,501 DLBCL potential cases where chemotherapy was used, MS–DRGs 846 and 847 accounted for 6,181 (95 percent) of the 6,501 cases. Of the 16,088 DLBCL potential cases where chemotherapy was not used, the applicant chose the top 20 MS–DRGs which made up a total of 9,333 potential cases at 58 percent of total cases. The applicant believed the distribution of patients that may be eligible for treatment using KYMRIAH will include a wide variety of MS–DRGs. As such, the applicant conducted an analysis of three scenarios: potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy.

The applicant removed reported historic charges that would be avoided through the use of KYMRIAH. Next, the applicant removed 50 percent of the chemotherapy pharmacy charges that would not be required for patients that may be eligible to receive treatment using KYMRIAH. The applicant standardized the charges and then applied an inflation factor of 1.09357, which is the 2-year inflation factor in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527), to update the charges from FY 2016 to FY 2018. The applicant did not add charges for KYMRIAH to its analysis. However, the applicant provided a cost analysis related to the three categories of claims data it previously researched (that is, potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy). The applicant's analysis showed the inflated average case-weighted standardized charge per case for

potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy was $63,271, $39,723, and $72,781, respectively. The average case-weighted threshold amount for potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy was $58,278, $48,190, and $62,355 respectively. While the inflated average case-weighted standardized charge per case ($39,723) is lower than the average case-weighted threshold amount ($48,190) for potential DLBCL cases with chemotherapy, the applicant expected the cost of KYMRIAH to be higher than the new technology add-on payment threshold amount for all three cohorts. Therefore, the applicant maintained that it met the cost criterion.

We noted in the proposed rule that, as discussed in section II.F.2.d. of the preamble of the proposed rule, we proposed to assign the ICD–10–PCS procedure codes that describe procedures involving the utilization of these CAR T-cell therapy drugs and cases representing patients receiving treatment involving CAR T-cell therapy procedures to Pre-MDC MS–DRG 016 for FY 2019. Therefore, in addition to the analysis above, we compared the inflated average case-weighted standardized charge per case from all three cohorts above to the average case-weighted threshold amount for MS–DRG 016. The average case-weighted threshold amount for MS–DRG 016 from Table 10 in the FY 2018 IPPS/LTCH PPS final rule is $161,058. Although the inflated average case-weighted standardized charge per case for all three cohorts ($63,271, $39,723, and $72,781) is lower than the average case-weighted threshold amount for MS–DRG 016, we noted that similar to above, the applicant expected the cost of KYMRIAH to be higher than the new technology add-on payment threshold amount for MS–DRG 016. Therefore, it appeared that KYMRIAH would meet the cost criterion under this scenario as well.

We stated in the proposed rule that we appreciated the applicant's analysis. However, we noted that the applicant did not provide information regarding which specific historic charges were removed in conducting its cost analysis. Nonetheless, we stated that we believed that even if historic charges were identified and removed, the applicant would meet the cost criterion because, as indicated, the applicant expected the cost of KYMRIAH to be higher than the new technology add-on payment threshold amounts listed earlier.

We invited public comments on whether KYMRIAH meets the cost criterion.

Comment: Commenters agreed with CMS that KYMRIAH meets the cost criterion for new technology add-on payments based on the analysis above. The commenters noted that more recent information indicates that the cost of the drug alone is more than twice the estimated new technology add-on payment MS–DRG threshold amount.

Response: We appreciate the commenters' input and note that, since the publication of the proposed rule, CMS has received supplemental information that the cost for each administration of KYMRIAH is $373,000.

After consideration of the public comments we received, we agree that KYMRIAH meets the cost criterion.

With regard to the cost criterion in reference to YESCARTA, the applicant conducted the following analysis. The applicant examined FY 2016 MedPAR claims data restricted to patients discharged in FY 2016. The applicant included potential cases reporting an ICD–10 diagnosis code of C83.38. Noting that only MS–DRGs 820 (Lymphoma and Leukemia with Major O.R. Procedure with MCC), 821 (Lymphoma and Leukemia with Major O.R. Procedure with CC), 823 and 824 (Lymphoma and Non-Acute Leukemia with Other O.R. Procedure with MCC, with CC, respectively), 825 (Lymphoma and Non Acute Leukemia with Other O.R Procedure without CC/MCC), and 840, 841 and 842 (Lymphoma and Non-Acute Leukemia with MCC, with CC and without CC/MCC, respectively) consisted of 10 or more cases, the applicant limited its analysis to these 8 MS–DRGs. The applicant identified 827 potential cases across these MS–DRGs. The average case-weighted unstandardized charge per case was $126,978. The applicant standardized charges using FY 2016 standardization factors and applied an inflation factor of 1.09357 from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527). The applicant for YESCARTA did not include the cost of its technology in its analysis.

Included in the average case-weighted standardized charge per case were charges for the current treatment components. Therefore, the applicant for YESCARTA removed 20 percent of radiology charges to account for chemotherapy, and calculated the adjusted average case-weighted standardized charge per case by subtracting these charges from the standardized charge per case. Based on the distribution of potential cases within the eight MS–DRGs, the applicant case-weighted the final inflated average case-weighted standardized charge per case. This resulted in an inflated average case-weighted standardized charge per case of $118,575. Using the FY 2018 IPPS Table 10 thresholds, the average case-weighted threshold amount was $72,858. Even without considering the cost of its technology, the applicant maintained that because the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the technology met the cost criterion.

We noted in the proposed rule that, as discussed in section II.F.2.d. of the preamble of the proposed rule, we proposed to assign the ICD–10–PCS procedure codes that describe procedures involving the utilization of these CAR T-cell therapy drugs and cases representing patients receiving treatment involving CAR T-cell therapy procedures to Pre-MDC MS–DRG 016 for FY 2019. Therefore, in addition to the analysis above, we compared the inflated average case-weighted standardized charge per case ($118,575) to the average case-weighted threshold amount for MS–DRG 016. The average case-weighted threshold amount for MS–DRG 016 from Table 10 in the FY 2018 IPPS/LTCH PPS final rule is $161,058. Although the inflated average case-weighted standardized charge per case is lower than the average case-weighted threshold amount for MS–DRG 016, we noted that the applicant expected the cost of YESCARTA to be higher than the new technology add-on payment threshold amount for MS–DRG 016. Therefore, we stated that it appeared that YESCARTA would meet the cost criterion under this scenario as well.

We invited public comments on whether YESCARTA technology meets the cost criterion.

Comment: Commenters agreed with CMS that YESCARTA meets the cost criterion for new technology add-on payments based on the analysis above. The commenters noted that more recent information indicates the cost of the drug alone is more than twice the estimated new technology add-on payment MS–DRG threshold amount.

Response: We appreciate the commenters' input and note that, since the publication of the proposed rule, CMS has received supplemental information that the cost for each administration of YESCARTA is $373,000.

After consideration of the public comments we received, we agree that YESCARTA meets the cost criterion.

With regard to substantial clinical improvement for KYMRIAH, the applicant asserted that several aspects of the treatment represent a substantial clinical improvement over existing technologies. The applicant believed that KYMRIAH allows access for a treatment option for those patients who are unable to receive standard-of-care treatment. The applicant stated in its application that there are no currently FDA-approved treatment options for patients with r/r DLBCL who are ineligible for or who have failed ASCT. Additionally, the applicant maintained that KYMRIAH significantly improves clinical outcomes, including ORR, CR, OS, and durability of response, and allows for a manageable safety profile. The applicant asserted that, when compared to the historical control data (SCHOLAR–1) and the currently available treatment options, it is clear that KYMRIAH significantly improves clinical outcomes for patients with r/r DLBCL who are not eligible for ASCT. The applicant conveyed that, given that the patient population has no other available treatment options and an expected very short lifespan without therapy, there are no randomized controlled trials of the use of KYMRIAH in patients with r/r DLBCL and, therefore, efficacy assessments must be made in comparison to historical control data. The SCHOLAR–1 study is the most comprehensive evaluation of the outcome of patients with refractory DLBCL. SCHOLAR–1 includes patients from two large randomized controlled trials (Lymphoma Academic Research Organization-CORAL and Canadian Cancer Trials Group LY.12) and two clinical databases (MD Anderson Cancer Center and University of Iowa/Mayo Clinic Lymphoma Specialized Program of Research Excellence).[35]

The applicant for KYMRIAH conveyed that the PARMA study established high-dose chemotherapy and ASCT as the standard treatment for patients with r/r DLBCL.[36] However, according to the applicant, many patients with r/r DLBCL are ineligible for ASCT because of medical frailty. Patients who are ineligible for ASCT because of medical frailty would also be adversely affected by high-dose chemotherapy regimens.[37] Lowering the toxicity of chemotherapy regimens becomes the only treatment option, leaving patients with little potential for therapeutic outcomes. According to the applicant, the lack of efficacy of these aforementioned salvage regimens was demonstrated in nine studies evaluating combined chemotherapeutic regimens in patients who were either refractory to first-line or first salvage. Chemotherapy response rates ranged from 0 percent to 23 percent with OS less than 10 months in all studies.[38] For patients who do not respond to combined therapy regimens, the National Comprehensive Cancer Network (NCCN) offers only clinical trials or palliative care as therapeutic options.[39]

According to the applicant for KYMRIAH, the immunomodulatory agent Lenalidomide was only able to show an ORR of 30 percent, a CR rate of 8 percent, and a 4.6-month median duration of response.[40] M-tor inhibitors such as Everolimus and Temserolimus have been studied as single agents, or in combination with Rituximab, as have newer monoclonal antibodies Dacetuzumab, Ofatumomab and Obinutuzumab. However, none induced a CR rate higher than 20 percent or showed a median duration of response longer than 1 year.[41]

According to the applicant, although controversial, allogeneic stem cell transplantation (allo-SCT) has been proposed for patients who have been diagnosed with r/r disease. It is hypothesized that the malignant cell will be less able to escape the immune targeting of allogenic T-cells—known as the graft-vs-lymphoma effect.[42] [43] The use of allo-SCT is limited in patients who are not eligible for ASCT because of the high rate of morbidity and mortality. This medically frail population is generally excluded from participation. The population most impacted by this is the elderly, who are often excluded based on age alone. In seven studies evaluating allo-SCT in patients with r/r DLBCL, the median age at transplant was 43 years old to 52 years old, considerably lower than the median age of patients with DLBCL of 64 years old. Only two studies included any patients over 66 years old. In these studies, allo-SCT provided OS rates ranging from 18 percent to 52 percent at 3 to 5 years, but was accompanied by treatment-related mortality rates ranging from 23 percent to 56 percent.[44] According to the applicant, this toxicity and efficacy profile of allo-SCT substantially limits its use, especially in patients 65 years old and older. Given the high unmet medical need, the applicant maintained that KYMRIAH represents a substantial clinical improvement by offering a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

To express how KYMRIAH has improved clinical outcomes, including ORR, CR rate, OS, and durability of response, the applicant referenced clinical trials in which KYMRIAH was tested. Study 1 was a single-arm, open-label, multi-site, global Phase II study to determine the safety and efficacy of tisagenlecleucel in patients with R/R DLBCL (CCTL019C2201/CT02445248/'JULIET' study).[45] [46] [47] Key inclusion criteria included patients who were 18 years old and older, patients with refractory to at least two lines of chemotherapy and either relapsed post ASCT or who were ineligible for ASCT, measurable disease at the time of infusion, and adequate organ and bone marrow function. The study was conducted in three phases. In the screening phase patient eligibility was

[35] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood–2017–03–769620.

[36] Philip, T., Guglielmi, C., Hagenbeek, A., et al., ''Autologous bone marrow transplantation as compared with salvage chemotherapy in relapses of chemotherapy-sensitive non-Hodgkin's lymphoma,'' *N Engl J Med,* 1995, vol. 333(23), pp. 1540–1545.

[37] Friedberg, J.W., ''Relapsed/refractory diffuse large B-cell lymphoma,'' *Hematology AM Soc Hematol Educ Program,* 2011, vol. (1), pp. 498–505.

[38] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood–2017–03–769620.

[39] National Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology (NCCN GuidelinesR), ''B-cell lymphomas: Diffuse large b-cell lymphoma and follicular lymphoma (Version 3.2017),'' May 25, 2017. Available at: *https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf.*

[40] Klyuchnikov, E., Bacher, U., Kroll, T., et al., ''Allogeneic hematopoietic cell transplantation for diffuse large B cell lymphoma: Who, when and how?,'' *Bone Marrow Transplant,* 2014, vol. 49(1), pp. 1–7.

[41] Ibid.

[42] Ibid.

[43] Maude, S.L., Teachey, D.T., Porter, D.L., Grupp, S.A., ''CD19-targeted chimeric antigen receptor T-cell therapy for acute lymphoblastic leukemia,'' *Blood,* 2015, vol. 125(26), pp. 4017–4023.

[44] Klyuchnikov, E., Bacher, U., Kroll, T., *et al.,* ''Allogeneic hematopoietic cell transplantation for diffuse large B cell lymphoma: Who, when and how?,'' *Bone Marrow Transplant,* 2014, vol. 49(1), pp. 1–7.

[45] Data on file, Oncology clinical trial protocol CCTL019C2201: ''A Phase II, single-arm, multi-center trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large Bcell lymphoma (DLBCL),'' Novartis Pharmaceutical Corp, 2015.

[46] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: An interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[47] *ClinicalTrials.gov*, ''Study of efficacy and safety of CTL019 in adult DLBCL patients (JULIET).''Available at: *https://clinicaltrials.gov/ct2/show/NCT02445248.*

assessed and patient cells collected for product manufacture. Patients were also able to receive bridging, cytotoxic chemotherapy during this time. In the pre-treatment phase patients underwent a restaging of disease followed by lymphodepleting chemotherapy with fludarabine 25mg/m2 × 3 and cyclophosphamide 250mg/m2/d × 3 or bendamustine 90mg/m2/d × 2 days. The treatment and follow-up phase began 2 to 14 days after lymphodepleting chemotherapy, when the patient received a single infusion of tisagenlecleucel with a target dose of 5 × 10^8 CTL019 transduced viable cells. The primary objective was to assess the efficacy of tisagenlecleucel, as measured by the best overall response (BOR), which was defined as CR or partial response (PR). It was assessed on the Chesson 2007 response criteria amended by Novartis Pharmaceutical Corporation as confirmed by an Independent Review Committee (IRC). One hundred forty-seven patients were enrolled, and 99 of them were infused with tisagenlecleucel. Forty-three patients discontinued prior to infusion (9 due to inability to manufacture and 34 due to patient-related issues).[48] The median age of treated patients was 56 years old with a range of 24 to 75; 20 percent were older than 65 years old. Patients had received 2 to 7 prior lines of therapy, with 60 percent receiving 3 or more therapies, and 51 percent having previously undergone ASCT. A primary analysis was performed on 81 patients infused and followed for more than or at least 3 months. In this primary analysis, the BOR was 53 percent; the study met its primary objective based on statistical analysis (that is, testing whether BOR was greater than 20 percent, a clinically relevant threshold chosen based on the response to chemotherapy in a patient with r/r DLBCL). Forty-three percent (43 percent) of evaluated patients reached a CR, and 14 percent reached a PR. ORR evaluated at 3 months was 38 percent with a distribution of 32 percent CR and 6 percent PR. All patients in CR at 3 months continued to be in CR. ORR was similar across subgroups including 64.7 percent response in patients who were older than 65 years old, 61.1 percent response in patients with Grade III/IV disease at the time of enrollment, 58.3 percent response in patients with Activated B-cell, 52.4 percent response in patients with Germinal Center B-cell subtype, and 60 percent response in patients with double and triple hit lymphoma. Durability of response was assessed based on relapse free survival (RFS), which was estimated at 74 percent at 6 months.

The applicant for KYMRIAH reported that Study 2 was a supportive Phase IIa single institution study of adults who were diagnosed with advanced CD19+ NHL conducted at the University of Pennsylvania.[49] [50] Tisagenlecleucel cells were produced at the University of Pennsylvania using the same genetic construct and a similar manufacturing technique as employed in Study 1. Key inclusion criteria included patients who were at least 18 years old, patients with CD19+ lymphoma with no available curative options, and measurable disease at the time of enrollment. Tisagenlecleucel was delivered in a single infusion 1 to 4 days after restaging and lymphodepleting chemotherapy. The median tisagenlecleucel cell dose was 5.0 × 108 transduced cells. The study enrolled 38 patients; of these, 21 were diagnosed with DLBCL and 13 received treatment involving KYMRIAH. Patients ranged in age from 25 to 77 years old, and had a median of 4 prior therapies. Thirty-seven percent had undergone ASCT and 63 percent were diagnosed with Grade III/IV disease. ORR at 3 months was 54 percent. Progression free survival was 43 percent at a median follow-up of 11.7 months. Safety and efficacy results are similar to those of the multi-center study.

The applicant for KYMRIAH reported that Study 3 was a supportive, patient-level meta-analysis of historical outcomes in patients who were diagnosed with refractory DLBCL (SCHOLAR–1).[51] This study included a pooled data analysis of two Phase III clinical trials (Lymphoma Academic Research Organization-CORAL and Canadian Cancer Trials Group LY.12) and two observational cohorts (MD Anderson Cancer Center and University of Iowa/Mayo Clinic Lymphoma Specialized Program of Research Excellence). Refractory disease was defined as progressive disease or stable disease as best response to chemotherapy (received more than or at least 4 cycles of first-line therapy or 2 cycles of later-line therapy, respectively) or relapse in less than or at 12 months post-ASCT. Of 861 abstracted records, 636 were included based on these criteria. All patients from each data source who met criteria for diagnosis of refractory DLBCL, including TFL and PMBCL, who went on to receive subsequent therapy were considered for analysis. Patients who were diagnosed with TFL and PMBCL were included because they are histologically similar and clinically treated as large cell lymphoma. Response rates were similar across the 4 datasets, ranging from 20 percent to 31 percent, with a pooled response rate of 26 percent. CR rates ranged from 2 percent to 15 percent, with a pooled CR rate of 7 percent. Subgroup analyses including patients with primary refractory, refractory to second or later-line therapy, and relapse in less than 12 months post-ASCT revealed response rates similar to the pooled analysis, with worst outcomes in the primary refractory group (20 percent). OS from the commencement of therapy was 6.3 months and was similar across subgroup analyses. Achieving a CR after last salvage chemotherapy predicted a longer OS of 14.9 months compared to 4.6 months in nonresponders. Patients who had not undergone ASCT had an OS of 5.1 months with a 2 year OS rate of 11 percent.

The applicant asserted that KYMRIAH provides a manageable safety profile when treatment is performed by trained medical personnel and, as opposed to ASCT, KYMRIAH mitigates the need for high-dose chemotherapy to induce response prior to infusion. Adverse events were most common in the 8 weeks following infusion and were manageable by a trained staff. Cytokine Relapse Syndrome (CRS) occurred in 58 percent of patients with 23 percent having Grade III or IV events as graded on the University of Pennsylvania grading system.[52] [53] Median time to

[48] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: an interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[49] *ClinicalTrials.gov*, ''Phase IIa study of redirected autologous T-cells engineered to contain anti-CD19 attached to TCRz and 4-signaling domains in patients with chemotherapy relapsed or refractory CD19+ lymphomas,'' Available at: *https://clinicaltrials.gov/ct2/show/NCT02030834*.

[50] Schuster, S.J., Svoboda, J., Nasta, S.D., et al., ''Sustained remissions following chimeric antigen receptor modified T-cells directed against CD–19 (CTL019) in patients with relapsed or refractory CD19+ lymphomas,'' Presented at: 57th Annual Meeting of the American Society of Hematology, December 6, 2015, Orlando, FL.

[51] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood–2017–03–769620.

[52] *ClinicalTrials.gov*, ''Phase IIa study of redirected autologous T-cells engineered to contain anti-CD19 attached to TCRz and 4-signaling domains in patients with chemotherapy relapsed or refractory CD19+ lymphomas.'' Available at: *https://clinicaltrials.gov/ct2/show/NCT02030834*.

[53] Schuster, S.J., Svoboda, J., Nasta, S.D., et al., ''Sustained remissions following chimeric antigen receptor modified T-cells directed against CD–19 (CTL019) in patients with relapsed or refractory

onset of CRS was 3 days and median duration was 7 days with a range of 2 to 30 days. Twenty-four percent of the patients required ICU admission. CRS was managed with supportive care in most patients. However, 16 percent required anti-cytokine therapy including tocilizumab (15 percent) and corticosteroids (11 percent). Other adverse events of special interest include infection in 34 percent (20 percent Grade III or IV) of patients, cytopenias not resolved by day 28 in 36 percent (27 percent Grade III or IV) of patients, neurologic events in 21 percent (12 percent Grade III or IV) of patients, febrile neutropenia in 13 percent (13 percent Grade III or IV) of patients, and tumor lysis syndrome 1 percent (1 percent Grade III). No deaths were attributed to tisagenlecleucel including no fatal cases of CRS or neurologic events. No cerebral edema was observed.[54] Study 2 safety results were consistent to those of Study 1.[55]

After reviewing the studies provided by the applicant, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20292), we stated that we were concerned the applicant included patients who were diagnosed with TFL and PMBCL in the SCHOLAR–1 data results for their comparison analysis, possibly skewing results. Furthermore, the discontinue rate of the JULIET trial was high. Of 147 patients enrolled for infusion involving KYMRIAH, 43 discontinued prior to infusion (9 discontinued due to inability to manufacture, and 34 discontinued due to patient-related issues). Finally, the rate of patients who experienced a diagnosis of CRS was high, 58 percent.[56]

The applicant for YESCARTA stated that YESCARTA represents a substantial clinical improvement over existing technologies when used in the treatment of patients with aggressive B-cell NHL. The applicant asserted that YESCARTA can benefit the patient population with the highest unmet need, patients with r/r disease after failure of first-line or second-line therapy, and patients who have failed or who are ineligible for ASCT. These patients, otherwise, have adverse outcomes as demonstrated by historical control data.

Regarding clinical data for YESCARTA, the applicant stated that historical control data was the only ethical and feasible comparison information for these patients with chemorefractory, aggressive NHL who have no other available treatment options and who are expected to have a very short lifespan without therapy. According to the applicant, based on meta-analysis of outcomes in patients with chemorefractory DLBCL, there are no curative options for patients with aggressive B-cell NHL, regardless of refractory subgroup, line of therapy, and disease stage with their median OS being 6.6 months.[57]

In the applicant's FY 2018 new technology add-on payment application for the KTE–C19 technology, which was discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19889), the applicant cited ongoing clinical trials. The applicant provided updated data related to these ongoing clinical trials as part of its FY 2019 application for YESCARTA.[58] [59] [60] The updated analysis of the pivotal Study 1 (ZUMA–1, KTE–C19–101), Phase I and II occurred when patients had been followed for 12 months after infusion of YESCARTA. Study 1 is a Phase I–II multi-center, open-label study evaluating the safety and efficacy of the use of YESCARTA in patients with aggressive refractory NHL. The trial consists of two distinct phases designed as Phase I (n=7) and Phase II (n=101). Phase II is a multi-cohort open-label study evaluating the efficacy of YESCARTA.[61] The applicant noted that, as of the analysis cutoff date for the interim analysis, the results of Study 1 demonstrated rapid and substantial improvement in objective, or ORR. After 6 and 12 months, the ORR was 82 and 83 percent, respectively. Consistent response rates were observed in both Study 1, Cohort 1 (DLBCL; n=77) and Cohort 2 (PMBCL or TFL; n=24) and across covariates including disease stage, age, IPI scores, CD–19 status, and refractory disease subset. In the updated analysis, results were consistent across age groups. In this analysis, 39 percent of patients younger than 65 years old were in ongoing response, and 50 percent of patients at least 65 years old or older were in ongoing response. Similarly, the survival rate at 12 months was 57 percent among patients younger than 65 years old and 71 percent among patients at least 65 years old or older versus historical control of 26 percent. The applicant further stated that evidence of substantial clinical improvement regarding the efficacy of YESCARTA for the treatment of patients with chemorefractory, aggressive B-cell NHL is supported by the CR of YESCARTA in Study 1, Phase II (54 percent) versus the historical control (7 percent).[62] [63] [64] [65] The applicant noted that CR rates were observed in both Study 1, Cohort 1. The applicant reported that, in the updated analysis, results were in ongoing response (46 percent of patients at least 65 years old or older were in ongoing response). Similarly, the survival rate at 12 months was 57 percent among patients younger than 65 years old and 71 percent among patients at least 65 years old or older.[66] [67] [68] [69] The applicant also

CD19+ lymphomas,'' Presented at: 57th Annual Meeting of the American Society of Hematology, December 6, 2015, Orlando, FL.

[54] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: an interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[55] Ibid.

[56] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: an interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[57] Seshardi, T., et al., ''Salvage therapy for relapsed/refractory diffuse large B-cell lymphoma,'' *Biol Blood Marrow Transplant,* 2008 Mar, vol. 14(3), pp. 259–67.

[58] Locke, F.L., et al., ''Ongoing complete remissions in Phase 1 of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[59] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[60] Locke, F.L., et al., ''Phase I results of ZUMA–1: a multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[61] Neelapu, S.S., Locke, F.L., et al., 2016, ''KTE–C19 (anti-CD19 CAR T cells) induces complete remissions in patients with refractory diffuse large B-cell lymphoma (DLBCL): results from the pivotal Phase II ZUMA–1,'' Abstract presented at American Society of Hematology (ASH) 58th Annual Meeting, December 2016.

[62] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[63] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[64] Locke, F.L., et al., ''Phase I results of ZUMA–1: a multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[65] Crump, et al., 2017, ''Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR–1 study,'' *Blood,* vol. 0, 2017, pp. blood–2017–03–769620v1.

[66] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

Continued

provided the following tables to depict data to support substantial clinical improvement (we refer readers to the two tables below).

OVERALL RESPONSE RATES ACROSS ALL YESCARTA STUDIES VS. SCHOLAR–1

	Study 1, Phase I n=7	Study 1, Phase II n=101	Scholar–1 n=529
Overall Response Rate (%)	71	83	26
Month 6 (%)	43	41.	
Ongoing with >15 Months of follow-up (%)	43	42.	
Ongoing with >18 Months of follow-up (%)	43	Follow-up ongoing.	

RESULTS FOR YESCARTA STUDY 1, PHASE II: COMPLETE RESPONSE

	Study 1, Phase II n=101
Complete Response (%) (95 Percent Confidence Interval)	54 (44,64).
Duration of Response, median (range in months)	not reached.
Ongoing Responses, CR (%) Median 8.7 months follow-up; median overall survival has not been reached	39.
Ongoing Responses, CR (%) Median 15.3 months follow-up; median overall survival has not been reached	40.

According to the applicant, the 6-month and 12-month survival rates (95 percent CI) for patients enrolled in the SCHOLAR–1 study were 53 percent (49 percent, 57 percent) and 28 percent (25 percent, 32 percent).[70] In contrast, the 6-month and 12-month survival rates (95 percent CI) in the Study 1 updated analysis were 79 percent (70 percent, 86 percent) and 60 percent (50 percent, 69 percent).[71] [72] [73]

The applicant also cited safety results from the pivotal Study 1, Phase II. According to the applicant, the clinical trial protocol stipulated that patients were infused with YESCARTA in the hospital inpatient setting and were monitored in the inpatient setting for at least 7 days for early identification and treatment involving YESCARTA-related toxicities, which primarily included CRS diagnoses and neurotoxicities. The applicant noted that the interim analysis showed the length of stay following infusion of YESCARTA was a median of 15 days. Ninety-three percent of patients experienced CRS diagnoses, 13 percent of whom experienced Grade III or higher (severe, life threatening or fatal) CRS diagnoses. The median time to onset of CRS diagnosis was 2 days (range 1 to 12 days) and the median time to resolution was 8 days. Ninety-eight percent of patients recovered from CRS diagnosis. Neurologic events occurred in 64 percent of patients, 28 percent of whom experienced Grade III or higher (severe or life threatening) events. The median time to onset of neurologic events was 5 days (range 1 to 17 days). The median time to resolution was 17 days. Nearly all patients recovered from neurologic events. The medications most often used to treat these complications included growth factors, blood products, anti-infectives, steroids, tocilizumab, and vasopressors. Two patients died from YESCARTA-related adverse events (hemophagocytic lymphohistiocytosis and cardiac arrest in the hospital setting as a result of CRS diagnoses). According to the applicant, there were no clinically important differences in adverse event rates across age groups (younger than 65 years old; 65 years old or older), including CRS diagnoses and neurotoxicity.[74] [75]

The applicant for YESCARTA provided information regarding a safety expansion cohort, Study 1 Phase II Safety Expansion Cohort 3 that was created and carried out in 2017. According to the applicant, this Safety Expansion Cohort investigated measures to mitigate the incidence and/or severity of anti-CD–19 CAR T therapy and evaluated an adverse event mitigation strategy by prophylactically using levetiracetam (Keppra), an anticonvulsant, and tocilizumab, an IL–6 receptor inhibitor. Of the 30 patients treated, 2 patients experienced Grade III CRS diagnoses; 1 of the 2 patients recovered. In late April 2017, the other patient also experienced multi-organ failure and a neurologic event that subsequently progressed to a fatal Grade V cerebral edema that was deemed related to YESCARTA treatment. This case of cerebral edema was observed in a 21 year-old male with refractory, rapidly progressive, symptomatic, stage IVB PMBCL. Analysis of the baseline serum and cerebrospinal fluid (CSF) obtained prior to any study treatment demonstrated high cytokine and

[67] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[68] Locke, F.L., et al., ''Phase I results of ZUMA–1: a multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[69] Crump, et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* vol. 0, 2017, pp. blood–2017–03–769620v1.

[70] Crump, et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* vol. 0, 2017, pp. blood–2017–03–769620v1.

[71] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[72] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[73] Locke, F.L., et al., ''Phase I results of ZUMA–1: a multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[74] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[75] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

chemokine levels. According to the applicant, this suggests a significant preexisting underlying inflammatory process, both systemically and within the central nervous system. Rapidly progressing disease, recent mediastinal XRT (external beam radiation therapy) and/or CMV (cytomegalovirus) reactivation may have contributed to the pre-existing state. There were no prior cases of cerebral edema in the 200 patients who have been treated with YESCARTA in the ZUMA clinical development program. The single patient event from the Study 1 Phase II Safety Expansion Cohort 3 was the first Grade V cerebral edema event.[76] [77]

After reviewing the information submitted by the applicant as part of its FY 2019 new technology add-on payment application for YESCARTA, we stated in the FY 2019 IPPS/LTCH PPS proposed rule that we were concerned that it does not appear to include patient mortality data that was included as part of the applicant's FY2018 new technology add-on payment application for the KTE–C19 technology. In that application, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19890), the applicant provided that by an earlier cutoff date for the interim analysis of Study 1, among all KTE–C19 treated patients, 12 patients in Study 1, Phase II, including 10 from Cohort 1, and 2 from Cohort 2, died. Eight of these deaths were due to disease progression. One patient had disease progression after receiving KTE–C19 treatment and subsequently had ASCT. After ASCT, the patient died due to sepsis. Two patients (3 percent) died due to KTE–C19-related adverse events (Grade V hemophagocytic lymphohistiocytosis event and Grade V anoxic brain injury), and one died due to an adverse event deemed unrelated to treatment involving KTE–C19 (Grade V pulmonary embolism), without disease progression. We believed it would be relevant to include this information because it is related to the same treatment that is the subject of the applicant's FY 2019 new technology add-on payment application.

We also stated that we were concerned that there are few published results showing any survival benefits from the use of this treatment. In addition, we were concerned with the limited number of patients (n=108) that were studied after infusion involving YESCARTA T-cell immunotherapy. Finally, we indicated that we were concerned about the data related to the percentage of patients who experienced complications or toxicities related to YESCARTA treatment. According to the applicant, of the patients who participated in YESCARTA clinical trials, 93 percent developed CRS diagnoses and 64 percent experienced neurological adverse events.

We invited public comments on whether KYMRIAH and YESCARTA meet the substantial clinical improvement criterion.

The applicants for KYMRIAH and YESCARTA, as well as others submitted comments regarding whether KYMRIAH and YESCARTA met the substantial clinical improvement criterion.

Comment: The applicant for KYMRIAH responded to CMS' concerns presented in the proposed rule regarding the JULIET trial and provided updated trial results. According to the applicant, of the 160 patients enrolled in the JULIET trial, 106 patients received treatment involving tisagenlecleucel, including 92 patients who received the product manufactured in the U.S. and were followed for at least 3 months or discontinued earlier. The applicant stated that 11 out of 160 patients (7 percent) enrolled did not receive treatment involving tisagenlecleucel due to manufacturing failure and 38 other patients did not receive treatment involving tisagenlecleucel due to patient-related issues.

In response to CMS' concerns that the use of the SCHOLAR–1 study as a baseline for comparison to the JULIET trial may have skewed results because the baseline population of the SCHOLAR–1 study included patient populations diagnosed with TFL and PMBCL, the applicant for KYMRIAH stated that the JULIET trial included patients diagnosed with TFL, making this patient population similar in nature to what was included in the SCHOLAR study. The applicant also indicated that, although it is true that patients diagnosed with PMBCL were excluded from the JULIET trial, these patients only make up 2 percent of the total population of the 636 patients evaluated in the SCHOLAR–1 study; limiting the impact that these patients could have had on the observed response rates. The applicant further explained that PMBCL is a form of large cell lymphoma, which differs from DLBCL in that the patient population is often younger and healthier and patients diagnosed with PMBCL are more likely to respond to first-line therapy, therefore, relapsed and refractory (r/r) patients are rare compared to those diagnosed with DLBCL. The applicant also stated that, due to the infrequency of patients diagnosed with r/r PMBCL, research isolating this pathology for treatment effect is limited. The applicant indicated that, although some studies estimate that chemorefractory PMBCL has a lower response rate than refractory DLBCL, those studies still report ORR equivalent to what was shown in SCHOLAR and each of these studies' results show r/r PMBCL patients having a CR rate that is equivalent or better than what was observed in the larger SCHOLAR study. The applicant believed that, given these outcomes and the small number of patients diagnosed with PMBCL in the SCHOLAR literature, it is unlikely that the results are skewed in such a way as to overestimate the comparative efficacy of KYMRIAH for patients diagnosed with r/r DLBCL.

In response to CMS' concerns regarding the drop-out rate within the JULIET trial, the applicant for KYMRIAH stated that the JULIET trial was designed to reflect a paradigm of patient management that the applicant believes reflects the real-world treatment decisions of health care providers. The applicant explained that in the JULIET trial, any patient who was identified as a candidate for treatment involving KYMRIAH and could undergo apheresis was enrolled in the trial at the time of apheresis collection, then patients were allowed to undergo bridging chemotherapy during the time that they awaited a manufacturing slot assignment and during the manufacturing process. The applicant indicated that this is in contrast with protocols of other trials in which patients are not enrolled until such time as a manufacturing slot is available because patients diagnosed with r/r DLBCL have rapidly progressive disease and they often have disease which is resistant or refractory to therapy and, therefore, patients may progress during this time. The applicant further stated that the design of the JULIET trial allowed these events to be captured, whereas other study designs that do not

[76] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[77] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (aci-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[77] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (aci-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

enroll patients until a manufacturing slot is available and assigned would not capture such events because such patients would never be enrolled in the study. The applicant explained that the median time from apheresis to infusion of 113 days is not a direct measure of manufacturing time and reflects the fact that cryopreserved apheresis allowed patients to be apheresed before trial enrollment. Additionally, the applicant stated that the point at which the patient is infused after manufacturing is at the discretion of the treating physician, based on what is appropriate for the patient. The applicant explained that the use of cryopreserved apheresis material allows physicians to maximize the timing of apheresis for the benefit of patients and to minimize the effect of preceding chemotherapy on the health of the cells, which is not accounted for in a measurement of apheresis to infusion. The applicant further stated that the clinical trial was managed differently than their commercial process. The applicant indicated that, early in the JULIET trial, capacity-limited manufacturing could have led to longer wait times compared to their current commercial (non-trial) process, where patient cells are manufactured on a first-in, first manufactured basis and, their target is a 22-day manufacturing cycle from receipt of leukapheresis material, according to Novartis's requirements, to return shipping of KYMRIAH.

The applicant also responded to CMS' concern regarding the percentage of patients who experienced CRS in the JULIET trial. The applicant for KYMRIAH stated that updated results show, using the conservative University of Pennsylvania Scale, CRS occurred in 78 percent of the patients enrolled in the JULIET clinical trial. However, only 23 percent of the patients had ≥Grade III CRS and no patient had Grade V CRS. The applicant further stated that patients with low grade CRS may reflect symptoms such as fever, myalgia, nausea or fatigue. The applicant noted that, in this context, the patients with ≥Grade III CRS represent those with a life-threatening condition that requires interventions to support respiratory or circulatory function. The applicant indicated that CRS was manageable by a trained staff according to a specific CRS treatment algorithm and current standard-of-care for these patients includes high-dose salvage chemotherapy regimens, as well as myeloablative therapy prior to autologous stem cell transplant, both of which have aggressive toxicity profiles. However, the applicant indicated that many of the toxicities of autologous stem cell transplant are managed without the benefit of treatment algorithms and directed therapies which aid in the management of CRS.

The applicant for YESCARTA responded to CMS' concern that its new technology add-on payment application did not appear to include patient mortality data that was included as part of the applicant's FY 2018 new technology add-on payment application for the KTE–C19 technology. The applicant acknowledged that the Study 1 interim analysis data included in the FY2018 new technology add-on payment application and depicted as CMS' concern was not explicitly detailed in the FY 2019 application, which focused on the primary analysis, nor in Supplement 2, which provided data from the updated analysis. The applicant confirmed that there were no new deaths from adverse events at the time of the Study 1 primary analysis (median follow-up of 6 months) or at the time of the updated analysis (median follow-up of 15.4 months).

The applicant also responded to CMS' concern that there are few published results describing survival benefits from the use of YESCARTA. The applicant indicated that information to address this issue was submitted to CMS in a new technology add-on payment supplemental file. The applicant indicated that this file provided data from the updated analysis (median follow-up of 15.4 months) and references for the published manuscripts. (We note that the information the applicant provided with its public comment was also previously provided to CMS in the supplemental file mentioned above). The applicant stated that, in December 2017, the long-term follow-up of Study 1 (ZUMA–1), Phase I (n=7), and Phase II (n=101) was published in the New England Journal of Medicine and presented at ASH 2017. The applicant explained that at median 15.4 months follow-up at the time of the updated analysis data cutoff (August 11, 2017), responses were ongoing in 42 percent of the patients where median duration of response for complete response has not been reached and median overall survival has not been reached. The applicant indicated that the authors concluded these high levels of durable response confirmed that YESCARTA is highly effective and provides substantial clinical benefit for patients diagnosed with large B-cell lymphoma who otherwise have no curative options. Additionally, the applicant stated that results show (best objective response, ongoing) ORR (82 percent, 42 percent) and CR (58 percent, 40 percent) at the time of the updated analysis (15.4 months) are significantly improved over results from SCHOLAR–1 historical control of 26 percent. The applicant stated that, based on the evidence of improved benefits provided to patients with no other treatment options, this study supports the finding that YESCARTA demonstrates that it represents a substantial clinical improvement over existing treatment options. The applicant further detailed that the results from the updated analysis show: The median time to response was rapid (1.0 month; range, 0.8 to 6.0) and that the median duration of complete response has not been reached. Additionally, the applicant explained that responses to treatment, including ongoing ones, were consistent across key covariates, including in individuals 65 years of age and younger and those individuals 65 years of age and older. The applicant also indicated that the median overall survival has not been reached. However, the applicant stated that the results of the updated analysis show the overall survival rate at 18 months was 52 percent and 56 percent of patients enrolled in the study were alive at the time of the updated analysis. The applicant also indicated that results show ongoing durable remissions have been observed in patients at 24 months.

The applicant for YESCARTA also responded to CMS' concern regarding the limited number of patients (n=108) that were studied after infusion involving YESCARTA T-cell immunotherapy. The applicant stated that the statistical plan for Study 1 was developed by Kite in close discussion with FDA. The applicant explained that the design of this statistical plan was developed so that the study size would be powered to show statistical significance for the primary end point: ORR. The applicant indicated that the primary analysis of Study 1, Phase II demonstrates that the primary endpoint has been met and that key secondary endpoints including Duration of Response and Overall Survival were also met. Therefore, the applicant believed that the results of the clinical data show YESCARTA has demonstrated substantial clinical improvement for patients who previously had no curative options, no standard therapy and a short expected survival. The applicant also explained that the sample size (the number of patients planned) for Study 1 was determined by the number of patients required to statistically demonstrate an improvement in the response rate with treatment involving YESCARTA and is

consistent with other single-arm oncology studies with a response rate endpoint. The applicant indicated that Study 1 had an adequate sample size to provide 90 percent power to statistically demonstrate an improvement in response rate relative to the historical control rate of 20 percent, and a historical control was the only ethical and feasible study design for these r/r large B-cell lymphoma patients who previously had no other treatment options and have a uniformly very poor outcome without therapy. The applicant stated that standard protocols, when evaluating a therapy with a profound improvement in the endpoint, usually require a smaller sample size and larger studies are required when the improvement in the endpoint is small or difficult to demonstrate. The applicant believed that, given the magnitude of improved benefit from treatment with YESCARTA, the sample size of n=108 was adequate to demonstrate efficacy and the trial was adequately sized to demonstrate a positive risk-benefit consistent with Good Clinical Practice (GCP)17 and International Conference on Harmonization (ICH) guidelines.

Response: We appreciate the applicants' submission of additional information to address the concerns presented in the proposed rule.

After consideration of the public comments we received, we agree that both, KYMRIAH and YESCARTA, represent a substantial clinical improvement over existing technologies because the technologies allow access for a treatment option for those patients who are unable to receive standard-of-care treatment. Additionally, there are no other currently FDA-approved treatment options for patients with r/r DLBCL who are ineligible for, or who have failed ASCT. Finally, both technologies appear to significantly improve clinical outcomes, including ORR, CR, OS, and durability of response, and allow for a manageable safety profile.

In summary, we have determined that KYMRIAH and YESCARTA meet all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for KYMRIAH and YESCARTA for FY 2019. We expect that KYMRIAH will be administered for the treatment of adult patients (18 years old and older) diagnosed with r/r DLBCL not eligible for ASCT, and YESCARTA will be administered for the treatment of adult patients diagnosed with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Cases involving KYMRIAH and YESCARTA that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033C3 and XW043C3. The applicants for both, KYMRIAH and YESCARTA, estimate that the average cost for an administered dose of KYMRIAH or YESCARTA is $373,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of KYMRIAH or YESCARTA is $186,500 for FY 2019.

We note that on May 16, 2018, CMS opened a national coverage determination (NCD) analysis on CAR T-cell therapy for Medicare beneficiaries with advanced cancer. The expected national coverage analysis completion date is May 17, 2019. For more information, we refer reader to the CMS website at: *https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=291*.

Lastly, we note that in the FY 2019 IPPS/LTCH proposed rule (83 FR 20294), we discussed possible payment alternatives and invited public comments regarding the most appropriate mechanism to provide payment to hospitals for new technologies such as CAR T-cell therapy drugs, including through the use of new technology add-on payments. We also invited public comments on how they would affect incentives to encourage lower drug prices.

As discussed further in section II.F.2.d. of the preamble of this final rule, building on President Trump's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,* the CMS Center for Medicare and Medicaid Innovation (Innovation Center) is soliciting public comment in the CY 2019 OPPS/ASC proposed rule on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out-of-pocket spending. Given the relative newness of CAR T-cell therapy, the potential model, and our request for feedback on this model approach, we believe that it would be premature to adopt changes to our existing payment mechanisms, including structural changes in new technology add-on payments. Therefore, we disagree with commenters who have requested such changes under the IPPS for FY 2019.

b. VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection)

Jazz Pharmaceuticals, Inc. submitted an application for new technology add-on payments for the VYXEOS™ technology for FY 2019. (We note that Celator Pharmaceuticals, Inc. submitted an application for new technology add-on payments for VYXEOS™ for FY 2018. However, Celator Pharmaceuticals did not receive FDA approval by the July 1, 2017 deadline for applications for FY 2018.) VYXEOS™ was approved by FDA on August 3, 2017, for the treatment of adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML–MRC).

AML is a type of cancer in which the bone marrow makes abnormal myeloblasts (immature bone marrow white blood cells), red blood cells, and platelets. If left untreated, AML progresses rapidly. Normally, the bone marrow makes blood stem cells that develop into mature blood cells over time. Stem cells have the potential to develop into many different cell types in the body. Stem cells can act as an internal repair system, dividing, essentially without limit, to replenish other cells. When a stem cell divides, each new cell has the potential to either remain a stem cell or become a specialized cell, such as a muscle cell, a red blood cell, or a brain cell, among others. A blood stem cell may become a myeloid stem cell or a lymphoid stem cell. Lymphoid stem cells become white blood cells. A myeloid stem cell becomes one of three types of mature blood cells: (1) Red blood cells that carry oxygen and other substances to body tissues; (2) white blood cells that fight infection; or (3) platelets that form blood clots and help to control bleeding. In patients diagnosed with AML, the myeloid stem cells usually become a type of myeloblast. The myeloblasts in patients diagnosed with AML are abnormal and do not become healthy white blood cells. Sometimes in patients diagnosed with AML, too many stem cells become abnormal red blood cells or platelets. These abnormal cells are called leukemia cells or blasts.

AML is defined by the World Health Organization (WHO) as greater than 20 percent blasts in the bone marrow or blood. AML can also be diagnosed if the blasts are found to have a chromosome change that occurs only in a specific type of AML diagnosis, even if the blast percentage does not reach 20 percent. Leukemia cells can build up in the bone

marrow and blood, resulting in less room for healthy white blood cells, red blood cells, and platelets. When this occurs, infection, anemia, or increased risk for bleeding may result. Leukemia cells can spread outside the blood to other parts of the body, including the central nervous system (CNS), skin, and gums.

Treatment of AML diagnoses usually consists of two phases; remission induction and post-remission therapy. Phase one, remission induction, is aimed at eliminating as many myeloblasts as possible. The most common used remission induction regimens for AML diagnoses are the ''7+3'' regimens using an antineoplastic and an anthracycline. Cytarabine and daunorubicin are two commonly used drugs for ''7+3'' remission induction therapy. Cytarabine is continuously administered intravenously over the course of 7 days, while daunorubicin is intermittently administered intravenously for the first 3 days. The ''7+3'' regimen typically achieves a 70 to 80 percent complete remission (CR) rate in most patients under 60 years of age.

High rates of CR are not generally seen in older patients for a number of reasons, such as different leukemia biology, much higher incidence of adverse cytogenetic abnormalities, higher rate of multidrug resistant leukemic cells, and comparatively lower patient performance status (the standard criteria for measuring how the disease impacts a patient's daily living abilities). Intensive induction therapy has worse outcomes in this patient population.[78] The applicant asserted that many older adults diagnosed with AML have a poor performance status [79] at presentation and multiple medical comorbidities that make the use of intensive induction therapy quite difficult or contraindicated altogether. Moreover, the CR rates of poor-risk patients diagnosed with AML are substantially higher in patients over 60 years of age; owing to a higher proportion of secondary AML, disease developing in the setting of a prior myeloid disorder.[80]

According to the applicant, the combination of cytarabine and an anthracycline, either as ''7+3'' regimens or as part of a different regimen incorporating other cytotoxic agents, may be used as so-called ''salvage'' induction therapy in the treatment of adults diagnosed with AML who experience relapse in an attempt to achieve CR. According to the applicant, while CR rates of success vary widely depending on underlying disease biology and host factors, there is a lower success rate overall in achievement of CR with ''7 +3'' regimens compared to VYXEOS™ therapy. According to the applicant, ''7+3'' regimens produce a CR rate of approximately 50 percent in younger adult patients who have relapsed, but were in CR for at least 1 year.[81]

VYXEOS™ is a nano-scale liposomal formulation containing a fixed combination of cytarabine and daunorubicin in a 5:1 molar ratio. This formulation was developed by the applicant using a proprietary system known as CombiPlex. According to the applicant, CombiPlex addresses several fundamental shortcomings of conventional combination regimens, specifically the conventional ''7+3'' free drug dosing, as well as the challenges inherent in combination drug development, by identifying the most effective synergistic molar ratio of the drugs being combined *in vitro,* and fixing this ratio in a nano-scale drug delivery complex to maintain the optimized combination after administration and ensuring exposure of this ratio to the tumor.

Cytarabine and daunorubicin are co-encapsulated inside the VYXEOS™ liposome at a fixed ratiometrically, optimized 5:1 cytarabine: daunorubicin molar ratio. According to the applicant, encapsulation maintains the synergistic ratios, reduces degradation, and minimizes the impact of drug transporters and the effect of known resistant mechanisms. The applicant stated that the 5:1 molar ratio has been shown, *in vitro,* to maximize synergistic antitumor activity across multiple leukemic and solid tumor cell lines, including AML, and in animal model studies to be optimally efficacious compared to other cytarabine: daunorubicin ratios. In addition, the applicant stated that in clinical studies, the use of VYXEOS™ has demonstrated consistently more efficacious results than the conventional ''7+3'' free drug dosing. VYXEOS™ is intended for intravenous administration after reconstitution with 19 mL sterile water for injection. VYXEOS™ is administered as a 90-minute intravenous infusion on days 1, 3, and 5 (induction therapy), as compared to the ''7+3'' free drug dosing, which consists of two individual drugs administered on different days, including 7 days of continuous infusion.

With regard to the newness criterion, as discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that VYXEOS™ does not use the same or similar mechanism of action to achieve a therapeutic outcome as any other drug assigned to the same or a different MS–DRG. The applicant stated that no other AML treatment is designed, nor is able, to deliver a fixed, ratiometrically optimized and synergistic drug:drug ratio of 5:1 cytarabine to daunorubicin, and selectively target and accumulate at the site of malignancy, while minimizing unwanted exposure, which the applicant based on the data results of preclinical and clinical studies of the use of VYXEOS™. The applicant indicated that VYXEOS™ is a nano-scale liposomal formulation of a fixed combination of cytarabine and daunorubicin. Further, the applicant stated that the rationale for the development of VYXEOS™ is based on prolonged delivery of synergistic drug ratios utilizing the applicant's proprietary, ratiometric CombiPlex technology. According to the applicant, conventional ''7+3'' free drug dosing has no delivery complex, and these individual drugs are administered without regard to their ratio dependent interaction. According to the applicant, enzymatic inactivation and imbalanced drug efflux and transporter expression reduce drug levels in the cell. Further, decreased cytotoxicity leads to cell survival, emergence of drug resistant cells, and decreased overall survival.

The applicant provided the results of clinical studies to demonstrate that the CombiPlex technology and the ratiometric dosing of VYXEOS™ represent a shift in anticancer agent delivery, whereby the fixed, optimized dosing provides less drug to achieve improved efficacy, while maintaining a favorable risk-benefit profile. The results of this ratiometric dosing approach are in contrast to the typical combination chemotherapy

[78] Juliusson, G., Lazarevic, V., Horstedt, A.S., Hagberg, O., Hoglund, M., ''Acute myeloid leukemia in the real world: why population-based registries are needed'', *Blood,* 2012 Apr 26; vol. 119(17), pp. 3890–9.

[79] Stone, R.M., et al., (2004), ''Acute myeloid leukemia. Hematology'', Am Soc Hematol Educ Program, 2004, pp. 98–117.

[80] Appelbaum, F.R., Gundacker, H., Head, D.R., ''Age and acute myeloid leukemia'', *Blood* 2006, vol. 107, pp. 3481–3485.

[81] Kantarjian, H., Rayandi, F., O'Brien, S., et al., ''Intensive chemotherapy does not benefit most older patients (age 70 years and older) with acute myeloid leukemia,'' *Blood,* 2010, vol. 116(22), pp. 4422.

development that establishes the recommended dose of one agent and then adds subsequent drugs to the combination at increasing concentrations until the aggregate effects of toxicity are considered to be limiting (the ''7+3'' drug regimen). According to the applicant, this current approach to combination chemotherapy development assumes that maximum therapeutic activity will be achieved with maximum dose intensity for all drugs in the combination, and ignores the possibility that more subtle concentration-dependent drug interactions could result in frankly synergistic outcomes.

The applicant maintained that, while VYXEOS™ contains no novel active agents, its innovative drug delivery mechanism appears to be a superior way to deliver the two active compounds in an effort to optimize their efficacy in killing leukemic blasts. However, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20296), we stated that we were concerned it is possible that VYXEOS™ may use a similar mechanism of action compared to currently available treatment options because both the current treatment regimen and VYXEOS™ are used in the treatment of AML by intravenous administration of cytarabine and daunorubicin. We specifically stated that we were concerned that the mechanism of action of the ratiometrically fixed liposomal formulation of VYXEOS™ is the same or similar to that of the current intravenous administration of cytarabine and daunorubicin.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, we stated that we believe that potential cases representing patients who may be eligible for treatment involving VYXEOS™ would be assigned to the same MS–DRGs as cases representing patients who receive treatment for diagnoses of AML.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that VYXEOS™ is indicated for use in the treatment of patients who have been diagnosed with high-risk AML. The applicant also asserted that VYXEOS™ is the first and only approved fixed combination of cytarabine and daunorubicin and is designed to uniquely control the exposure using a nano-scale drug delivery vehicle leading to statistically significant improvements in survival in patients who have been diagnosed with high-risk AML compared to the conventional ''7+3'' free drug dosing. We stated in the proposed rule that we believe that VYXEOS™ involves the treatment of the same patient population as other AML treatment therapies.

The following unique ICD–10–PCS codes were created to describe the administration of VYXEOS™: XW033B3 (Introduction of cytarabine and caunorubicin liposome antineoplastic into peripheral vein, percutaneous approach, new technology group 3) and XW043B3 (Introduction of cytarabine and daunorubicin liposome antineoplastic into central vein, percutaneous approach, new technology group 3).

In the FY 2019 IPPS/LTCH PPS proposed rule, we invited public comments on whether VYXEOS™ is substantially similar to existing technology, including whether the mechanism of action of VYXEOS™ differs from the mechanism of action of the currently available treatment regimen. We also invited public comments on whether VYXEOS™ meets the newness criterion.

Comment: Several commenters supported the novel and effective ratiometric dosing drug delivery mechanism of VYXEOS™. The applicant stated that preclinical and clinical evidence confirms the differentiated mechanism of action of VYXEOS™ from other available treatment options. The applicant also reiterated that it believed VYXEOS™ is not substantially similar to any other currently available drug and is highly differentiated from the conventional ''7+3'' free drug dosing treatment regimen.

Response: We appreciate the commenters' and the applicant's input on whether VYXEOS™ meets the newness criterion. After consideration of the public comments we received, we believe that VYXEOS™ has a unique mechanism of action and, therefore, is not substantially similar to other drug therapies. We believe that the liposomal formulation used to combine daunorubicin and cytarabine to create VYXEOS™ is unique and distinct from other anti-cancer agents and, therefore, we believe that VYXEOS™ meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant used the FY 2016 MedPAR Hospital Limited Data Set (LDS) to assess the MS–DRGs to which cases representing potential patient hospitalizations that may be eligible for treatment involving VYXEOS™ would most likely be assigned. These potential cases representing patients who may be VYXEOS™ candidates were identified if they: (1) Were diagnosed with acute myeloid leukemia (AML); and (2) received chemotherapy during their hospital stay. The cohort was further limited by excluding patients who had received bone marrow transplants. The cohort used in the analysis is referred to in this discussion as the primary cohort.

According to the applicant, the primary cohort of cases spans 131 unique MS–DRGs, 16 of which contained more than 10 cases. The most common MS–DRGs are MS–DRG 837, 834, 838, and 839. These 4 MS–DRGs account for 4,457 (81 percent) of the 5,483 potential cases in the cohort.

The case-weighted unstandardized charge per case is approximately $185,844. The applicant then removed charges related to other chemotherapy agents because VYXEOS™ would replace the need for the use of current chemotherapy agents. The applicant explained that charges for chemotherapy drugs are grouped with charges for oncology, diagnostic radiology, therapeutic radiology, nuclear medicine, CT scans, and other imaging services in the ''Radiology Charge Amount.'' According to the applicant, removing 100 percent of the ''Radiology Charge Amount'' would understate the cost of care for treatment involving VYXEOS™ for patients who may be eligible because treatment involving VYXEOS™ would be unlikely to replace many of the services captured in the ''Radiology Charge Amount'' category. The applicant found that chemotherapy charges represent less than 20 percent of the charges associated with revenue centers grouped into the ''Radiology Charge Amount'' and removed 20 percent of the radiology charge amount in order to capture the effect of removing chemotherapy pharmacy charges. The applicant noted that regardless of the type of induction chemotherapy, patients being treated for AML have AML-related complications, such as bleeding or infection that require supportive care drug therapy. For this reason, it is expected that eligible patients receiving treatment involving VYXEOS™ will continue to incur other pharmacy and IV therapy charges for AML-related complications.

After removing the charges for the prior technology, the applicant standardized the charges. The applicant then applied an inflation factor of 1.09357, the value used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to update the charges from FY 2016 to FY 2018. According to the applicant, for the primary new technology add-on payment cohort, the cost criterion was

met without consideration of VYXEOS™ charges. The average case-weighted standardized charge was $170,458, which exceeded the average case-weighted Table 10 MS–DRG threshold amount of $82,561 by $87,897.

The applicant provided additional analyses with the inclusion of VYXEOS™ charges under 3-vial, 4-vial, 6-vial, and 10-vial treatment scenarios. According to the applicant, the cost criterion was satisfied in each of these scenarios, with charges in excess of the average case-weighted threshold amount.

Finally, the applicant also provided the following sensitivity analyses (that did not include charges for VYXEOS™) using the methodology above:

- Sensitivity Analysis 1—limited the cohort to patients who have been diagnosed with AML without remission (C92.00 or C92.50) who received chemotherapy and did not receive bone marrow transplant.
- Sensitivity Analysis 2—the modified cohort was limited to patients who have been diagnosed with relapsed AML who received chemotherapy and did not receive bone marrow transplant.
- Sensitivity Analysis 3—the modified cohort was limited to patients who have been diagnosed with AML and who did not receive bone marrow transplant.
- Sensitivity Analysis 4—the primary cohort was maintained, but 100 percent of the charges for revenue centers grouped into the ''Pharmacy Charge Amount'' were excluded.
- Sensitivity Analysis 5—identified patients who have been diagnosed with AML in remission.

The applicant noted that, in all of the sensitivity analysis scenarios, the average case-weighted standardized charge per case exceeded the average case-weighted Table 10 MS–DRG threshold amount. Based on all of the analyses above, the applicant maintained that VYXEOS™ met the cost criterion. We invited public comments on whether VYXEOS™ meets the cost criterion.

Comment: The applicant noted the detailed summary presented in the proposed rule of the cost analysis of the VYXEOS™, including a primary cohort analysis and five sensitivity analyses. The applicant stated that, in each of the analyses, it was demonstrated that the average case-weighted standardized charge per case for the applicable MS–DRGs exceeded the average case-weighted threshold amount before considering the average per patient cost of VYXEOS™ to the hospital.

Response: We appreciate the applicant's input.

After consideration of the public comments we received, we believe that VYXEOS™ meets the cost criterion.

With regard to substantial clinical improvement, according to the applicant, clinical data results have shown that the use of VYXEOS™ represents a substantial clinical improvement for the treatment of AML in newly diagnosed high-risk, older (60 years of age and older) patients, marked by statistically significant improvements in overall survival, event free survival and response rates, and in relapsed patients age 18 to 65 years of age, where a statistically significant improvement in overall survival has been documented for the poor-risk subset of patients as defined by the European Prognostic Index. In both groups of patients, the applicant stated that there was significant improvement in survival for the high-risk patient group. The applicant provided the following specific clinical data results.

- The applicant stated that clinical data results show that treatment with VYXEOS™ for older patients (60 years of age and older) who have been diagnosed with untreated, high-risk AML will result in superior survival rates, as compared to patients treated with conventional ''7+3'' free drug dosing. The applicant provided a summary of the pivotal Phase III Study 301 in which 309 patients were enrolled, with 153 patients randomized to the VYXEOS™ treatment arm and 156 to the ''7+3'' free drug dosing treatment arm. Among patients who were 60 to 69 years old, there were 96 patients in the VYXEOS™ treatment arm and 102 in the ''7+3'' free drug dosing treatment arm. For patients who were 70 to 75 years old, there were 57 and 54 patients in each treatment arm, respectively. The applicant noted that the data results from the Phase III Study 301 demonstrated that first-line treatment of patients diagnosed with high-risk AML in the VYXEOS™ treatment arm resulted in substantially greater median overall survival of 9.56 months versus 5.95 months in the ''7+3'' free drug dosing treatment arm (hazard ratio of 0.69; p=0.005).
- The applicant further asserted that high-risk, older patients (60 years old and older) previously untreated for diagnoses of AML will have a lower risk of early death when treated with VYXEOS™ than those treated with the conventional ''7+3'' free drug dosing. The applicant cited Medeiros, et al.,[82] which reported a large observational study of Medicare beneficiaries and noted the following: The data result of the study showed that 50 to 60 percent of elderly patients diagnosed with AML remain untreated following diagnosis; treated patients were more likely younger, male, and married, and less likely to have secondary diagnoses of AML, poor performance indicators, and poor comorbidity scores compared to untreated patients; and in multivariate survival analyses, treated patients exhibited a significant 33 percent lower risk of death compared to untreated patients.

Based on data from the Phase III Study 301,[83] the applicant cited the following results: The rate of 60-day mortality was less in the VYXEOS™ treatment arm (13.7 percent) versus the ''7+3'' free drug dosing treatment arm (21.2 percent); the reduction in early mortality was due to fewer deaths from refractory AML (3.3 percent versus 11.3 percent), with very similar rates of 60-day mortality due to adverse events (10.4 percent versus 9.9 percent); there were fewer deaths in the VYXEOS™ treatment arm versus the ''7+3'' free drug dosing treatment arm during the treatment phase (7.8 percent versus 11.3 percent); and there were fewer deaths in the VYXEOS™ treatment arm during the follow-up phase than in the ''7+3'' free drug dosing treatment arm (59.5 percent versus 71.5 percent).

- The applicant asserted that high-risk, older patients (60 years old and older) previously untreated for a diagnosis of AML exhibited statistically significant improvements in response rates after treatment with VYXEOS™ versus treatment with the conventional ''7+3'' free drug chemotherapy dosing, suggesting that the use of VYXEOS™ is a superior pre-transplant induction treatment versus ''7+3'' free drug dosing. Restoration of normal hematopoiesis is the ultimate goal of any therapy for AML diagnoses. The first phase of treatment consists of induction chemotherapy, in which the goal is to ''empty'' the bone marrow of all hematopoietic elements (both benign and malignant), and to allow repopulation of the marrow with normal cells, thereby yielding remission. According to the applicant, post-induction response rates were

[82] Medeiros, B., et al., ''Big data analysis of treatment patterns and outcomes among elderly acute myeloid leukemia patients in the United States'', *Ann Hematol,* 2015, vol. 94(7), pp. 1127–1138.

[83] Lancet, J., et al., ''Final results of a Phase III randomized trial of VYXEOS (CPX–351) versus 7+3 in older patients with newly diagnosed, high-risk (secondary) AML''. Abstract and oral presentation at American Society of Clinical Oncology (ASCO), June 2016.

significantly higher following the use of VYXEOS™, which elicited a 47.7 percent total response rate and a 37.3 percent rate for CR, whereas the total response and CR rates for the ''7+3'' free drug dosing arm were 33.3 percent and 25.6 percent, respectively. The CR+CRi rates for patients who were 60 to 69 years of age were 50.0 percent in the VYXEOS™ treatment arm and 36.3 percent in the ''7+3'' free drug dosing treatment arm, with an odds ratio of 1.76 (95 percent CI, 1.00–3.10). For patients who were 70 to 75 years old, the rates of CR+CRi were 43.9 percent in the VYXEOS™ treatment arm and 27.8 percent in the ''7+3'' free drug dosing treatment arm.

• The applicant asserted that VYXEOS™ treatment will enable high-risk, older patients (60 years old and older) to bridge to allogeneic transplant, and VYXEOS™ treated responding patients will have markedly better outcomes following transplant. The applicant stated that diagnoses of secondary AML are considered incurable with standard chemotherapy approaches and, as with other high-risk hematological malignancies, transplantation is a useful treatment alternative. The applicant further stated that autologous HSCT has limited effectiveness and at this time, only allogeneic HSCT with full intensity conditioning has been reported to produce long-term remissions. However, the applicant stated that the clinical study by Medeiros, et al. reported that, while the use of allogeneic HSCT is considered a potential cure for AML, its use is limited in older patients because of significant baseline comorbidities and increased transplant-related morbidity and mortality. Patients in either treatment arm of the Phase III Study 301 responding to induction with a CR or CR+CRi (n=125) were considered for allogeneic hematopoietic cell transplant (HCT) when possible. In total, 91 patients were transplanted: 52 (34 percent) from the VYXEOS™ treatment arm and 39 (25 percent) from the ''7+3'' free drug dosing treatment arm. Patient and AML characteristics were similar according to randomized arm, including percentage of patients in each treatment arm that underwent transplant in CR+CRi status. However, the applicant noted that the VYXEOS™ treatment arm contained a higher percentage of older patients (70 years old or older) who were transplanted (VYXEOS™, 31 percent; ''7+3'' free drug dosing, 15 percent).[84]

According to the applicant, patient outcome following transplant strongly favored patients in the VYXEOS™ treatment arm. The Kaplan-Meier analysis of the 91 transplanted patients landmarked at the time of HCT showed that patients in the VYXEOS™ treatment arm had markedly better overall survival (hazard ratio 0.46; p=0.0046). The time-dependent Adjustment Model (Cox proportional hazard ratio) was used to evaluate the contribution of VYXEOS™ treatment to overall survival rate after adjustment for transplant and showed that VYXEOS™ treatment remained a significant contributor, even after adjusting for transplant. The time-dependent Cox hazard ratio for overall survival rates in the VYXEOS™ treatment arm versus the ''7+3'' free drug dosing treatment arm was 0.51 (95 percent CI, 0.35–0.75; p=.0007).

• The applicant asserted that VYXEOS™ treatment of previously untreated older patients (60 years old and older) diagnosed with high-risk AML increases the response rate and improves survival compared to conventional ''7+3'' free drug dosing treatment in patients diagnosed with FLT3 mutation. The applicant noted the following: Approximately 20 to 30 percent of AML patients harbor some form of FLT3 mutation, AML patients with a FLT3 mutation have a higher relapse rate and poorer prognosis than the overall population diagnosed with AML, and the most common type of mutation is internal tandem duplication (ITD) mutation localized to a membrane region of the receptor.

The applicant cited Gordon, et al., 2016,[85] which reported on the significant anti-leukemic activity of VYXEOS™ treatment in AML blasts exhibiting high-risk characteristics, including FLT3–ITD, that are typically associated with poor outcomes when treated with conventional ''7+3'' free drug dosing treatment. To determine whether the improved complete remission and overall survival rates of treatment using VYXEOS™ as compared to conventional ''7+3'' free drug dosing treatment are attributable to liposome-mediated altered drug PK or direct cellular interactions with specific AML blast samples, the authors evaluated cytotoxicity in 53 AML patient specimens. Cytotoxicity results were correlated with patient characteristics, as well as VYXEOS™ treatment cellular uptake and molecular phenotype status including FLT3–ITD, which is a predictor of poor patient outcomes to conventional ''7+3'' free drug dosing treatment. The applicant stated that a notable result from this research was the observation that AML blasts exhibiting the FLT3–ITD phenotype exhibited some of the lowest IC_{50} (the 50 percent inhibitory concentration) values and, as a group, were five-fold more sensitive to the VYXEOS™ treatment than those with wild type FLT3. In addition, there was evidence that increased sensitivity to VYXEOS™ treatment was associated with increased uptake of the drug-laden liposomes by the patient-derived AML blasts. The applicant noted that Gordon, et al. 2016, concluded taken together, the data are consistent with clinical observations where VYXEOS™ treatment retains significant anti-leukemic activity in AML patients exhibiting high-risk characteristics. The applicant also noted that a subanalysis of Phase III Study 301 identified 22 patients who had been diagnosed with FLT3 mutation in the VYXEOS™ treatment arm and 20 in the ''7+3'' free drug dosing treatment arm, which resulted in the following response rates of FLT3 mutated patients, which were higher with VYXEOS™ treatments (15 of 22, 68.2 percent) versus ''7+3'' free drug dosing treatments (5 of 20, 25.0 percent); and the Kaplan-Meier analysis of the 42 FLT3 mutated patients showed that patients in the VYXEOS™ treatment arm had a trend towards better overall survival rates (hazard ratio 0.57; p=0.093).

• The applicant asserted that younger patients (18 to 65 years old) with poor risk first relapse AML have shown higher response rates with VYXEOS™ treatment versus conventional ''salvage'' chemotherapy. Overall, the applicant stated that the use of VYXEOS™ had an acceptable safety profile in this patient population based on 60-day mortality data. Study 205 [86] was a randomized study comparing VYXEOS™ treatment against the investigator's choice of first ''salvage'' chemotherapy in patients who had been diagnosed with relapsed AML after a first remission lasting greater than 1 month (VYXEOS™ treatment arm, n=81 and ''7+3'' free drug dosing treatment arm, n=44; 18 to 65 years old). Investigator's choice was almost always based on cytarabine + anthracycline, usually with the addition

[84] Stone Hematology 2004; Gordon AACR 2016; NCI. Available at: *www.cancer.gov*.

[85] Gordon, M., Tardi, P., Lawrence, M.D., et al., ''CPX–351 cytotoxicity against fresh AML blasts increased for FLT3–ITD+ cells and correlates with drug uptake and clinical outcomes,'' Abstract 287 and poster presented at AACR (American Association for Cancer Research), April 2016.

[86] Cortes, J., et al., ''Significance of prior HSCT on the outcome of salvage therapy with CPX–351 or conventional chemotherapy among first relapse AML patients.'' Abstract and poster presented at ASH 2011.

of one or two new agents. According to the applicant, treatment involving VYXEOS™ demonstrated a higher rate of morphological leukemia clearance among all patients, 43.2 percent versus 40.0 percent, and the advantage was most apparent in poor-risk patients, 78.7 percent versus 44.4 percent, as defined by the European Prognostic Index (EPI). In the subset analysis of this EPI poor-risk patient subset, the applicant stated there was a significant improvement in survival rate (6.6 versus 4.2 months median, hazard ratio=0.55, p=0.02) and improved response rate (39.3 percent versus 27 percent). The applicant also noted the following: The safety profile for the use of VYXEOS™ was qualitatively similar to that of control ''salvage'' therapy, with nearly identical 60-day mortality rates (14.8 percent versus 15.9 percent); among VYXEOS™ treated patients, those with no history of prior HSCT (n=59) had higher response rates (54.2 percent versus 37.8 percent) and lower 60-day mortality (10.2 percent versus 16.2 percent); overall, the use of VYXEOS™ had acceptable safety based on 60-day mortality data, with somewhat higher frequency of neutropenia and thrombocytopenia-related grade III–IV adverse events. Even though these patients are younger (18 to 65 years old) than the population studied in Phase III Study 301 (60 years old and older), Study 205 patients were at a later stage of the disease and almost all had responded to first-line therapy (cytarabine + anthracycline) and had relapsed. The applicant also cited Cortes, et al. 2015,[87] which reported that patients who have been diagnosed with first relapse AML have limited likelihood of response and short expected survival following ''salvage'' treatment with the results from literature showing that:

- Mitoxantrone, etoposide, and cytarabine induced response in 23 percent of patients, with median overall survival of only 2 months.
- Modulation of deoxycitidine kinase by fludarabine led to the combination of fludarabine and cytarabine, resulting in a 36 percent CR rate with median remission duration of 39 weeks.
- First salvage gemtuzumab ozogamicin induced CR+CRp (or CR+CRi) response in 30 percent of patients with CD33+AML and, for patients with short first CR durations, appeared to be superior to cytarabine-based therapy.

[87] Cortes, J., et al., (2015), ''Phase II, multicenter, randomized trial of CPX–351 (cytarabine:daunorubicin) liposome injection versus intensive salvage therapy in adults with first relapse AML,'' *Cancer,* January 2015, pp. 234–42.

The applicant noted that Study 205 results showed the use of VYXEOS™ retained greater anti-leukemic efficacy in patients who have been diagnosed with poor-risk first relapse AML, and produced higher morphological leukemia clearance rates (78.7 percent) compared to conventional ''salvage'' therapy (44 percent). The applicant further noted that, overall, the use of VYXEOS™ had acceptable safety profile in this patient population based on 60-day mortality data.

Based on all of the data presented above, the applicant concluded that VYXEOS™ represents a substantial clinical improvement over existing technologies. However, in the proposed rule, we stated we were concerned that, although there was an improvement in a number of outcomes in Phase III Study 301, specifically overall survival rate, lower risk of early death, improved response rates, better outcomes following transplant, increased response rate and overall survival in patients diagnosed with FLT3 mutation, and higher response rates versus conventional ''salvage'' chemotherapy in younger patients diagnosed with poor-risk first relapse, the improved outcomes may not be statistically significant. Furthermore, we indicated we were concerned that the overall improvement in survival from 5.95 months to 9.56 months may not represent a substantial clinical improvement. In addition, the rate of adverse events in both treatment arms of Study 205, given the theoretical benefit of reduced toxicity with the liposomal formulation, was similar for both the VYXEOS™ and ''7+3''free drug treatment groups. Therefore, we also were concerned that there is a similar rate of adverse events, such as febrile neutropenia (68 percent versus 71 percent), pneumonia (20 percent versus 15 percent), and hypoxia (13 percent versus 15 percent), with the use of VYXEOS™ as compared with the conventional ''7+3'' free drug regimen.

We invited public comments on whether VYXEOS™ meets the substantial clinical improvement criterion.

Comment: Several commenters supported the use of VYXEOS™ as a viable treatment option in the treatment of older adults who have been diagnosed with high-risk AML, and believed that clinically meaningful survival and response improvements have been and can be achieved for a highly difficult to treat population of patients with extremely limited treatment options. The applicant summarized the efficacy outcomes of the pivotal Phase III Study 301 and noted that significant improvement in overall survival was achieved with a hazard ratio of 0.69, p=0.005. The applicant indicated that, although many days of increased survival are desired rather than few, clinical benefit cannot be determined solely by the absolute number of days or months of survival increase. Rather, clinical benefit is determined by the relative improvement in survival. The applicant stated that, based on the data results from the Phase III Study 301, the observed improvement in median survival was 3.61 months (Control, 5.95m versus VYXEOS, 9.56m). In other words, a 3.61 month increase in median survival is substantial and of great benefit given an expected median survival of only 5.95 months for patients treated with control arm therapy. The applicant believed that this result was statistically significant and demonstrates clinically high benefits.

Response: We appreciate the commenters' and the applicant's input in response to our concerns. After consideration of the public comments we received, we believe that based on the statistically significant increase in median survival rate from the Phase III Study 301, VYXEOS™ is a treatment option which offers a substantial clinical improvement over standard therapy for patients who have been diagnosed with AML. Therefore, we believe that VYXEOS™ meets the substantial clinical improvement criterion.

Based on evaluation of the new technology add-on payment application and consideration of the public comments we received, we have determined that VYXEOS™ meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for VYXEOS™ for FY 2019. We expect that VYXEOS™ will be administered, as indicated, for use in the treatment of adults who have been newly diagnosed with therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML–MRC). Cases involving the use of VYXEOS™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: XW033B3 (Introduction of cytarabine and caunorubicin liposome antineoplastic into peripheral vein, percutaneous approach, new technology group 3); and XW043B3 (Introduction of cytarabine and daunorubicin liposome antineoplastic into central vein, percutaneous approach, new technology group 3).

In its application, the applicant estimated that the average cost of a single vial for VYXEOS™ is $7,750 (daunorubicin 44 mg/m2 and cytarabine 100 mg/m2). The applicant stated that the first induction of 6 vials is administered in the inpatient hospital setting, with 31 percent of the patients receiving a second induction of an administration of 4 vials. Of the 31 percent of the patients that receive the second induction, 85 percent of the patients receive the second induction in the inpatient hospital setting during the same inpatient stay of the first induction. The applicant further stated that 32 percent of all of the patients receive a first consolidation therapy of an administration of 3 vials, with 50 percent of these patients being treated in the inpatient hospital setting. The applicant also indicated that 50 percent of all of the patients receive a second consolidation therapy of an administration of 3 vials, with 40 percent of these patients being treated in the inpatient hospital setting. As is our past practice, based on the information above, we believe that it is appropriate to use an average to set the maximum amount of vials used in the inpatient hospital setting. For the induction therapy, all patients receive an administration of 6 vials for the first induction in the inpatient hospital setting, with 31 percent of all of the patients receiving a second induction therapy of an administration of 4 vials—of which 85 percent of these patients are treated in the inpatient hospital setting during the same stay as the first induction therapy. Therefore, we computed the average of 6 vials for the first induction plus 3.4 vials for the second induction (4 vials * 0.85), which results in a maximum average of 9.4 vials used in the inpatient hospital setting. Therefore, the maximum average cost for VYXEOS™ used in the inpatient hospital setting is $72,850 ($7,750 cost per vial * 9.4 vials). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of VYXEOS™ is $36,425.

c. VABOMERE™ (Meropenem-vaborbactam)

Melinta Therapeutics, Inc., submitted an application for new technology add-on payments for VABOMERE™ for FY 2019. VABOMERE™ is indicated for use in the treatment of adult patients who have been diagnosed with complicated urinary tract infections (cUTIs), including pyelonephritis, caused by designated susceptible bacteria. VABOMERE™ received FDA approval on August 29, 2017.

Complicated urinary tract infections (cUTIs) are defined as chills, rigors, or fever (temperature of greater than or equal to 38.0 °C); elevated white blood cell count (greater than 10,000/mm3), or left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; lower abdominal pain or pelvic pain. Acute pyelonephritis is defined as chills, rigors, or fever (temperature of greater than or equal to 38.0 °C); elevated white blood cell count (greater than 10,000/mm3), or left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; flank pain; costo-vertebral angle tenderness on physical examination. Risk factors for infection with drug-resistant organisms do not, on their own, indicate a cUTI.[88] The increasing incidence of multidrug-resistant gram-negative bacteria, such as carbapenem-resistant Enterobacteriacea (CRE), has resulted in a critical need for new antimicrobials.

The applicant reported that it has developed a beta-lactamase combination antibiotic, VABOMERE™, to treat cUTIs, including those caused by certain carbapenem-resistant organisms. By combining the carbapenem class antibiotic meropenem with vaborbactam, VABOMERE™ protects meropenem from degradation by certain CRE strains.

The applicant stated that meropenem, a carbapenem, is a broad spectrum beta-lactam antibiotic that works by inhibiting cell wall synthesis of both gram-positive and gram-negative bacteria through binding of penicillin-binding proteins (PBP). Carbapenemase producing strains of bacteria have become more resistant to beta-lactam antibiotics, such as meropenem. However, meropenem in combination with vaborbactam, inhibits the carbapenemase activity, thereby allowing the meropenem to bind PBP and kill the bacteria.

According to the applicant, vaborbactam, a boronic acid inhibitor, is a first-in class beta-lactamase inhibitor. Vaborbactam blocks the breakdown of carbapenems, such as meropenem, by bacteria containing carbapenemases. Although vaborbactam has no antibacterial properties, it allows for the treatment of resistant infections by increasing bacterial sensitivity to meropenem. New carbapenemase producing strains of bacteria have become more resistant to beta-lactam antibiotics. However, meropenem in combination with vaborbactam, can inhibit the carbapenemase enzyme, thereby allowing the meropenem to bind PBP and kill the bacteria. The applicant stated that the vaborbactem component of VABOMERE™ helps to protect the meropenem from degradation by certain beta-lactamases, such as Klebsiella pneumonia carbapenemase (KPC). According to the applicant, VABOMERE™ is the first of a novel class of beta-lactamase inhibitors. The applicant asserted that VABOMERE™'s use of vaborbactam to restore the efficacy of meropenem is a novel approach to fighting antimicrobial resistance.

The applicant stated that VABOMERE™ is indicated for use in the treatment of adult patients 18 years old and older who have been diagnosed with cUTIs, including pyelonephritis. The recommended dosage of VABOMERE™ is 4 grams (2 grams of meropenem and 2 grams of vaborbactam) administered every 8 hours by intravenous (IV) infusion over 3 hours with an estimated glomerular filtration rate (eGFR) greater than or equal to 50 ml/min/1.73m^2. The recommended dosage of VABOMERE™ for patients with varying degrees of renal function is included in the prescribing information. The duration of treatment is for up to 14 days.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, VABOMERE™ is designed primarily for the treatment of gram-negative bacteria that are resistant to other current antibiotic therapies. The applicant stated that VABOMERE™ does not use the same or similar mechanism of action to achieve a therapeutic outcome. The applicant asserted that the vaborbactam component of VABOMERE™ is a new class of beta-lactamase inhibitor that protects meropenem from degradation by certain enzymes such as carbapenamases. The applicant indicated that the structure of

[88] Hooton, T. and Kalpana, G., 2018, ''Acute complicated urinary tract infection (including pyelonephritis) in adults,'' In A. Bloom (Ed.), UpToDate. Available at: *https://www.uptodate.com/contents/acute-complicated-urinary-tract-infection-including-pyelonephritis-in-adults.*

vaborbactam is distinctly optimized for inhibition of serine carbapenamases and for combination with a carbapenem antibiotic. Beta-lactamase inhibitors are agents that inhibit bacterial enzymes—enzymes that destroy beta-lactam antibiotics and result in resistance to first-line as well as ''last defense'' antimicrobials used in hospitals. According to the applicant, in order for carbapenems to be effective these enzymes must be inhibited. The applicant stated that the addition of vaborbactam as a potent inhibitor against Class A and C serine beta-lactamases, particularly KPC, represents a new mechanism of action. According to the applicant, VABOMERE™'s use of vaborbactam to restore the efficacy of meropenem is a novel approach and that the FDA's approval of VABOMERE™ for the treatment of cUTIs represents a significant label expansion because mereopenem alone (without the addition of vaborbactam) is not indicated for the treatment of patients with cUTI infections. Therefore, the applicant maintained that this technology and resistance-fighting mechanism involved in the therapeutic effect achieved by VABOMERE™ is distinct from any other existing product. The applicant noted that VABOMERE™ was designated as a qualified infectious disease product (QIDP) in January 2014. This designation is given to antibacterial products that treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20300), we stated that we believed, although the molecular structure of the vaborbactam component of VABOMERE™ is unique, the bactericidal action of VABOMERE™ is the same as meropenem alone. In addition, we noted that there are other similar beta-lactam/beta-lactamase inhibitor combination therapies currently available as treatment options. We invited public comments on whether VABOMERE™'s mechanism of action is similar to other existing technologies.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that patients who may be eligible to receive treatment involving VABOMERE™ include hospitalized patients who have been diagnosed with a cUTI. These potential cases can be identified by a variety of ICD–10–CM diagnosis codes. Therefore, potential cases representing patients who have been diagnosed with a cUTI who may be eligible for treatment involving VABOMERE™ can be mapped to multiple MS–DRGs. The following are the most commonly used MS–DRGs for patients who have been diagnosed with a cUTI: MS–DRG 690 (Kidney and Urinary Tract Infections without MCC); MS–DRG 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC); MS–DRG 870 (Septicemia or Sever Sepsis with Mechanical Ventilation 96+ Hours); MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ Hours with MCC); and MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ Hours without MCC). Potential cases representing patients who may be eligible for treatment with VABOMERE™ would be assigned to the same MS–DRGs as cases representing hospitalized patients who have been diagnosed with a cUTI.

With respect to the third criterion, whether the use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that the use of VABOMERE™ would treat a different patient population than existing and currently available treatment options. According to the applicant, VABOMERE™'s use of vaborbactam to restore the efficacy of meropenem is a novel approach to fighting the global and national public health crisis of antimicrobial resistance, and as such, the use of VABOMERE™ reaches different and expanded patient populations. The applicant further asserted that future patient populations are saved as well because the growth of resistant infections is slowed. The applicant believed that, because of the threat posed by gram-negative bacterial infections and the limited number of available treatments currently on the market or in development, the combination structure and development of VABOMERE™ and its potential expanded use is new. We stated in the proposed rule that while the applicant believes that VABOMERE™ treats a different patient population, we note that VABOMERE™ is only approved for use in the treatment of adult patients who have been diagnosed with cUTIs. Therefore, we stated that it appears that VABOMERE™ treats the same population (adult patients with a cUTI) and there are already other treatment options available for diagnoses of cUTIs.

In the proposed rule, we stated that we were concerned VABOMERE™ may be substantially similar to existing beta-lactam/beta-lactamase inhibitor combination therapies. As noted in the proposed rule and above, we were concerned that VABOMERE™ may have a similar mechanism of action, treats the same population (patients with a cUTI) and would be assigned to the same MS–DRGs (similar to existing beta-lactam/beta-lactamase inhibitor combination therapies currently available as treatment options). We invited public comments on whether VABOMERE™ meets the substantial similarity criteria and the newness criterion.

Comment: The applicant addressed the issue regarding the substantial similarity criteria and recommended CMS apply its standards under the newness criterion in a manner that recognizes the innovative nature and unique aspects of VABOMERE™. The applicant explained that meropenem alone is not indicated to treat a diagnosis of a cUTI and, moreover, is not active against KPC-producing CRE. The applicant stated that the action of the vaborbactam's protection of the meropenem is fundamental and essential to how VABOMERE™ acts on and inhibits bacterial enzymes, and allows VABOMERE™ to treat even those infections that would otherwise be resistant and not susceptible to therapy with meropenem alone. The applicant believed that, accordingly, VABOMERE™'s mechanism of action is distinct from that of meropenem and is not the same. The applicant further explained that, meropenem is degraded by beta-lactamases enzymes, including KPC enzymes, and, therefore, is ineffective against KPC-producing CRE. The applicant indicated that VABOMERE™, in contrast, is not degraded by these enzymes and is able to provide effective treatment against infections that are not susceptible to meropenem. The applicant also reiterated that, unlike meropenem alone, VABOMERE™ is on-label indicated for the use in the treatment of a cUTI diagnosis.

Several commenters believed that VABOMERE™ may be substantially similar to other existing therapies. The applicant believed that CMS' application of the ''substantial similarity'' standards for newness as described in prior IPPS rulemakings, including aspects of CMS' discussion of these criteria in the FY 2019 IPPS/LTCH PPS proposed rule as applied to VABOMERE™, are restrictive and may impose unnecessarily narrow standards for newness that are not included in the statute or regulations. The applicant stated that, if applied as suggested in the proposed rule, CMS may not account for the realities and circumstances involved in developing and bringing a new therapy—particularly a new antibiotic—to the U.S. market. The applicant

suggested CMS apply its newness standards in a manner that recognizes the innovative nature and unique aspects of new technologies, like VABOMERE™, consistent with the text and spirit of the new technology add-on payment provisions.

Other commenters stated that, given the recognized shortage of new antibiotics, the unique benefits of VABOMERE™ should not be ignored because of substantial similarities to other medicines.

Response: We appreciate the applicant's and commenters' input. We agree that VABOMERE™ has a unique mechanism of action that is not similar to other existing technologies because it is a new class of beta-lactamase inhibitor that protects meropenem from degradation by certain enzymes such as carbapenamases. We agree that the addition of vaborbactam as a potent inhibitor against Class A and C serine beta-lactamases, particularly KPC, represents a new mechanism of action. After consideration of the public comments we received, we believe that VABOMERE™ is not substantially similar to existing technologies and meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. In order to identify the range of MS–DRGs to which cases representing potential patients who may be eligible for treatment using VABOMERE™ may map, the applicant used the Premier Research Database from 2nd Quarter 2015 to 4th Quarter 2016. According to the applicant, Premier is an electronic laboratory, pharmacy, and billing data repository that collects data from over 600 hospitals and captures nearly 20 percent of U.S. hospitalizations. The applicant's list of most common MS–DRGs is based on data regarding CRE from the Premier Research Database. According to the applicant, approximately 175 member hospitals also submit microbiology data, which allowed the applicant to identify specific pathogens such as CRE infections. Using the Premier Research Database, the applicant identified over 350 MS–DRGs containing data for 2,076 cases representing patients who had been hospitalized for CRE infections. The applicant used the top five most common MS–DRGs: MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC), MS–DRG 853 (Infectious and Parasitic Disease with O.R. Procedure with MCC), MS–DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours), MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours without MCC), and MS–DRG 690 (Kidney and Urinary Tract Infections without MCC), to which 627 cases representing potential patients who may be eligible for treatment involving VABOMERE™, or approximately 30.2 percent of the total cases identified, mapped.

The applicant reported that the resulting 627 cases from the identified top 5 MS–DRGs have an average case-weighted unstandardized charge per case of $74,815. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20301), we noted that, instead of using actual charges from the Premier Research Database, the applicant computed this amount based on the average case-weighted threshold amounts in Table 10 from the FY 2018 IPPS/LTCH PPS final rule. For the rest of the analysis, the applicant adjusted the average case-weighted threshold amounts (referred to above as the average case-weighted unstandardized charge per case) rather than the actual average case-weighted unstandardized charge per case from the Premier Research Database. According to the applicant, based on the Premier data, $1,999 is the mean antibiotic costs of treating patients hospitalized with CRE infections with current therapies. The applicant explained that it identified 69 different regimens that ranged from 1 to 4 drugs from a study conducted to understand the current management of patients diagnosed with CRE infections. Accordingly, the applicant estimated the removal of charges for a prior technology of $1,999. The applicant then standardized the charges. The applicant applied an inflation factor of 9.357 percent from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to inflate the charges. At the time of the development of the proposed rule, the applicant noted that it did not yet have sufficient charge data from hospitals and would work to supplement its application with the information once it was available. However, for purposes of calculating charges, the applicant used the average charge as the wholesale acquisition cost (WAC) price for a treatment duration of 14 days and added this amount to the average charge per case. Using this estimate, the applicant calculated the final inflated case-weighted standardized charge per case as $91,304, which exceeded the average case-weighted threshold amount of $74,815. Therefore, the applicant asserted that VABOMERE™ met the cost criterion.

In the proposed rule, we indicated we were concerned that, as noted earlier, instead of using actual charges from the Premier Research Database, the applicant computed the average case-weighted unstandardized charge per case based on the average case-weighted threshold amounts in Table 10 from the FY 2018 IPPS/LTCH PPS final rule. Because the applicant did not demonstrate that the average case-weighted standardized charge per case for VABOMERE™ (using actual charges from the Premier Research Database) would exceed the average case-weighted threshold amounts in Table 10, we were unable to determine if the applicant met the cost criterion. We invited public comments on whether VABOMERE™ met the cost criterion, including with respect to the concern regarding the applicant's analysis.

Comment: The applicant addressed CMS' concern regarding the cost criterion and analysis and submitted a revised cost analysis in response. The applicant conducted a revised analysis using claims from the FY 2016 MedPAR to demonstrate that VABOMERE™ meets the cost criterion. To identify potential cases representing patients who may be eligible for treatment involving VABOMERE™, the applicant identified 34 ICD–10–CM diagnosis codes from claims from the FY 2016 MedPAR specific to the anticipated VABOMERE™ patient population. The applicant distinguished the 34 ICD–10–CM diagnosis codes by three different subsets, with Subset 1 based on 17 of the 34 ICD–10–CM diagnosis codes; Subset 2 based on 13 of the 34 ICD–10–CM diagnosis codes; and Subset 3 based on 8 of the 34 ICD–10–CM diagnosis codes. The applicant noted that the 8 ICD–10–CM diagnosis codes used in the Subset 3 analysis also are included in all three of the analyses, and the 13 ICD–10–CM diagnosis codes included in the Subset 2 analysis also are included among the 17 diagnosis codes used in the Subset 1 analysis.

For each subset, the applicant conducted a cost analysis for 100 percent of the identified cases, 75 percent of the identified cases, the top 20 MS–DRGs to which potential cases would map, and the top 10 MS–DRGs to which potential cases would map. For each subset, the applicant performed the following: (1) Calculated the case-weighted unstandardized charge per case; (2) removed 100 percent of the drug charges from the relevant cases in order to conservatively estimate for charges for drugs that potentially may be replaced by VABOMERE™; (3) standardized the charges; (4) applied the 2-year inflation factor of 9.357 percent from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527); (5) added the charges for VABOMERE™ (the

applicant calculated the charges for VABOMERE™ by converting the costs of VABOMERE™ to charges and dividing the costs by the national CCR of 0.194 for ''Drugs'' from the FY2018 IPPS/LTCH PPS final rule (82 FR 38103)); and (6) computed the inflated average case-weighted standardized charge per case and the average case-weighted threshold amount.

The applicant stated that the cost of VABOMERE™ is $165 per vial. The applicant indicated that a patient receives two vials per dose and three doses per day. Therefore, the per-day cost of VABOMERE™ is $990 per patient. The duration of therapy, consistent with the Prescribing Information, is up to 14 days. Therefore, the applicant estimated that the cost of VABOMERE™ to the hospital, per patient, is $13,860. The applicant believed that, based on limited data from the product's launch, approximately 80 percent of VABOMERE™'s usage would be in the inpatient hospital setting, and approximately 20 percent of VABOMERE™'s usage may take place outside of the inpatient hospital setting. Therefore, the applicant stated that the average number of days of VABOMERE™ administration in the inpatient hospital setting is estimated at 80 percent of 14 days, or approximately 11.2 days. As a result, the applicant calculated that the total inpatient cost is $11,088 ($990 * 11.2 days), which was then converted to charges in the calculations above.

The applicant stated that each subset demonstrated the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Below are three tables, one for each subset, showing that the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount.

Subset 1 cost analysis	100 Percent of the identified cases	75 Percent of the identified cases	Top 20 MS-DRGs	Top 10 MS-DRGs
Case-Weighted Unstandardized Charge Per Case	$66,978	$61,313	$54,894	$56,004
Inflated Average Case-Weighted Standardized Charge Per Case	112,692	107,943	102,924	103,444
Average Case-Weighted Threshold	56,213	54,782	51,993	52,941
Difference	56,479	53,161	50,931	50,503

Subset 2 cost analysis	100 Percent of the identified cases	75 Percent of the identified cases	Top 20 MS-DRGs	Top 10 MS-DRGs
Case-Weighted Unstandardized Charge Per Case	$66,135	$60,486	$54,220	$55,267
Inflated Average Case-Weighted Standardized Charge Per Case	112,108	107,340	102,430	102,892
Average Case-Weighted Threshold	55,924	54,421	51,749	52,683
Difference	56,184	52,919	50,681	50,209

Subset 3 cost analysis	100 Percent of the identified cases	75 Percent of the identified cases	Top 20 MS-DRGs	Top 10 MS-DRGs
Case-Weighted Unstandardized Charge Per Case	$66,295	$60,215	$54,264	$55,273
Inflated Average Case-Weighted Standardized Charge Per Case	112,168	107,111	102,444	102,886
Average Case-Weighted Threshold	56,014	54,333	51,823	52,733
Difference	56,154	52,778	50,621	50,153

Response: We appreciate the applicant's response and revised cost analysis. After consideration of the public comment and revised cost analysis we received, we believe that VABOMERE™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant believed that the results from the VABOMERE™ clinical trials clearly establish that VABOMERE™ represents a substantial clinical improvement for treatment of deadly, antibiotic resistant infections. Specifically, the applicant asserted that VABOMERE™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, and the use of VABOMERE™ significantly improves clinical outcomes for a patient population as compared to currently available treatments. The applicant provided the results of the Targeting Antibiotic Non-sensitive Gram-Negative Organisms (TANGO) I and II clinical trials to support its assertion.

TANGO I [89] was a prospective, randomized, double-blinded trial of VABOMERE™ versus piperacillin-tazobactam in patients with cUTIs and acute pyelonephritis (A/P). TANGO I is also a noninferiority (NI) trial powered to evaluate the efficacy, safety, and tolerability of VABOMERE™ compared to piperacillin-tazobactam in the treatment of cUTI, including AP, in adult patients. There were two primary endpoints for this study, one for the FDA, which was cure or improvement and microbiologic outcome of eradication at the end-of-treatment (EOT) (day 5 to 14) in the proportion of patients in the Microbiologic Evaluable Modified Intent-to-Treat (m-MITT) population who achieved overall success (clinical cure or improvement and eradication of baseline pathogen to <104 CFU/mL), and one for the European Medicines Agency (EMA), which was the proportion of patients in the co-primary m-MITT and Microbiologic Evaluable (ME) populations who achieve a microbiologic outcome of eradication (eradication of baseline pathogen to <103 CFU/mL) at the test-of-cure (TOC) visit (day 15 to 23). The trial enrolled 550 adult patients who were randomized 1:1 to receive

[89] Vabomere Prescribing Information, Clinical Studies (August 2017), available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209776lbl.pdf.*

VABOMERE™ as a 3-hour IV infusion every 8 hours, or piperacillin 4g-tazobactam 500 mg as a 30 minute IV infusion every 8 hours, for at least 5 days for the treatment of a cUTI. Therapy was set at a minimum of 5 days to fully assess the efficacy and safety of VABOMERE™. After a minimum of 5 days of IV therapy, patients could be switched to oral levofloxacin (500 mg once every 24 hours) to complete a total of 10-day treatment course (IV+oral), if they met pre-specified criteria. Treatment was allowed for up to 14 days, if clinically indicated.

Patient demographic and baseline characteristics were balanced between treatment groups in the m-MITT population.

- Approximately 93 percent of patients were Caucasian and 66 percent were females in both treatment groups.
- The mean age was 54 years old with 32 percent and 42 percent of the patients 65 years old and older in the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- Mean body mass index was approximately 26.5 kg/m2 in both treatment groups.
- Concomitant bacteremia was identified in 12 (6 percent) and 15 (8 percent) of the patients at baseline in the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- The proportion of patients who were diagnosed with diabetes mellitus at baseline was 17 percent and 19 percent in the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- The majority of the patients (approximately 90 percent) were enrolled from Europe, and approximately 2 percent of the patients were enrolled from North America. Overall, in both treatment groups, 59 percent of the patients had pyelonephritis and 40 percent had a cUTI, with 21 percent and 19 percent of the patients having a non-removable and removable source of infection, respectively.

Mean duration of IV treatment in both treatment groups was 8 days and mean total treatment duration (IV and oral) was 10 days; patients with baseline bacteremia could receive up to 14 days of therapy (IV and oral). Approximately 10 percent of the patients in each treatment group in the m-MITT population had a levofloxacin-resistant pathogen at baseline and received levofloxacin as the oral switch therapy. According to the applicant, this protocol violation may have impacted the assessment of the outcomes at the TOC visit. These patients were not excluded from the analysis of adverse reactions (headache, phlebitis, nausea, diarrhea, and others) occurring in 1 percent or more of the patients receiving VABOMERE™, as the decision to switch to oral levofloxacin was based on post-randomization factors.

Regarding the FDA primary endpoint, the applicant stated the following:

- Overall success rate at the end of IV treatment (day 5 to 14) was 98.4 percent and 94 percent for the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- The TOC—7 days post IV therapy was 76.5 percent (124 of 162 patients) for the VABOMERE™ group and 73.2 percent (112 of 153 patients) for the piperacillin/tazobactam group.
- Despite being an NI trial, TANGO–I showed a statistically significant difference favoring VABOMERE™ in the primary efficacy endpoint over piperacillin/tazobactam (a commonly used agent for gram-negative infections in U.S. hospitals).
- VABOMERE™ demonstrated statistical superiority over piperacillin-tazobactam with overall success of 98.4 percent of patients treated with VABOMERE™ in the TANGO–I clinical trial compared to 94.0 percent for patients treated with piperacillin/tazobactam, with a treatment difference of 4.5 percent and 95 percent CI of (0.7 percent, 9.1 percent).
- Because the lower limit of the 95 percent CI is also greater than 0 percent, VABOMERE™ was statistically superior to piperacillin/tazobactam.
- Because non-inferiority was demonstrated, then superiority was tested. Further, the applicant asserted that a non-inferiority design may have a ''superiority'' hypothesis imbedded within the study design that is appropriately tested using a non-inferiority design and statistical analysis. As such, according to the applicant, superiority trials concerning antibiotics are impractical and even unethical in many cases because one cannot randomize patients to receive inactive therapies. The applicant stated that it would be unethical to leave a patient with a severe infection without any treatment.
- The EMA endpoint of eradication rates at TOC were higher in the VABOMERE™ group compared to the piperacillin/tazobactam group in both the m-MITT (66.7 percent versus 57.7 percent) and ME (66.3 percent and 60.4 percent) populations; however, it was not a statistically significant improvement.

In the proposed rule, we noted that the eradication rates of the EMA endpoint were not statistically significant. We invited public comments with respect to our concern as to whether the FDA endpoints demonstrating non-inferiority are statistically sufficient data to support that VABOMERE™ is a substantial clinical improvement in the treatment of patients with a cUTI.

In its application, the applicant offered data from the TANGO–I trial comparing VABOMERE™ to piperacillin-tazobactam EOT/TOC rates in the setting of cUTIs/AP, but in the proposed rule we stated that the applicant did not offer a comparison to other antibiotic treatments of cUTIs known to be effective against gram-negative uropathogens, specifically other carbapenems.[90] In the proposed rule, we also noted that the study population is largely European (98 percent), and given the variable geographic distribution of antibiotic resistance we indicated we were concerned that the use of piperacillin/tazobactam as the comparator may have skewed the eradication rates in favor of VABOMERE™, or that the favorable results would not be applicable to patients in the United States. We invited public comments regarding the lack of a comparison to other antibiotic treatments of cUTIs known to be effective against gram-negative uropathogens, whether the comparator the applicant used in its trial studies may have skewed the eradication rates in favor of VABOMERE™, and if the favorable results would be applicable to patients in the United States to allow for sufficient information in evaluating substantial clinical improvement.

In the proposed rule we noted that the applicant asserted that the TANGO II study[91] of monotherapy with VABOMERE™ compared to best available therapy (BAT) (salvage care of cocktails of toxic/poorly efficacious last resort agents) for the treatment of CRE infections showed important differences in clinical outcomes, including reduced mortality, higher clinical cure at EOT and TOC, benefit in important patient subgroups of HABP/VABP, bacteremia, renal impairment, and immunocompromised and reduced AEs, particularly lower nephrotoxicity in the study group. TANGO II is a multi-

[90] Golan, Y., 2015, ''Empiric therapy for hospital-acquired, Gram-negative complicated intra-abdominal infection and complicated urinary tract infections: a systematic literature review of current and emerging treatment options,'' *BMC Infectious Diseases,* vol. 15, pp. 313. *http://doi.org/10.1186/s12879-015-1054-1.*

[91] Alexander, et al., ''CRE Infections: Results From a Retrospective Series and Implications for the Design of Prospective Clinical Trials,'' *Open Forum Infectious Diseases.*

center, randomized, Phase III, open-label trial of patients with infections due to known or suspected CRE, including cUTI, AP, HABP/VABP, bacteremia, or complicated intra-abdominal infection (cIAI). Eligible patients were randomized 2:1 to monotherapy with VABOMERE™ or BAT for 7 to 14 days. There were no consensus BAT regimes, it could include (alone or in combination) a carbapenem, aminoglycoside, polymyxin B, colistin, tigecycline or ceftazidime-avibactam.

A total of 72 patients were enrolled in the TANGO II trial. Of these, 50 of the patients (69.4 percent) had a gram-negative baseline organism (m-MITT population), and 43 of the patients (59.7 percent) had a baseline CRE (mCRE–MITT population). Within the mCRE–MITT population, 20 of the patients had bacteremia, 15 of the patients had a cUTI/AP, 5 of the patients had HABP/VABP, and 3 of the patients had a cIAI. The most common baseline CRE pathogens were K. pneumoniae (86 percent) and Escherichia coli (7 percent). Cure rates of the mCRE–MITT population at EOT for VABOMERE™ and BAT groups were 64.3 percent and 40 percent, respectively, TOC, 7 days after EOT, were 57.1 percent and 26.7 percent, respectively, 28-day mortality was 17.9 percent (5 of 28 patients) and 33.3 percent (5 of 15 patients), respectively. The applicant asserted that with further sensitivity analysis, taking into account prior antibiotic failures among the VABOMERE™ study arm, the 28-day all-cause mortality rates were even lower among VABOMERE™ versus BAT patients (5.3 percent (1 of 19 patients) versus 33.3 percent (5 of 15 patients). Additionally, in July 2017, randomization in the trial was stopped early following a recommendation by the TANGO II Data Safety Monitoring Board (DSMB) based on risk-benefit considerations that randomization of additional patients to the BAT comparator arm should not continue.

According to the applicant, subgroup analyses of the TANGO II studies include an analysis of adverse events in which VABOMERE™ compared to BAT demonstrated the following:

- VABOMERE™ was associated with less severe treatment emergent adverse events of 13.3 percent versus 28 percent.
- VABOMERE™ was less likely to be associated with a significant increase in creatinine 3 percent versus 26 percent.
- Efficacy results of the TANGO II trial cUTI/AP subgroup demonstrated VABOMERE™ was associated with an overall success rate at EOT for the mCRE–MITT populations of 72 percent (8 of 11 patients) versus 50 percent (2 of 4 patients) and an overall success rate at TOC of 27.3 percent (3 of 7 patients) versus 50 percent (2 of 4 patients).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20303), we noted that many of the TANGO II trial outcomes showing improvements in the use of VABOMERE™ over BAT are not statistically significant. We also noted that the TANGO II study included a small number of patients; the study population in the mCRE–MITT only included 43 patients. Additionally, the cUTI/AP subgroup analysis only included a total of 15 patients and did not show an increased overall success rate at TOC (27.3 percent versus 50 percent) over the BAT group. We invited public comments with respect to our concern as to whether the lack of statistically significant outcomes and the small number of study participants allows for enough information to evaluate substantial clinical improvement.

We invited public comments on whether the VABOMERE™ technology meets the substantial clinical improvement criterion, including with respect to the specific concerns we have raised.

Comment: The applicant stated that VABOMERE™ represents and has demonstrated a substantial clinical improvement over other existing available therapies. The applicant also stated that, in particular, the results from the TANGO I and TANGO II, Phase III clinical trials establish that VABOMERE™ represents a ''substantial clinical improvement'' for treatment of deadly, antibiotic-resistant infections. The applicant reiterated the results of the TANGO I and TANGO II trials and noted the results show VABOMERE™ had a statistically significant higher response rate than piperacillin/tazobactam in clinical cure and microbial eradication. The applicant stated that, in TANGO I, piperacillin-tazobactam was used as a comparator because it is very commonly used in U.S. hospitals to treat infections, including severe UTIs. The applicant indicated that, for example, as reflected in the VABOMERE™ Prescribing Information, the results of the TANGO I demonstrate superiority as evidenced by the overall success rate at the end of IV treatment (day 5 to 14) at 98.4 percent and 94 percent for the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively, and the TOC—7 days post IV therapy at 76.5 percent (124 of 162 patients) for the VABOMERE™ group and 73.2 percent (112 of 153 patients) for the piperacillin/tazobactam group. The applicant noted that, regarding non-inferiority and superiority data, the statutory and regulatory standards for new technology add-on payments do not preclude the relevance of non-inferiority data for purposes of demonstrating that a new therapy meets the ''substantial clinical improvement'' criterion. The applicant indicated that CMS has previously approved an application for new technology add-on payments and agreed that it represented a substantial clinical improvement over existing technologies on the basis of non-inferior data.

The applicant further indicated that, with regard to the size of the study population for TANGO II, this study focused specifically on a patient population known to have or suspected of having CRE. The applicant further stated that, despite a concerted effort to search for patients with CRE infection and intensive pre-screening and screening activities across the globe, it took more than 2.5 years to enroll 77 patients. The applicant also noted that many other clinical studies in the context of new antibiotics development and other areas have involved similar or smaller cohorts of patients. According to the applicant, in the specific context of TANGO II, approximately 100 patients were pre-screened for each individual enrolled patient. The applicant stated that challenges are typical of the ''ultra-orphan'' world of antimicrobial development, where new treatments are needed, and pathogen-focused or resistance-focused clinical trials are crucial to accurately determine the efficacy of the treatment. The applicant further stated that unfortunately, study challenges (including difficulty consenting seriously-ill patients and their families, restricted entry criteria, exclusion for prior antibiotics, among others), along with a rare diagnosis, make larger trials with this life-threatening condition quite difficult to conduct. The applicant indicated that the patients enrolled in this study had a high incidence of underlying comorbidities and a high disease severity, with approximately 40 percent of the patients being immunocompromised and 75 percent with a Charlson Comorbidity Score >5. The applicant also noted appreciation that CMS recognized these challenges, particularly in the context of clinical trials for new antibiotic products that treat serious and life-threatening infections. The applicant believed that, for these reasons, the sample size used in the TANGO II trial does not undermine or diminish the significance of its results. The applicant indicated that the study focused specifically on

patients with known or suspected CRE and was powered specifically to test certain endpoints, which it demonstrated—and, notably—did so using VABOMERE™ as a monotherapy. The applicant believed that this is distinct from other clinical trials and underscores the significance of the TANGO II results. The applicant further noted that the TANGO II trial demonstrated certain improved outcomes with such statistical significance that the independent data monitoring review board recommended early termination of the randomization in the trial to allow patients to cross over to the VABOMERE™ arm instead of the BAT arm in the trial.

One commenter agreed with CMS' concern that improved outcomes in some trials may not be statistically significant and that the small number of patients, and the lack of a comparison to other antibiotic treatments of cUTIs known to be effective against uropathogens may not support that VABOMERE™ represents a substantial clinical improvement in the treatment of patients diagnosed with a cUTI.

Response: We appreciate the commenter's input and the applicant's responses to our concerns. After consideration of the public comments we received, we believe that VABOMERE™ offers a substantial clinical improvement for patients who have limited or no alternative treatment options because it is a new antibiotic that offers a treatment option for a patient population unresponsive to currently available treatments. Specifically, VABOMERE™ is a novel, first-in-class beta-lactamase inhibitor helps to protect the meropenem from degradation by certain beta-lactamases, such as KPC. Additionally, results from the TANGO II study demonstrate better outcomes regarding 28-day all-cause mortality taking into account prior antibiotic failures (VABOMERE™ patients (5.3 percent) versus BAT patients (33.3 percent), p=0.03), as well as decreases nephrotoxicity (VABOMERE™ 11.1 percent versus BAT 24.0 percent). Therefore, based on the above, we believe that VABOMERE™ represents a substantial clinical improvement.

In summary, we have determined that VABOMERE™ meets all of the criteria for approval of new technology add-on payments. Therefore, we approving new technology add-on payments for VABOMERE™ for FY 2019. We note that, the applicant did not request approval for the use of a unique ICD–10–PCS procedure code for VABOMERE™ for FY 2019. As a result, hospitals will be unable to uniquely identify the use of VABOMERE™ on an inpatient claim using the typical coding of an ICD–10–PCS procedure code. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53352), with regard to the oral drug DIFICID™, we revised our policy to allow for the use of an alternative code set to identify oral medications where no inpatient procedure is associated for the purposes of new technology add-on payments. We established the use of a National Drug Code (NDC) as the alternative code set for this purpose and described our rationale for this particular code set. This change was effective for payments for discharges occurring on or after October 1, 2012. We acknowledge that VABOMERE™ is not an oral drug and is administered by IV infusion, but it is the first approved new technology aside from an oral drug with no uniquely assigned inpatient procedure code. We, therefore, believe that the circumstances with respect to the identification of eligible cases using VABOMERE™ are similar to those addressed in the FY 2013 IPPS/LTCH PPS final rule with regard to DIFICID™ because we do not have current ICD–10–PCS code(s) to uniquely identify the use of VABOMERE™ to make the new technology add-on payment. Because we have determined that VABOMERE™ has met all of the new technology add-on payment criteria and cases involving the use of VABOMERE™ will be eligible for such payments for FY 2019, we need to use an alternative coding method to identify these cases and make the new technology add-on payment for use of VABOMERE™ in FY 2019. Therefore, similar to the policy in the FY 2013 IPPS/LTCH PPS final rule, in the place of an ICD–10–PCS procedure code, FY 2019 cases involving the use of VABOMERE™ that are eligible for the FY 2019 new technology add-on payments will be identified by the NDC of 65293–009–01 (VABOMERE™ Meropenem-Vaborbactam Vial). Providers must code the NDC in data element LIN03 of the 837i Health Care Claim Institutional form in order to receive the new technology add-on payment for procedures involving the use of VABOMERE™. The applicant may request approval for a unique ICD–10–PCS procedure code for FY 2020.

As discussed above, according to the applicant, the cost of VABOMERE™ is $165 per vial. A patient receives two vials per dose and three doses per day. Therefore, the per-day cost of VABOMERE™ is $990 per patient. The duration of therapy, consistent with the Prescribing Information, is up to 14 days. Therefore, the estimated cost of VABOMERE™ to the hospital, per patient, is $13,860. Based on the limited data from the product's launch, approximately 80 percent of VABOMERE™'s usage would be in the inpatient hospital setting, and approximately 20 percent of VABOMERE™'s usage may take place outside of the inpatient hospital setting. Therefore, the average number of days of VABOMERE™ administration in the inpatient hospital setting is estimated at 80 percent of 14 days, or approximately 11.2 days. As a result, the total inpatient cost for VABOMERE™ is $11,088 ($990 * 11.2 days). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of VABOMERE™ is $5,544 for FY 2019.

d. remedē® System

Respicardia, Inc. submitted an application for new technology add-on payments for the remedē® System for FY 2019. According to the applicant, the remedē® System is indicated for use as a transvenous phrenic nerve stimulator in the treatment of adult patients who have been diagnosed with moderate to severe central sleep apnea. The remedē® System consists of an implantable pulse generator, and a stimulation and sensing lead. The pulse generator is placed under the skin, in either the right or left side of the chest, and it functions to monitor the patient's respiratory signals. A transvenous lead for unilateral stimulation of the phrenic nerve is placed either in the left pericardiophrenic vein or the right brachiocephalic vein, and a second lead to sense respiration is placed in the azygos vein. Both leads, in combination with the pulse generator, function to sense respiration and, when appropriate, generate an electrical stimulation to the left or right phrenic nerve to restore regular breathing patterns.

The applicant describes central sleep apnea (CSA) as a chronic respiratory disorder characterized by fluctuations in respiratory drive, resulting in the cessation of respiratory muscle activity and airflow during sleep.[92] The applicant reported that CSA, as a primary disease, has a low prevalence in the United States population; and it is

[92] Jagielski, D., Ponikowski, P., Augostini, R., Kolodziej, A., Khayat, R., Abraham, W.T., 2016, ''Transvenous Stimulation of the Phrenic Nerve for the Treatment of Central Sleep Apnoea: 12 months' experience with the remedē® Ssystem,'' *European Journal of Heart Failure,* pp. 1–8.

more likely to occur in those individuals who have cardiovascular disease, heart failure, atrial fibrillation, stroke, or chronic opioid usage. The apneic episodes which occur in patients with CSA cause hypoxia, increased blood pressure, increased preload and afterload, and promotes myocardial ischemia and arrhythmias. In addition, CSA ''enhances oxidative stress, causing endothelial dysfunction, inflammation, and activation of neurohormonal systems, which contribute to progression of underlying diseases.'' [93]

According to the applicant, prior to the introduction of the remedē® System, typical treatments for CSA took the form of positive airway pressure devices. Positive airway pressure devices, such as continuous positive airway pressure (CPAP), have previously been used to treat patients diagnosed with obstructive sleep apnea. Positive airway devices deliver constant pressurized air via a mask worn over the mouth and nose, or nose alone. For this reason, positive airway devices may only function when the patient wears the necessary mask. Similar to CPAP, adaptive servo-ventilation (ASV) provides noninvasive respiratory assistance with expiratory positive airway pressure. However, ASV adds servo-controlled inspiratory pressure, as well, in an effort to maintain airway patency.[94]

On October 6, 2017, the remedē® System was approved by the FDA as an implantable phrenic nerve stimulator indicated for the use in the treatment of adult patients who have been diagnosed with moderate to severe CSA. The device was available commercially upon FDA approval. Therefore, the newness period for the remedē® System is considered to begin on October 6, 2017. The applicant has indicated that the device also is designed to restore regular breathing patterns in the treatment of CSA in patients who also have been diagnosed with heart failure.

The applicant was approved for two unique ICD–10–PCS procedure codes for the placement of the leads: 05H33MZ (Insertion of neurostimulator lead into right innominate (brachiocephalic) vein) and 05H03MZ (Insertion of neurostimulator lead into azygos vein), effective October 1, 2016. The applicant indicated that implantation of the pulse generator is currently reported using ICD–10–PCS procedure code 0JH60DZ (Insertion of multiple array stimulator generator into chest subcutaneous tissue).

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

As stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20309), with regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, the remedē® System provides stimulation to nerves to stimulate breathing. Typical treatments for hyperventilation CSA include supplemental oxygen and CPAP. Mechanical ventilation also has been used to maintain a patent airway. The applicant asserted that the remedē® System is a neurostimulation device resulting in negative airway pressure, whereas devices such as CPAP and ASV utilize positive airway pressure.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the remedē® System is assigned to MS–DRGs 040 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC), 041 (Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator), and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC). The current procedures for the treatment options of CPAP and ASV are not assigned to these MS–DRGs.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the remedē® System is indicated for the use as a transvenous unilateral phrenic nerve stimulator in the treatment of adult patients who have been diagnosed with moderate to severe CSA. The applicant stated that the remedē® System reduces the negative symptoms associated with CSA, particularly among patients who have been diagnosed with heart failure. The applicant asserted that patients who have been diagnosed with heart failure are particularly negatively affected by CSA and currently available CSA treatment options of CPAP and ASV. According to the applicant, the currently available treatment options, CPAP and ASV, have been found to have worsened mortality and morbidity outcomes for patients who have been diagnosed with both CSA and heart failure. Specifically, ASV is currently contraindicated in the treatment of CSA in patients who have been diagnosed with heart failure.

The applicant also suggested that the remedē® System is particularly suited for the treatment of CSA in patients who also have been diagnosed with heart failure. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20310), we stated we were concerned that, while the remedē® System may be beneficial to patients who have been diagnosed with both CSA and heart failure, the FDA-approved indication is for use in the treatment of adult patients who have been diagnosed with moderate to severe CSA. We noted that the applicant's clinical analyses and data results related to patients who specifically were diagnosed with CSA and heart failure. We invited public comments on whether the remedē® System meets the newness criterion.

Comment: The applicant stated that the remedē® System uses a different mechanism of action because neurostimulation of the phrenic nerve to treat patients who have been diagnosed with CSA is a new concept, both, in terms of its mechanism of action and approach. The applicant explained that utilizing small electrical pulses delivered to the phrenic nerve via a transvenous lead helps restore a more normal breathing pattern and indicated that there are no other FDA-approved CSA therapies that either utilize transvenous neurostimulation or generate negative pressure to treat patients who have been diagnosed with CSA.

The applicant explained that currently, cases representing Medicare patients who have been admitted to the hospital with a diagnosis of CSA to receive treatment map to a wide array of MS–DRGs. However, the applicant believed that cases representing patients eligible for treatment involving the remedē® System would be assigned to a different MS–DRG than cases representing patients treated using standard treatment options, including CPAP or ASV. The applicant further explained that, based on an analysis of FY 2018 MedPAR data, claims including a diagnosis of CSA mapped to 458 MS–DRGs with no single MS–DRG representing more than 4.5 percent of the total claims. The applicant believed this variant assignment of cases representing patients who have been diagnosed with CSA and received treatment is likely due to the fact that

[93] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T., ''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lacet,* 2016, vol. 388, pp. 974–982.

[94] Cowie, M.R., Woehrle, H., Wegscheider, K., Andergmann, C., d'Ortho, M.P., Erdmann, E., Teschler, H., ''Adaptive Servo-Ventilation for Central Sleep Apneain Systolic Heart Failure,'' *N Eng Jour of Med,* 2015, pp. 1–11.

the vast majority of claims in the MedPAR data included the CSA diagnosis as a secondary or tertiary diagnosis reported on the claim. The applicant indicated that cases representing patients receiving treatment involving the remedē® System with CSA as a primary diagnosis would typically be assigned to MS–DRGs 040 or 041.

Several other commenters also supported approval of new technology add-on payments for the remedē® System, and asserted that the neurostimulation of the phrenic nerve is a different mechanism of action. The commenters indicated that they believed positive airway pressure (PAP) treatment is inferior to phrenic nerve stimulation because of patient intolerability, a lack of evidence in support of the success of PAP treatment in this population, or evidence showing that PAP such as ASV being contraindicated in the treatment of patients who have been diagnosed with CSA and heart failure. Another commenter agreed with the applicant, and stated that the remedē® System's mechanism of action to deliver treatment, the neurostimulation of the phrenic nerve, is a new treatment approach that has never previously been used.

Response: We appreciate the commenters' support and the applicant's further analysis and explanation regarding why the remedē® System is not substantially similar to other currently available treatment options, as well as the input provided by the commenters. Based on review of the comments, we agree that utilization of the neurostimulation of the phrenic nerve, as performed by the remedē® System, is a different mechanism of action and that cases representing patients receiving treatment involving the use of the remedē® System would be assigned to a different MS–DRG than currently available treatment options. Therefore, we believe that the remedē® System is not substantially similar to any other existing technology. We also note that the applicant provided additional information regarding patients who have been diagnosed with CSA, without a diagnosis of heart failure, and we considered this additional information in our evaluation of the application.

After consideration of the public comments we received, for the reasons discussed, we believe that the remedē® System is not substantially similar to any existing technology and it meets the newness criterion.

Comment: The applicant stated that the remedē® received FDA approval on October 6, 2017. However, the applicant noted that the first implant procedure was completed on February 01, 2018. Therefore, the applicant believed that the newness period should begin on February 01, 2018, rather than the FDA approval date.

Response: As we discuss in section II.H.4. and in our discussion of Voraxaze included in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. However, the applicant did not provide additional information to explain why there was a delay from the time of FDA approval until the completion of the first implant procedure to establish a different date of availability. Without additional information, we continue to believe that the newness period for the remedē® System begins on October 6, 2017. We may consider any further information that may be provided regarding the date of availability in future rulemaking.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate that the technology meets the cost criterion. The applicant identified cases representing potential patients who may be eligible for treatment involving the remedē® System within MS–DRGs 040, 041, and 042. Using the Standard Analytical File (SAF) Limited Data Set (MedPAR) for FY 2015, the applicant included all claims for the previously stated MS–DRGs for its cost threshold calculation. The applicant stated that typically claims are selected based on specific ICD–10–PCS parameters, however this is a new technology for which no ICD–10–PCS procedure code and ICD–10–CM diagnosis code combination exists. Therefore, all claims for the selected MS–DRGs were included in the cost threshold analysis. This process resulted in 4,462 cases representing potential patients who may be eligible for treatment involving the remedē® System assigned to MS–DRG 040; 5,309 cases representing potential patients who may be eligible for treatment involving the remedē® System assigned to MS–DRG 041; and 2,178 cases representing potential patients who may be eligible for treatment involving the remedē® System assigned to MS–DRG 042, for a total of 11,949 cases.

Using the 11,949 identified cases, the applicant determined that the average unstandardized case-weighted charge per case was $85,357. Using the FY 2015 MedPAR dataset to identify the total mean charges for revenue code 0278, the applicant removed charges associated with the current treatment options for each MS–DRG as follows: $9,153.83 for MS–DRG 040; $12,762.31 for MS–DRG 041; and $21,547.73 for MS–DRG 042. The applicant anticipated that no other related charges would be eliminated or replaced. The applicant then standardized the charges and applied a 2-year inflation factor of 1.104055 obtained from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524). The applicant then added charges for the new technology to the inflated average case-weighted standardized charges per case. No other related charges were added to the cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $175,329 and a Table 10 average case-weighted threshold amount of $78,399. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology met the cost criterion. With regard to the analysis above, in the proposed rule, we stated that we were concerned that all cases in MS–DRGs 040, 041, and 042 were used in the analysis. We further stated that we were unsure if all of these cases represent patients that may be truly eligible for treatment involving the remedē® System. We invited public comments on whether the remedē® System meets the cost criterion.

Comment: In response to our concern presented in the FY 2019 IPPS/LTCH PPS proposed rule, the applicant submitted a revised analysis with regard to the cost criterion. In its revised cost calculations, the applicant searched the FY 2016 MedPAR data for cases reporting an ICD–10–CM procedure code for the insertion of an array stimulator generator, in combination with a neurostimulator lead. Below is a table listing the codes searched by the applicant.

ICD–10–PCS code	Description (array stimulator generator)
0JH60BZ	INSERTION 1 ARRAY STIM GEN CHEST SUBQ TISS FASC OPEN.
0JH60CZ	INSERTION 1 ARRAY RCHG STIM GEN CHST SUBQ FASCIA OPN.

ICD–10–PCS code	Description (array stimulator generator)
0JH60DZ	INSERTION MX ARRAY STIM GEN CHST SUBQ TISS FASC OPEN.
0JH60EZ	INSERTION MX ARRAY RCHG STIM GEN CHST SUBQ FASC OPEN.
0JH63BZ	INSERTION 1 ARRAY STIM GEN CHEST SUBQ FASCIA PERQ.
0JH63CZ	INSERTION 1 ARRAY RCHG STIM GEN CHST SUBQ FASC PERQ.
0JH63DZ	INSERTION MX ARRAY STIM GEN CHEST SUBQ FASCIA PERQ.
0JH63EZ	INSERTION MX ARRAY RCHG STIM GEN CHST SUBQ FASC PERQ.
0JH70BZ	INSERTION 1 ARRAY STIM GEN BACK SUBQ TISS FASC OPEN.
0JH70CZ	INSERTION 1 ARRAY RCHG STIM GEN BACK SUBQ FASC OPEN.
0JH70DZ	INSERTION MX ARRAY STIM GEN BACK SUBQ TISS FASC OPEN.
0JH70EZ	INSERTION MX ARRAY RCHG STIM GEN BACK SUBQ FASC OPEN.
0JH73BZ	INSERTION 1 ARRAY STIM GEN BACK SUBQ TISS FASC PERQ.
0JH73CZ	INSERTION 1 ARRAY RCHG STIM GEN BACK SUBQ FASC PERQ.
0JH73DZ	INSERTION MX ARRAY STIM GEN BACK SUBQ TISS FASC PERQ.
0JH73EZ	INSERTION MX ARRAY RCHG STIM GEN BACK SUBQ FASC PERQ.
0JH80BZ	INSERTION 1 ARRAY STIM GEN ABDOMEN SUBQ FASCIA OPEN.
0JH80CZ	INSERTION 1 ARRAY RCHG STIM GEN ABDOMN SUBQ FASC OPN.
0JH80DZ	INSERTION MX ARRAY STIM GEN ABDOMN SUBQ FASCIA OPEN.
0JH80EZ	INSERTION MX ARRAY RCHG STIM GEN ABDMN SUBQ FASC OPN.
0JH83BZ	INSERTION 1 ARRAY STIM GEN ABDOMEN SUBQ FASCIA PERQ.
0JH83CZ	INSERTION 1 ARRAY RCHRG STIM GEN ABDOMN SUBQ FASC PC.
0JH83DZ	INSERTION MX ARRAY STIM GEN ABDOMN SUBQ FASCIA PERQ.
0JH83EZ	INSERTION MX ARRAY RCHRG STIM GEN ABDMN SUBQ FASC PC.

ICD–10–PCS code	Description (neurostimulator lead)
00HE0MZ	INSERTION NEURSTIM LEAD CRANIAL NERVE OPEN.
00HE3MZ	INSERTION NEURSTIMULATOR LEAD CRANIAL NERVE PERQ.
00HE4MZ	INSERTION NEURSTIMUL LEAD CRANIAL NERV PERQ ENDO.
01HY0MZ	INSERTION NEURSTIM LEAD PERIPHERAL NERVE OPEN.
01HY3MZ	INSERTION NEURSTIMULT LEAD PERIPHERAL NERVE PERQ.
01HY4MZ	INSERTION NEURSTIM LEAD PERIPH NERVE PERQ ENDO APPR.
05H00MZ	INSERTION NEUROSTIMULATOR LEAD IN AZYGOS VEIN OP.
05H03MZ	INSERTION NEUROSTIMULATOR LEAD IN AZYGOS VEIN PQ.
05H04MZ	INSERTION NEURSTIM LEAD INTO AZYGOS VEIN PQ ENDO.
05H30MZ	INSERTION NEUROSTIMULATOR LEAD IN RT INNOMIN VEIN OPN.
05H33MZ	INSERTION NEURSTIM LEAD IN RT INNOMIN VEIN PERQ.
05H34MZ	INSERTION NEURSTIM LEAD RT INNOMINATE VEIN PERQ ENDO.
05H40MZ	INSERTION NEUROSTIMULATOR LEAD LT INNOMIN VEIN OP.
05H43MZ	INSERTION NEUROSTIMULATOR LEAD LT INNOMINATE VEIN PQ.
05H44MZ	INSERTION NEURSTIM LEAD IN LT INNOMIN VEIN PQ END.
0DH60MZ	INSERTION STIMULATOR LEAD STOMACH OPEN APPROACH.
0DH63MZ	INSERTION STIMULATOR LEAD STOMACH PERCUTANEOUS.
0DH64MZ	INSERTION STIM LEAD STOMACH PERQ ENDO APPRCH.

The applicant identified a total of 2,416 cases representing potential patients who may be eligible for treatment involving the remedē® System, with 1,762 cases (72.9 percent of all of the cases) mapping to MS–DRG 41 and 654 cases (27.1 percent of all of the cases) mapping to MS–DRG 42, resulting in an average case-weighted charge per case of $86,744. The applicant removed 100 percent of the charges associated with the services provided in connection with the prior technology. The applicant then standardized the charges and inflated the charges by an inflation factor of 9.36 percent, which resulted in an inflated average case-weighted standardized charge per case of $61,426. According to the applicant, the cost of the remedē® System is $34,500. The applicant converted the costs of the technology to charges by dividing the costs by the national CCR of 0.332 for ''Implantable Devices'' from the FY 2018 IPPS/LTCH PPS final rule. This resulted in $103,916 in estimated hospital charges for the new technology, which were added to the inflated standardized charges per case. The final inflated average case-weighted standardized charge per case is $165,342, which is $87,877 more than the Table 10 average case-weighted threshold amount of $77,465. Therefore, the applicant maintained that it meets the cost criterion.

Response: We appreciate the applicant's submission of revised cost calculations in response to our concerns.

After consideration of the additional information provided by the applicant, we agree that the remedē® System meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the remedē® System meets the substantial clinical improvement criterion. The applicant stated that the remedē® System offers a treatment option for a patient population unresponsive to, or ineligible for, treatment involving currently available options. According to the applicant, patients who have been diagnosed with CSA have no other available treatment options than the remedē® System. The applicant stated that published studies on both CPAP and ASV have proven that primary endpoints have not been met for treating patients who have been diagnosed with CSA. In addition, according to the ASV study, there was an increase in cardiovascular mortality.

According to the applicant, the remedē® System will prove to be a better treatment for the negative effects associated with CSA in patients who have been diagnosed with heart failure, such as cardiovascular insults resulting from sympathetic nervous system

activation, pulmonary hypertension, and arrhythmias, which ultimately contribute to the downward cycle of heart failure,[95] when compared to the currently available treatment options. The applicant also indicated that prior studies have assessed CPAP and ASV as options for the treatment of diagnoses of CSA primarily in patients who have been diagnosed with heart failure.

The applicant shared the results from two studies concerning the effects of positive airway pressure ventilation treatment:

- The Canadian Continuous Positive Airway Pressure for Patients with Central Sleep Apnea and Heart Failure trial found that, while CPAP managed the negative symptoms of CSA, such as improved nocturnal oxygenation, increased ejection fraction, lower norepinephrine levels, and increased walking distance, it did not affect overall patient survival; [96] and
- In a randomized trial of 1,325 patients who had been diagnosed with heart failure who received treatment with ASV plus standard treatment or standard treatment alone, ASV was found to increase all-cause and cardiovascular mortality as compared to the control treatment.[97]

The applicant also stated that published literature indicates that currently available treatment options do not meet primary endpoints with concern to the treatment of CSA; patients treated with ASV experienced an increased likelihood of mortality,[98] and patients treated with CPAP experienced alleviation of symptoms, but no change in survival.[99] The applicant provided further research, which suggested that a primary drawback of CPAP in the treatment of diagnoses of CSA is a lack of patient adherence to therapy.[100]

The applicant also stated that the remedē® System represents a substantial clinical improvement over existing technologies because of the reduction in the number of future hospitalizations, few device-related complications, and improvement in CSA symptoms and quality of life. Specifically, the applicant stated that the clinical data has shown a statistically significant reduction in Apnea-hypopnea index (AHI), improvement in quality of life, and significantly improved Minnesota Living with Heart Failure Questionnaire score. In addition, the applicant indicated that study results showed the remedē® System demonstrated an acceptable safety profile, and there was a trend toward fewer heart failure hospitalizations.

The applicant provided six published articles as evidence. All six articles were prospective studies. In three of the six studies, the majority of patients studied had been diagnosed with CSA with a heart failure comorbidity, while the remaining three studies only studied patients who had been diagnosed with CSA with a heart failure comorbidity. The first study [101] assessed the treatment of patients who had been diagnosed with CSA in addition to heart failure. According to the applicant, as referenced in the results of the published study, Ponikowski, et al., assessed the treatment effects of 16 of 31 enrolled patients with evidence of CSA within 6 months prior to enrollment who met inclusion criteria (apnea-hypopnea index of greater than or equal to 15 and a central apnea index of greater than or equal to 5) and who did not meet exclusion criteria (a baseline oxygen saturation of less than 90 percent, being on supplemental oxygen, having evidence of phrenic nerve palsy, having had severe chronic obstructive pulmonary disease (COPD), having hard angina or a myocardial infarction in the past 3 months, being pacemaker dependent, or having inadequate capture of the phrenic nerve during neurostimulation). Of the 16 patients whose treatment was assessed, all had various classifications of heart failure diagnoses: 3 (18.8 percent) were classified as class I on the New York Heart Association classification scale (No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)); 8 (50 percent) were classified as a class II (Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath)); and 5 (31.3 percent) were classified as class III (Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea).[102] After successful surgical implantation of a temporary transvenous lead for unilateral phrenic nerve stimulation, patients underwent a control night without nerve stimulation and a therapy night with stimulation, while undergoing polysomnographic (PSG) testing. Comparison of both nights was performed.

According to the applicant, some improvements of CSA symptoms were identified in statistical analyses. Sleep time and efficacy were not statistically significantly different for control night and therapy night, with median sleep times of 236 minutes and 245 minutes and sleep efficacy of 78 percent and 71 percent, respectively. There were no statistical differences across categorical time spent in each sleep stage (for example, N1, N2, N3, and REM) between control and therapy nights. The average respiratory rate and hypopnea index did not differ statistically across nights. Marginal positive statistical differences occurred between control and therapy nights for the baseline oxygen saturation median values (95 and 96 respectively) and obstructive apnea index (OAI) (1 and 4, respectively). Beneficial statistically significant differences occurred from control to therapy nights for the average heart rate (71 to 70, respectively), arousal index events per hour (32 to 12, respectively), apnea-hypopnea index (AHI) (45 to 23, respectively), central apnea index (CAI) (27 to 1, respectively), and oxygen desaturation index of 4 percent (ODI = 4 percent) (31 to 14, respectively). Two adverse events were noted: (1) Lead tip thrombus noted when lead was removed; the patient was anticoagulated without central nervous system sequelae; and (2) an episode of ventricular tachycardia upon lead placement and before stimulation was initiated. The episode was successfully treated by defibrillation of the patient's implanted ICD. Neither adverse event was directly related to the phrenic nerve stimulation therapy.

[95] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

[96] Bradley, T.D., Logan, A.G., Kimoff, R.J., Series, F., Morrison, D., Ferguson, K., Phil, D., 2005, ''Continous Positive Airway Pressure for Central Sleep Apnea and Heart Failure,'' *N Eng Jour of Med,* vol. 353(19), pp. 2025–2033.

[97] Cowie, M.R., Woehrle, H., Wegscheider, K., Andergmann, C., d'Ortho, M.-P., Erdmann, E., Teschler, H., ''Adaptive Servo-Ventilation for Central Sleep Apneain Systolic Heart Failure,'' *N Eng Jour of Med,* 2015, pp. 1–11.

[98] Ibid.

[99] Bradley, T.D., Logan, A.G., Kimoff, R.J., Series, F., Morrison, D., Ferguson, K., Phil, D., 2005, ''Continous Positive Airway Pressure for Central Sleep Apnea and Heart Failure,'' *N Engl Jour of Med,* vol. 353(19), pp. 2025–2033.

[100] Ponikowski, P., Javaheri, S., Michalkiewicz, D., Bart, B.A., Czarnecka, D., Jastrzebski, M., Abraham, W.T., ''Transvenous Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnoea in Heart Failure,'' *European Heart Journal,* 2012, vol. 33, pp. 889–894.

[101] Ponikowski, P., Javaheri, S., Michalkiewicz, D., Bart, B.A., Czarnecka, D., Jastrzebski, M., Abraham, W.T., ''Transvenous Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnoea in Heart Failure,'' *European Heart Journal,* 2012, vol. 33, pp. 889–894.

[102] American Heart Association: ''Classes of Heart Failure,'' May 8, 2017. Available at: *http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp#.WmE2rlWnGUk.*

The second study [103] was a prospective, multi-center, nonrandomized study that followed patients diagnosed with CSA and other underlying comorbidities. According to the applicant, as referenced in the results of the published study, Abraham, et al., 49 of the 57 enrolled patients who were followed indicated a primary endpoint of a reduction of AHI with secondary endpoints of feasibility and safety of the therapy. Patients were included if they had an AHI of 20 or greater and apneic events that were related to CSA. Among the study patient population, 79 percent had diagnoses of heart failure, 2 percent had diagnoses of atrial fibrillation, 13 percent had other cardiac etiology diagnoses, and the remainder of patients had other cardiac unrelated etiology diagnoses. Exclusion criteria were similar to the previous study (that is, (Ponikowski P., 2012)), with the addition of a creatinine of greater than 2.5 mg/dl. After implantation of the remedē® System, patients were assessed at baseline, 3 months (n=47) and 6 months (n=44) on relevant measures. At 3 months, statistically nonsignificant results occurred for the OAI and hypopnea index (HI) measures. The remainder of the measures showed statistically significant differences from baseline to 3 months: AHI with a −27.1 episodes per hour of sleep difference; CAI with a −23.4 episodes per hour of sleep difference; MAI with a −3 episodes per hour of sleep difference; ODI = 4 percent with a −23.7 difference; arousal index with −12.5 episodes per hour of sleep difference; sleep efficiency with a 8.4 percent increase; and REM sleep with a 4.5 percent increase. Similarly, among those assessed at 6 months, statistically significant improvements on all measures were achieved, including OAI and HI. Regarding safety, a data safety monitoring board (DSMB) adjudicated and found the following 3 of 47 patients (6 percent) as having serious adverse events (SAE) related to the device, implantation procedure or therapy. None of the DSMB adjudicated SAEs was due to lead dislodgement. Two SAEs of hematoma or headache were related to the implantation procedure and occurred as single events in two patients. A single patient experienced atypical chest discomfort during the first night of stimulation, but on reinitiation of therapy on the second night no further discomfort occurred.

The third study [104] assessed the safety and feasibility of phrenic nerve stimulation for 6 monthly follow-ups of 8 patients diagnosed with heart failure with CSA. Of the eight patients assessed, one was lost to follow-up and one died from pneumonia. According to the applicant, as referenced in the results in the published study, Zheng, et al. (2015), no unanticipated serious adverse events were found to be related to the therapy; in one patient, a lead became dislodged and subsequently successfully repositioned. Three patients reported improved sleep quality, and all patients reported increased energy. A reduction in sleep apneic events and decreases in AHI and CAI were related to application of the treatment. Gradual increases to the 6-minute walking time occurred through the study.

The fourth study [105] extended the previous Phase I study [106] from 6 months to 12 months, and included only 41 of the original 49 patients continuing in the study. Of the 57 patients enrolled at the time of the Phase I study, 41 were evaluated at the 12-month follow-up. Of the 41 patients examined at 12 months, 78 percent had diagnoses of CSA related to heart failure, 2 percent had diagnoses of atrial fibrillation with related CSA, 12 percent had diagnoses of CSA related to other cardiac etiology diagnoses, and the remainder of patients had diagnoses of CSA related to other noncardiac etiology diagnoses. At 12 months, 6 sleep parameters remained statistically different and 3 were no longer statistically significant. The HI, OAI, and arousal indexes were no longer statistically significantly different from baseline values. A new parameter, time spent with peripheral capillary oxygen saturation (SpO2) below 90 percent was not statistically different at 12 months (31.4 minutes) compared to baseline (38.2 minutes). The remaining 6 parameters showed maintenance of improvements at the 12-month time point as compared to the baseline: AHI from 49.9 to 27.5 events per hour; CAI from 28.2 to 6.0 events per hour; MAI from 3.0 to 0.5 events per hour; ODI = 4 percent from 46.1 to 26.9 events per hour; sleep efficiency from 69.3 percent to 75.6 percent; and REM sleep from 11.4 percent to 17.1 percent. At the 3-month, 6-month, and 12-month time points, patient quality of life was assessed to be 70.8 percent, 75.6 percent, and 83.0 percent, respectively, indicating that patients experienced mild, moderate, or marked improvement. Seventeen patients were followed at 18 months with statistical differences from baseline for AHI and CAI. Three patients died over the 12-month follow-up period: 2 Died of end-stage heart failure and 1 died from sudden cardiac death. All three deaths were adjudicated by the DSMB and none were related to the procedure or to phrenic nerve stimulation therapy. Five patients were found to have related serious adverse events over the 12-month study time. Three events were previously described in the results referenced in the published study, Abraham, et al., and an additional 2 SAEs occurred during the 12-month follow-up. One patient experienced impending pocket perforation resulting in pocket revision, and another patient experienced lead failure.

The fifth study [107] was a randomized control trial with a primary outcome of achieving a reduction in AHI of 50 percent or greater from baseline to 6 months enrolling 151 patients with the neurostimulation treatment (n=73) and no stimulation control (n=78). Of the total sample, 96 (64 percent) of the patients had been diagnosed with heart failure; 48 (66 percent) of the treated patients had been diagnosed with heart failure, and 48 (62 percent) of the control patients had been diagnosed with heart failure. Sixty-four (42 percent) of all of the patients included in the study had been diagnosed with atrial fibrillation and 84 (56 percent) had been diagnosed with coronary artery disease. All of the patients had been treated with the remedē® System device implanted; the system was activated in the treatment group during the first month. ''Over about 12 weeks, stimulation was gradually increased in the treatment group until diaphragmatic capture was consistently achieved without disrupting sleep.'' [108] While patients and physicians were unblinded, the polysomnography core laboratory remained blinded. The per-

[103] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

[104] Zhang, X., Ding, N., Ni, B., Yang, B., Wang, H., & Zhang, S.J., ''Satefy and Feasibility of Chronic Transvenous Phrenic Nerve Stimulation for Treatment of Central Sleep Apnea in Heart Failure Patients,'' *The Clinical Respiratory Journal,* 2015, pp. 1–9.

[105] Jagielski, D., Ponikowski, P., Augostini, R., Kolodziej, A., Khayat, R., & Abraham, W.T., ''Transvenous Stimulation of the Phrenic Nerve for the Treatment of Central Sleep Apnoea: 12 months' experience with the remede®system,'' *European Journal of Heart Failure,* 2016, pp. 1–8.

[106] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., 2015, ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

[107] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T.,''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lacet,* 2016, vol. 388, pp. 974–982.

[108] Ibid.

protocol population from which statistical comparisons were made is 58 patients treated with the remedē® System and 73 patients in the control group. The authors appropriately controlled for Type I errors (false positives), which arise from performing multiple tests. Thirty-five treated patients and 8 control patients met the primary end point, the number of patients with a 50 percent or greater reduction in AHI from baseline; the difference of 41 percent is statistically significant. All seven of the secondary endpoints were assessed and found to have statistically significant difference in change from baseline between groups at the 6-month follow-up after controlling for multiple comparisons: CAI of −22.8 events per hour lower for the treatment group; AHI (continuous) of −25.0 events per hour lower for the treatment group; arousal events per hour of −15.2 lower for the treatment group; percent of sleep in REM of 2.4 percent higher for the treatment group; patients with marked or moderate improvement in patient global assessment was 55 percent higher in the treatment group; ODI = 4 percent was −22.7 events per hour lower for the treatment group; and the Epworth sleepiness scale was −3.7 lower for the treatment group. At 12 months, 138 (91 percent) of the patients were free from device, implant, and therapy related adverse events.

The final study data was from the pivotal study with limited information in the form of an abstract [109] and an executive summary.[110] The executive summary detailed an exploratory analysis of the 141 patients enrolled in the pivotal trial which were patients diagnosed with CSA. The abstract indicated that the 141 patients from the pivotal trial were randomized to either the treatment arm (68 patients) in which initiation of treatment began 1 month after implantation of the remedē® System device with a 6-month follow-up period, or to the control group arm (73 patients) in which the initiation of treatment with the remedē® System device was delayed for 6 months after implantation. Randomization efficacy was compared across baseline polysomnography and associated respiratory indices in which four of the five measures showed no statistical differences between those treated and controls; treated patients had an average MAI score of 3.1 as compared to control patients with an average MAI score of 2.2 (p=0.029). Patients included in the trial must have been medically stable, at least 18 years old, have had an electroencephalogram within 40 days of scheduled implantation, had an apnoea-hypopnoea index (AHI) of 20 events per hour or greater, a central apnoea index at least 50 percent of all apneas, and an obstructive apnea index less than or equal to 20 percent.[111] Primary exclusion criteria were CSA caused by pain medication, heart failure of state D from the American Heart Association, a new implantable cardioverter defibrillator, pacemaker dependent subjects without any physiologic escape rhythm, evidence of phrenic nerve palsy, documented history of psychosis or severe bipolar disorder, a cerebrovascular accident within 12 months of baseline testing, limited pulmonary function, baseline oxygen saturation less than 92 percent while awake and on room air, active infection, need for renal dialysis, or poor liver function.[112] Patients included in this trial were primarily male (89 percent), white (95 percent), with at least one comorbidity with cardiovascular conditions being most prevalent (heart failure at 64 percent), with a concomitant implantable cardiovascular stimulation device in 42 percent of patients at baseline. The applicant stated that, after randomization, there were no statistically significant differences between the treatment and control groups, with the exception of the treated group having a statistically higher rate of events per hour on the mixed apnea index (MAI) at baseline than the control group.

The applicant asserted that the results from the pivotal trial [113] allow for the comparison of heart failure status in patients; we note that patients with American Heart Association objective assessment Class D (Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest) were excluded from this pivotal trial. The primary endpoint in the pivotal trial was the proportion of patients with an AHI reduction greater than or equal to 50 percent at 6 months. When controlling for heart failure status, both treated groups experienced a statistically greater proportion of patients with AHI reductions than the controls at 6 months (58 percent more of treated patients with diagnoses of heart failure and 35 percent more of treated patients without diagnoses of heart failure as compared to their respective controls). The secondary endpoints assessed were the CAI average events per hour, AHI average events per hour, arousal index (ArI) average events per hour, percent of sleep in REM, and oxygen desaturation index 4 percent (ODI = 4 percent) average events per hour. Excluding the percent of sleep in REM, the treatment groups for both patients with diagnoses of heart failure and non-heart failure conditions experienced statistically greater improvements at 6 months on all secondary endpoints as compared to their respective controls. Lastly, quality of life secondary endpoints were assessed by the Epworth sleepiness scale (ESS) average scores and the patient global assessment (PGA). For both the ESS and PGA assessments, both treatment groups of patients with diagnoses of heart failure and non-heart failure conditions had statistically beneficial changes between baseline and 6 months as compared to their respective control groups.

The applicant provided analyses from the above report focusing on the primary and secondary polysomnography endpoints, specifically, across patients who had been diagnosed with CSA with heart failure and non-heart failure. Eighty patients included in the study from the executive summary report had comorbid heart failure, while 51 patients did not. Of those patients with heart failure, 35 were treated while 45 patients were controls. Of those patients without heart failure, 23 were treated and 28 patients were controls. The applicant did not provide baseline descriptive statistical comparisons between treated and control groups controlling for heart failure status. Across all primary and secondary endpoints, the patient group who were diagnosed with CSA and comorbid heart failure experienced statistically significant improvements. Excepting percent of sleep in REM, the patient group who were diagnosed with CSA without comorbid heart failure experienced statistically significant improvements in all primary and secondary endpoints. In the FY 2019 IPPS/LTCH PPS proposed rule, we invited public comments on whether this current study design is sufficient to support substantial clinical improvement of the remedē® System with respect to all patient populations,

[109] Goldberg, L., Ponikowski, P., Javaheri, S., Augostini, R., McKane, S., Holcomb, R., Costanzo, M.R., ''In Heart Failure Patients with Central Sleep Apnea, Transvenous Stimulation of the Phrenic Nerve Improves Sleep and Quality of Life,'' Heart Failure Society of America, 21st annual meeting. 2017.

[110] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

[111] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

[112] Ibid.

[113] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

particularly the non-heart failure population.

As previously noted, the applicant also contends that the technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment options. Specifically, the applicant stated that the remedē® System is the only treatment option for patients who have been diagnosed with moderate to severe CSA; published studies on positive pressure treatments like CPAP and ASV have not met primary endpoints; and there was an increase in cardiovascular mortality according to the ASV study. According to the applicant, approximately 40 percent of patients who have been diagnosed with CSA have heart failure. The applicant asserted that the use of the remedē® System not only treats and improves the symptoms of CSA, but there is evidence of reverse remodeling in patients with reduced left ventricular ejection fraction (LVEF).

In the proposed rule we stated we were concerned that the remedē® System is not directly compared to the CPAP or ASV treatment options, which, to our understanding, are the current treatment options available for patients who have been diagnosed with CSA without heart failure. We noted that the FDA-approved indication for the implantation of the remedē® System is for use in the treatment of adult patients who have been diagnosed with moderate to severe CSA. We also noted that the applicant's supporting studies were directed primarily at patients who had been treated with the remedē® System who also had been diagnosed with heart failure. The applicant asserted that it would not be appropriate to use CPAP and ASV treatment options when comparing CPAP and ASV to the remedē® System in the patient population of heart failure diagnoses because these treatment options have been found to increase mortality outcomes in this population. In light of the limited length of time in which the remedē® System has been studied, we indicated we were concerned that any claims on mortality as they relate to treatment involving the use of the remedē® System may be limited. Therefore, we were concerned as to whether there is sufficient data to determine that the technology represents a substantial clinical improvement with respect to patients who have been diagnosed with CSA without heart failure.

We stated in the proposed rule that the applicant has shown that, among the subpopulation of patients who have been diagnosed with CSA and heart failure, the remedē® System decreases morbidity outcomes as compared to the CPAP and ASV treatment options. In the proposed rule, we noted that we understood that not all patients evaluated in the applicant's supporting clinical trials had been diagnosed with CSA with a comorbidity of heart failure. However, in all of the supporting studies for this application, the vast majority of study patients did have this specific comorbidity of CSA and heart failure. Of the three studies which enrolled both patients diagnosed with CSA with and without heart failure,[114] [115] [116] [117] only two studies performed analyses controlling for heart failure status.[118] [119] The data from these two studies, the Costanzo, et al. (2016) and the Respicardia, Inc. executive report, are analyses based on the same pivotal trial data and, therefore, do not provide results from two separate samples. Descriptive comparisons are made in the executive summary of the pivotal trial [120] between all treated and control patients. However, we were unable to determine the similarities and differences between patients with heart failure and non-heart failure treated versus controlled groups. Because randomization resulted in one difference between the overall treated and control groups (MAI events per hour), we stated that it is possible that further failures of randomization may have occurred when controlling for heart failure status in unmeasured variables. Finally, the sample size analyzed and the subsample sizes of the heart failure patients (80) and non-heart failure patients (51) are particularly small. We stated that it is possible that these results are not representative of the larger population of patients who have been diagnosed with CSA.

Therefore, in the proposed rule we stated we were concerned that differences in morbidity and mortality outcomes between CPAP, ASV, and the remedē® System in the general CSA patient population have not adequately been tested or compared. Specifically, the two patient populations, those who have been diagnosed with heart failure and CSA versus those who have been diagnosed with CSA alone, may experience different symptoms and outcomes associated with their disease processes. Patients who have been diagnosed with CSA alone present with excessive sleepiness, poor sleep quality, insomnia, poor concentration, and inattention.[121] Conversely, patients who have been diagnosed with the comorbid conditions of CSA as a result of heart failure experience significant cardiovascular insults resulting from sympathetic nervous system activation, pulmonary hypertension, and arrhythmias, which ultimately contribute to the downward cycle of heart failure.[122]

We also noted that the clinical study had a small patient population (n=151), with follow-up for 6 months. We stated that we were interested in longer follow-up data that would further validate the points made by the applicant regarding the beneficial outcomes seen in patients who have been diagnosed with CSA who have been treated using the remedē® System. We also expressed interest in additional information regarding the possibility of electrical stimulation of unintended targets and devices combined with the possibility of interference from outside devices. Furthermore, we stated that we were unsure with regard to the longevity of the implanted device, batteries, and leads because it appears that the technology is meant to remain in use for the remainder of a patient's life. We invited public comments on whether the remedē® System represents a substantial clinical improvement over existing technologies.

Comment: The applicant provided responses to CMS' substantial clinical improvement concerns presented in the FY 2019 IPPS/LTCH PPS proposed rule

[114] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776*.

[115] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T., ''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lacet,* 2016, vol. 388, pp. 974–982.

[116] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776*.

[117] Jagielski, D., Ponikowski, P., Augostini, R., Kolodziej, A., Khayat, R., & Abraham, W.T., ''Transvenous Stimulation of the Phrenic Nerve for the Treatment of Central Sleep Apnoea: 12 months' experience with the remede®system,'' *European Journal of Heart Failure,* 2016, pp. 1–8.

[118] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776*.

[119] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T., ''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lacet,* 2016, vol. 388, pp. 974–982.

[120] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776*.

[121] Badr, M.S., 2017, Dec 11, ''Central sleep apnea: Risk factors, clinical presentation, and diagnosis,'' Available at: *https://www.uptodate.com/contents/central-sleep-apnea-risk-factors-clinical-presentation-and-diagnosis?csi=d3a535e6-1cca-4cd5-ab5e-50e9847bda6c&source=contentShare*.

[122] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

regarding the use of the remedē® System. With regard to CMS' concern that the clinical studies of the remedē® System did not include comparisons to PAP treatments, which are available treatment options for non-heart failure patients who have been diagnosed with CSA, the applicant stated that the following are several reasons for not using PAP treatments as comparators in their clinical trials:

- Other clinical trials, such as the CANPAP and SERVE–HF, which used PAP treatments in the course of treating patients who had been diagnosed with CSA were halted early due to the possibility of increased mortality;
- There exists little evidence showing that PAP treatments are effective for treatment of non-heart failure patients who have been diagnosed with CSA, according to the AASM; and
- Prior to the development of the remedē® System's pivotal trial, there was a lack of prospective, randomized data showing a relationship between PAP treatments and morbidity outcomes.

The applicant also believed that positive airway pressure devices were more likely to be considered for use in the treatment of patients who have been diagnosed with CSA, but without a diagnosis of heart failure. Another commenter stated that it agreed with the applicant's reasons and supported the rationale for not using PAP treatments as comparators in its clinical trials.

With regard to CMS' concern that claims related to mortality following treatment with the remedē® System are limited, the applicant agreed with CMS' assessment and stated that limited research on the system's impact on mortality for patients who have been diagnosed with CSA has been completed. The applicant further noted that mortality information was collected primarily for safety purposes during the pivotal trial. Another commenter also agreed with CMS' and the applicant's assessment and reiterated the applicant's statements.

The applicant addressed CMS' concern that the FDA-approved indication for the remedē® System is for all patients diagnosed with moderate to severe CSA and not specifically those diagnosed with a heart failure comorbidity. The applicant stated that the data from the pivotal trial provided evidence that the use of the remedē® System as a treatment option is safe and effective for patients who have been diagnosed with CSA, regardless of a heart failure comorbidity. Another commenter agreed with the applicant and stated that the data from the pivotal trial supported the applicant's response regarding the concern of the FDA-approved indication.

Regarding the concern that baseline statistical comparisons between treatment groups were not provided controlling for heart failure status, the applicant stated that there were no significant differences in baseline CSA disease burden between the treatment and control groups. The applicant further stated that, as expected, the heart failure and non-heart failure groups differed slightly by age and cardiac (for example, atrial fibrillation and hypertension) and other comorbidities (for example, hospitalizations within the last 12 months, diabetes, renal disease, depression).

In regard to the results at 6 and 12 months, the applicant stated that in all categories, except for quality of life, both the heart failure and non-heart failure groups showed statistically significant improvements from the baseline. The applicant asserted that for quality of life, which did not have a baseline, both groups had greater than 50 percent of respondents, which demonstrates marked or moderate improvement to their quality of life with a higher proportion in the non-heart failure group as compared to the heart failure group. Another commenter added that given the overall consistent balance achieved between the treatment and control groups across the many baseline variables examined, there is no evidence suggesting noteworthy imbalances to be expected in these subgroups.

The applicant addressed CMS' concerns related to the differences between heart failure and non-heart failure patients who received treatment with the remedē® System. The applicant asserted that it is well established that a significant proportion of patients who have been diagnosed with CSA have a heart failure comorbidity; 64 percent of patients enrolled in the pivotal trial had a diagnosis of heart failure. The applicant stated that it expected a higher proportion of heart failure patients enrolled in the study of CSA due to the correlated incidence of these diseases and the pivotal trial inclusion criteria being based on conventional sleep apnea metrics and not comorbidities. The applicant further stated that, regardless of the patients' comorbidity status, patients experienced consistent and durable improvements with the use of the remedē® System as a treatment option.

The applicant responded to CMS' concern regarding the small sample size used for the pivotal trial. The applicant stated that the sample size was chosen with an alpha error of 0.025, a power of 80 percent, an expected 50 percent response rate in the treatment group, and a 25 percent response rate in the control group. The applicant further stated that the study accounted for a 15 percent implantation failure and a 10 percent drop-out rate. The applicant indicated that, ultimately, the trial randomized 151 patients, with 147 successful implantations. Another commenter stated that the results showing highly statistical significance were derived from a sample size of patients across 31 different places around the world and, therefore, are generalizable.

The applicant responded to CMS' interest in longer term follow-up data. The applicant stated that 12-month follow-up data was recently published providing 12 months of treatment data for patients enrolled in the treated group and 6 months of treatment data for patients enrolled in the control group. Other commenters stated that 12-month follow-up data results are available and show continued durability of 6-month results.

The applicant addressed CMS' concern about the potential for electrical stimulation of unintended targets and interference from outside devices. The applicant stated that 42 percent of the patients involved in the pivotal trial had a concomitant cardiac device. The applicant stated that interactions between devices are not unique to the remedē® System and that only three serious device interactions were reported, all of which were resolved with reprogramming. The applicant further indicated that, all except 1 of the 21 extra-respiratory stimulation cases that occurred were resolved with routine reprogramming of the remedē® System, the other required repositioning of the lead. Ultimately, 96 percent of the patients enrolled in the pivotal trial would elect to have the medical procedure again.

Lastly, the applicant addressed CMS' concern about longevity of the implanted device, batteries, and leads. The applicant stated that the expected typical battery life is 41 months, which is consistent with other implanted neurostimulation devices. The applicant further stated that the leads were FDA pre-market approved and designed based on predicate, permanent cardiac pacing leads for which the standards are more rigorous than those for neurostimulation. The applicant indicated that, the leads, therefore, compare favorably to leads used for neurostimulation in categories such as lead breakage, connector failure, lead dislodgement, and infection.

Another commenter responded to CMS' concern about the possible failure in randomization when controlling for heart failure status. The commenter stated that it does not consider the reported baseline difference as a failure of randomization. The commenter further noted that, of the approximately 50 baseline factors examined and reported in the clinical study report from the pivotal trial, only MAI had a p-value equal to less than 0.05 associated with a study group difference.

Many commenters stated that the remedē® System represented a substantial clinical improvement and referenced clinical data, in general, and others specifically mentioned the pivotal trial results as demonstration of the improved benefit over existing treatment options. These commenters also noted that the use of the remedē® System and the mechanism of action of phrenic nerve stimulation showed sustained benefits for patients who have been diagnosed with CSA and received treatment using the system.

Response: We appreciate the thoroughness of the additional information and analyses provided by the applicant and commenters in response to our concerns regarding whether the technology meets the substantial clinical improvement criterion. We agree with the applicant and commenters that the use of the remedē® System represents a substantial clinical improvement over existing technologies because, based on the information provided by the applicant, it substantially improves relevant metrics related to the CSA condition, regardless of whether there is the presence of heart failure comorbidities. Specifically, the applicant provided data which demonstrated the effectiveness of the remedē® System for the treatment of moderate and severe CSA in all treated patients, regardless of a heart failure comorbidity. Patients without a diagnosis of heart failure benefited from treatment involving the remedē® System, as well as those with a diagnosis of heart failure. Furthermore, the applicant and commenters provided evidence to allay our concerns as they related to a lack of use of CPAP as a comparator for the remedē® System in clinical trials, baseline data regarding differences between heart failure and non-heart failure groups, a small sample size in the pivotal trial, longer term follow-up data, the potential for interplay between concomitant devices, and the longevity of the device, batteries, and leads.

After consideration of the public comments we received, we have determined that the remedē® System meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for the remedē® System for FY 2019. Cases involving the use of the remedē® System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedures codes 0JH60DZ and 05H33MZ in combination with procedure code 05H03MZ (Insertion of neurostimulator lead into right innominate vein, percutaneous approach) or 05H043MZ (Insertion of neurostimulator lead into left innominate vein, percutaneous approach).

In its application, the applicant estimated that the average Medicare beneficiary would require the surgical implantation of one remedē® System per patient. According to the application, the cost of the remedē® System is $34,500 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the remedē® System is $17,250 for FY 2019. In accordance with the current indication for the use of the remedē® System, CMS expects that the remedē® System will be used for the treatment of adult patients who have been diagnosed with moderate to severe CSA.

e. Titan Spine nanoLOCK® (Titan Spine nanoLOCK® Interbody Device)

Titan Spine submitted an application for new technology add-on payments for the Titan Spine nanoLOCK® Interbody Device (the Titan Spine nanoLOCK®) for FY 2019. (We note that the applicant previously submitted an application for new technology add-on payments for this device for FY 2017.) The Titan Spine nanoLOCK® is a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients diagnosed with degenerative disc disease (DDD). One of the key distinguishing features of the device is the surface manufacturing technique and materials, which produce macro, micro, and nano-surface textures. According to the applicant, the combination of surface topographies enables initial implant fixation, mimics an osteoclastic pit for bone growth, and produces the nano-scale features that interface with the integrins on the outside of the cellular membrane. Further, the applicant noted that these features generate better osteogenic and angiogenic responses that enhance bone growth, fusion, and stability. The applicant asserted that the Titan Spine nanoLOCK®'s clinical features also reduce pain, improve recovery time, and produce lower rates of device complications such as debris and inflammation.

On October 27, 2014, the Titan Spine nanoLOCK® received FDA clearance for the use of five lumbar interbody devices and one cervical interbody device: The nanoLOCK® TA—Sterile Packaged Lumbar ALIF Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TAS—Sterile Packaged Lumbar ALIF Stand Alone Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TL—Sterile Packaged Lumbar Lateral Approach Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TO—Sterile Packaged Lumbar Oblique/PLIF Approach Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TT—Sterile Packaged Lumbar TLIF Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; and the nanoLOCK® TC—Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy.

The applicant received FDA clearance on December 14, 2015, for the nanoLOCK® TCS—Sterile Package Cervical Stand Alone Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy. According to the applicant, July 8, 2016, was the first date that the nanotechnology production facility completed validations and clearances needed to manufacture the nanoLOCK® interbody fusion devices. Once validations and clearances were completed, the technology was available on the U.S. market on October 1, 2016. Therefore, the applicant believes that the newness period for nanoLOCK® would begin on October 1, 2016. Procedures involving the Titan Spine nanoLOCK® technology can be identified by the following ICD–10–PCS Section ''X'' New Technology codes:

- XRG0092 (Fusion of occipital-cervical joint using nanotextured surface interbody fusion device, open approach);

- XRG1092 (Fusion of cervical vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRG2092 (Fusion of 2 or more cervical vertebral joints using nanotextured surface interbody fusion device, open approach);
- XRG4092 (Fusion of cervicothoracic vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRG6092 (Fusion of thoracic vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRG7092 (Fusion of 2 to 7 thoracic vertebral joints using nanotextured surface interbody fusion device, open approach);
- XRG8092 (Fusion of 8 or more thoracic vertebral joints using nanotextured surface interbody fusion device, open approach);
- XRGA092 (Fusion of thoracolumbar vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRGB092 (Fusion of lumbar vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRGC092 (Fusion of 2 or more lumbar vertebral joints using nanotextured surface interbody fusion device, open approach); and
- XRGD092 (Fusion of lumbosacral joint using nanotextured surface interbody fusion device, open approach).

We note that the applicant expressed concern that interbody fusion devices that have failed to gain or apply for FDA clearance with nanoscale features could confuse health care providers with marketing and advertising using terms related to nanotechnology and ultimately adversely affect patient outcomes.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments. In the proposed rule we noted that the substantial similarity discussion is applicable to both the lumbar and the cervical interbody devices because all of the devices use the Titan Spine nanoLOCK® technology.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that, for both interbody devices (the lumbar and the cervical interbody device), the Titan Spine nanoLOCK®'s surface stimulates osteogenic cellular response to assist in bone formation during fusion. According to the applicant, the mechanism of action exhibited by the Titan Spine's nanoLOCK® surface technology involves the ability to create surface features that are meaningful to cellular regeneration at the nano-scale level. During the manufacturing process, the surface produces macro, micro, and nano-surface textures. The applicant believed that this unique combination and use of these surface topographies represents a new approach to stimulating osteogenic cellular response. The applicant further asserted that the macro-scale textured features are important for initial implant fixation; the micro-scale textured features mimic an osteoclastic pit for supporting bone growth; and the nano-scale textured features interface with the integrins on the outside of the cellular membrane, which generates the osteogenic and angiogenic (mRNA) responses necessary to promote healthy bone growth and fusion. The applicant stated that when correctly manufactured, an interbody fusion device includes a hierarchy of complex surface features, visible at different levels of magnification, that work collectively to impact cellular response through mechanical, cellular, and biochemical properties. The applicant stated that Titan Spine's proprietary and unique surface technology, the Titan Spine nanoLOCK® interbody devices, contain optimized nano surface characteristics, which generate the distinct cellular responses necessary for improved bone growth, fusion, and stability. The applicant further stated that the Titan Spine nanoLOCK®'s surface engages with the strongest portion of the vertebral endplate, which enables better resistance to subsidence because a unique dual acid-etched titanium surface promotes earlier bone in-growth. According to the applicant, the Titan Spine nanoLOCK®'s surface is created by using a reductive process of the titanium itself. The applicant asserted that use of the Titan Spine nanoLOCK® significantly reduces the potential for debris generated during impaction when compared to treatments using Polyetheretherketone (PEEK)-based implants coated with titanium. According to the results of an in vitro study (provided by the applicant), which examined factors produced by human mesenchymal stem cells on spine implant materials that compared angiogenic factor production using PEEK-based versus titanium alloy surfaces, osteogenic production levels were greater with the use of rough titanium alloy surfaces than the levels produced using smooth titanium alloy surfaces. Human mesenchymal stem cells were cultured on tissue culture polystyrene, PEEK, smooth TiAlV, or macro-/micro-/nanotextured rough TiAlV (mmnTiAlV) disks. Osteoblastic differentiation and secreted inflammatory interleukins were assessed after 7 days. The results of an additional study provided by the applicant examined whether inflammatory microenvironment generated by cells as a result of use of titanium aluminum-vanadium (Ti-alloy, TiAlV) surfaces is effected by surface micro texture, and whether it differs from the effects generated by PEEK-based substrates. This in vitro study compared angiogenic factor production and integrin gene expression of human osteoblast-like MG63 cells cultured on PEEK or titanium-aluminum vanadium (titanium alloy). Based on these study results, the applicant asserted that the use of micro textured surfaces has demonstrated greater promotion of osteoblast differentiation when compared to use of PEEK-based surfaces.

The applicant maintains that the nanoLOCK® was the first, and remains the only, device in spinal fusion, to apply for and successfully obtain a clearance for nanotechnology from the FDA. According to the applicant, in order for a medical device to receive a nanotechnology FDA clearance, the burden of proof includes each of the following to be present on the medical device in question: (1) Proof of specific nano scale features, (2) proof of capability to manufacture nano-scale features with repeatability and documented frequency across an entire device, and (3) proof that those nano-scale features provide a scientific benefit, not found on devices where the surface features are not present. The applicant further stated that many of the commercially available interbody fusion devices are created using additive manufacturing processes to mold or build surface from the ground up. Conversely, Titan Spine applied a subtractive surface manufacturing to remove pieces of a surface. The surface features that remain after this subtractive process generate features visible at magnifications that additive manufacturing has not been able to produce. According to the applicant, this subtractive process has been validated by the White House Office of Science and Technology, the National Nanotechnology Initiative, and the FDA that provide clearances to products that

exhibit unique and repeatable features at predictive frequency due to a manufacturing technique.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, cases representing patients that may be eligible for treatment involving the Titan Spine nanoLOCK® technology would map to the same MS–DRGs as other (lumbar and cervical) interbody devices currently available to Medicare beneficiaries and also are used for the treatment of patients who have been diagnosed with DDD (lumbar or cervical).

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the Titan Spine nanoLOCK® can be used in the treatment of patients who have been diagnosed with similar types of diseases, such as DDD, and for a similar patient population receiving treatment involving both lumbar and cervical interbody devices.

In summary, the applicant maintained that the Titan Spine nanoLOCK® technology has a different mechanism of action when compared to other spinal fusion devices. Therefore, the applicant did not believe that the Titan Spine nanoLOCK® technology is substantially similar to existing technologies.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20316), we stated we were concerned that the Titan Spine nanoLOCK® interbody devices may be substantially similar to currently available titanium interbody devices because other roughened surface interbody devices also stimulate bone growth. While there is a uniqueness to the nanotechnology used by the applicant, other devices also stimulate bone growth such as PEEK-based surfaces and, therefore, we were concerned that the Titan Spine nanoLOCK® interbody devices use the same or similar mechanism of action as other devices.

We invited public comments on whether the Titan Spine nanoLOCK® interbody devices are substantially similar to existing technologies and whether these devices meet the newness criterion.

Comment: One commenter stated that similar products to the nanoLOCK® interbody devices exist, and there is no unbiased research to support the applicant's claims of the technology's results. Several commenters referenced studies that show that nano-scale enhanced Ti6A14V interbody fusion device surfaces promote a cellular response to bone growth. The commenters stated that these studies show that cells in the osteoblast lineage (MSCs, osteoprogenitor cells, and osteoblasts) exhibited a more mature osteoblast phenotype when grown on microtextured Ti and Ti6Al4V surfaces than on tissue culture polystyrene (TCPS) or on other polymers like PEEK. The commenters further stated that, moreover, cells on the Ti6Al4V surfaces produced less inflammatory mediators, less apoptotic factors and less necrosis factors than cells on PEEK surfaces (rough < smooth Ti6Al4V <<< smooth PEEK) and that PEEK surfaces have long been associated with increased fibrous encapsulation *in vivo,* which was recently identified to be due to a direct upregulation of inflammatory factors from mesenchymal stem cells growing on PEEK.

Response: We agree with the commenter that similar products to the nanoLOCK® interbody devices exist. We also believe that the current research supports the applicant's assertion that the technology's nanoscale features, which exhibit a biological effect (osteoblastic activity), have not been seen in other interbody fusion devices. After consideration of the public comments we received, we believe that the Titan Spine nanoLock® uses a unique mechanism of action, a nano-scale level surface technology, to enhance bone growth. Therefore, we believe the Titan Spine nanoLock® is not substantially similar to other existing technologies and meets the newness criterion.

The applicant provided three analyses of claims data from the FY 2016 MedPAR file to demonstrate that the Titan Spine nanoLOCK® interbody devices meet the cost criterion. In the proposed rule, we noted that cases reporting procedures involving lumbar and cervical interbody devices would map to different MS–DRGs. As discussed in the Inpatient New Technology Add On Payment Final Rule (66 FR 46915), two separate reviews and evaluations of the technologies are necessary in this instance because cases representing patients receiving treatment for diagnoses associated with lumbar procedures that may be eligible for use of the technology under the first indication would not be expected to be assigned to the same MS DRGs as cases representing patients receiving treatment for diagnoses associated with cervical procedures that may be eligible for use of the technology under the second indication. Specifically, cases representing patients who have been diagnosed with lumbar DDD and who have received treatment that involved implanting a lumbar interbody device would map to MS DRG 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), MS DRG 030 (Spinal Procedures without CC/MCC), MS–DRG 453 (Combined Anterior/Posterior Spinal Fusion with MCC), MS–DRG 454 (Combined Anterior/Posterior Spinal Fusion with CC), MS–DRG 455 (Combined Anterior/Posterior Spinal Fusion without CC/MCC), MS–DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC), MS DRG 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusion without MCC), MS–DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC), MS–DRG 459 (Spinal Fusion Except Cervical with MCC), and MS–DRG 460 (Spinal Fusion Except Cervical without MCC). Cases representing patients who have been diagnosed with cervical DDD and who have received treatment that involved implanting a cervical interbody device would map to MS DRG 471 (Cervical Spinal Fusion with MCC), MS–DRG 472 (Cervical Spinal Fusion with CC), and MS–DRG 473 (Cervical Spinal Fusion without CC/MCC). Procedures involving the implantation of lumbar and cervical interbody devices are assigned to separate MS DRGs. Therefore, the devices categorized as lumbar interbody devices and the devices categorized as cervical interbody devices must distinctively (each category) meet the cost criterion and the substantial clinical improvement criterion in order to be eligible for new technology add on payments beginning in FY 2019.

The first analysis searched for any of the ICD–10–PCS procedure codes within the code series Lumbar–0SG [body parts 0 1 3] [open approach only 0] [device A only] [anterior column only 0, J], which typically are assigned to MS DRGs 028, 029, 030, and 453 through 460. The average case-weighted unstandardized charge per case was $153,005. The applicant then removed charges related to the predicate technology and then standardized the charges. The applicant then applied an inflation factor of 1.09357, the value used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to update the charges from FY 2016 to FY 2018. The applicant added charges related to the Titan Spine nanoLOCK® lumbar interbody devices. This resulted in a final inflated average case-weighted standardized charge per case of $174,688, which exceeded the average

case-weighted Table 10 MS–DRG threshold amount of $83,543.

The second analysis searched for any of the ICD–10–PCS procedure codes within the code series Cervical–0RG [body parts 0–A] [open approach only 0] [device A only] [anterior column only 0, J], which typically are assigned to MS–DRGs 028, 029, 030, 453 through 455, and 471 through 473. The average case-weighted unstandardized charge per case was $88,034. The methodology used in the first analysis was used for the second analysis, which resulted in a final inflated average case-weighted standardized charge per case of $101,953, which exceeded the average case-weighted Table 10 MS–DRG threshold amount of $83,543.

The third analysis was a combination of the first and second analyses described earlier that searched for any of the ICD–10–PCS procedure codes within the Lumbar and Cervical code series listed above that are assigned to the MS–DRGs in the analyses above. The average case-weighted unstandardized charge per case was $127,736. The methodology used for the first and second analysis was used for the third analysis, which resulted in a final inflated average case-weighted standardized charge per case of $149,915, which exceeded the average case-weighted Table 10 MS–DRG threshold amount of $104,094.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all of the applicant's analyses, the applicant maintained that the technology met the cost criterion.

We invited public comments on whether the Titan Spine nanoLOCK® meets the cost criterion.

We did not receive any public comments concerning whether the Titan Spine nanoLOCK® meets the cost criterion or the cost analysis presented in the proposed rule. We believe that the Titan Spine nanoLOCK® meets the cost criterion.

With regard to the substantial clinical improvement criterion for the Titan Spine nanoLOCK® Interbody Lumbar and Cervical Devices, the applicant submitted the results of two clinical evaluations. The first clinical evaluation was a case series and the second was a case control study. Regarding the case series, 4 physicians submitted clinical information on 146 patients. The 146 patients resulted from 2 surgery groups: A cervical group of 73 patients and a lumbar group of 73 patients. The division into cervical and lumbar groups was due to differences in surgical procedure and expected recovery time. Subsequently, the collection and analyses of data were presented for lumbar and cervical nanoLOCK® device implants. Data was collected using medical record review. Patient baseline characteristics, the reason for cervical and lumbar surgical intervention, inclusion and exclusion criteria, details on the types of pain medications and the pattern of usage preoperatively and postoperatively were not provided. In the proposed rule, we noted that the applicant did not provide an explanation of why the outcomes studied in the case series were chosen for review. However, the applicant noted that the case series data were restricted to patients treated with the Titan Spine nanoLOCK® device, with both retrospective and prospective data collection. These data appeared to be clinically related and included: (1) Pain medication usage; (2) extremity and back pain (assessed using the Numeric Pain Rating Scale (NPRS)); and (3) function (assessed using the Oswestry Disability Index (ODI)). Clinical data collection began with time points defined as ''Baseline (pre-operation), Month 1 (0–4 weeks), Month 2 (5–8 weeks), Month 3 (9–12 weeks), Month 4 (13–16 weeks), Month 5 (17–20 weeks) and Month 6+ (>20 weeks)''. The n, mean, and standard deviation were presented for continuous variables (NPRS extremity pain, back pain, and ODI scores), and the n and percentage were presented for categorical variables (subjects taking pain medications). All analyses compared the time point (for example, Month 1) to the baseline.

Pain scores for extremities (leg and arm) were assessed using the NPRS, an 11 category ordinal scale where 0 is the lowest value and 10 is the highest value and, therefore, higher scores indicate more severe pain. Of the 73 patients in the lumbar group, the applicant presented data on 18 cases for leg or arm pain at baseline that had a mean score of 6.4, standard deviation (SD) 2.3. Between Month 1 and Month 6+ the number of lumbar patients for which data was submitted for leg or arm pain ranged from 3 patients (Month 5, mean score 3.7, SD 3.5) to 15 patients (Month 6+, mean score 2.5, SD 2.4), with varying numbers of patients for each of the other defined time points of Month 1 through Month 4. None of the defined time points of Month 1 through Month 4 had more than 14 patients or less than 3 patients that were assessed.

Of the 73 patients in the cervical group, 7 were assessed for leg or arm pain at baseline and had a mean score of 5.1, SD 3.5. Between Month 1 and Month 6+ the number of cervical patients assessed for leg or arm pain ranged from 0 patients (Month 5, no scores) to 5 patients (Month 1, mean score 4.2, SD 2.6), with varying numbers of patients for each of the other defined time points of Month 1 through Month 4. None of the defined time points of Month 1 through Month 4 had more than 5 patients or less than 2 patients that were assessed.

Back pain scores were also assessed using the NPRS, where 0 is the lowest value and 10 is the highest value and, therefore, higher scores indicate more severe pain. Of the 73 patients in the lumbar group, 66 were assessed for back pain at baseline and had a mean score of 7.9, SD 1.8. Between Month 1 and Month 6+ the number of lumbar patients assessed for back pain ranged from 4 patients (Month 5, mean score 4.0, SD 2.7) to 43 patients (Month 1, mean score 4.5, SD 2.7), with varying numbers of patients for each defined time point.

Of the 73 patients in the cervical group, 71 were assessed for back pain at baseline and had a mean score of 7.5, SD 2.3. Between Month 1 and Month 6+ the number of cervical patients assessed for back pain ranged from 2 patients (Month 5, mean score 7.0, SD 2.8) to 47 patients (Month 1, mean score 4.4, SD 2.9), with varying numbers of patients for each defined time point.

Function was assessed using the ODI, which ranges from 0 to 100, with higher scores indicating increased disability/impairment. Of the 73 patients in the lumbar group, 59 were assessed for ODI scores at baseline and had a mean score of 52.5, SD 18.7. Between Month 1 and Month 6+ the number of lumbar patients assessed for ODI scores ranged from 3 patients (Month 5, mean score 33.3, SD 19.8) to 38 patients (Month 1, mean score 48.1, SD 19.7), with varying numbers of patients for each defined time point. Of the 73 patients in the cervical group, 56 were assessed for ODI scores at baseline and had a mean score of 53.6, SD 18.2. Between Month 1 and Month 6+ the number of cervical patients assessed for ODI score ranged from 1 patient (Month 5, mean score 80, no SD noted) to 41 patients (Month 1, mean score 48.6, SD 20.5), with varying numbers of patients for each defined time point.

The percentages of patients not taking pain medicines per day for the lumbar and cervical groups over time were assessed. Of the 73 patients in the lumbar group, 69 were assessed at baseline and 27.5 percent of the 69 patients were not taking pain medication. Between Month 1 and Month 6+ the number of lumbar patients assessed for not taking pain medicines ranged from 5 patients

(Month 5, 80 percent were not taking pain medicines) to 46 patients (Month 1, 54.3 percent were not taking pain medicines), with varying numbers of patients for each defined time point. Of the 73 patients in the cervical group, 72 were assessed and 22.2 percent of the 72 patients were not taking pain medicines at baseline. Between Month 1 and Month 6+ the number of cervical patients assessed for not taking pain medicines ranged from 2 patients (Month 5, 100 percent were not taking pain medicines) to 50 patients (Month 1, 70 percent were not taking pain medicines), with varying numbers of patients for each defined time point.

According to the applicant, both the lumbar and cervical groups showed a trend of improvement in all four clinical outcomes over time for which they collected data in their case series. However, the applicant also indicated that the trend was difficult to assess due to the relatively limited number of subjects with available assessments more than 4 months post-implant. The applicant shared that it had missing values for over 80 percent of the subjects in the study after the 4th post-operative month. According to the applicant and its results of the clinical evaluation, which was based on data from less than 20 percent of subjects, there was a statistically significant reduction in back pain for nanoLOCK® patients from ''Baseline,'' based on improvement at earlier than standard time points.

In the proposed rule, we stated we were concerned that the small sample size of patients assessed at each timed follow-up point for each of the clinical outcomes evaluated in the case series limited our ability to draw meaningful conclusions from these results. The applicant provided t-test results for the lumbar and cervical groups assessed for pain (back, leg, and arm). We indicated we were concerned that the t-test resulting from small sample sizes (for example, 2 of 73 patients in Month 5, and 5 of 73 patients in Month 6+) does not indicate a statistically meaningful improvement in pain scores.

Based on the results of the case series provided by the applicant, we stated that we were unable to determine whether the findings regarding extremity and back pain, ODI scores, and percentage of subjects not taking pain medication for patients who received treatment involving the Titan Spine nanoLOCK® devices represent a substantial clinical improvement due to the inconsistent sample size over time across both treatment arms in all evaluated outcome measures. The quantity of missing data in this case series, along with the lack of explanation for the missing data, raised concerns for the interpretation of these results. We also stated that we were unable to determine based on this case series whether there were improvements in extremity pain and back pain, ODI scores, and percentage of subjects not taking pain medicines for patients who received treatment involving the Titan Spine nanoLOCK® devices versus conventional and other intervertebral body fusion devices, as there were no comparisons to current therapies. As noted in the proposed rule and above, the applicant did not provide an explanation of why the outcomes studied in the case series were chosen for review. Therefore, we believed that we may have had insufficient information to determine if the outcomes studied in the case series are validated proxies for evidence that the nanoLOCK®'s surface promotes greater osteoblast differentiation when compared to use of PEEK-based surfaces. We invited public comments regarding our concerns, including with respect to why the outcomes studied in the case series were chosen for review.

We note that, we did not receive any public comments with respect to why the outcomes in the case series were selected for review.

The applicant's second clinical evaluation was a case-control study with a 1:5 case to control ratio. The applicant used deterministically linked, de-identified, individual level health care claims, electronic medical records (EMR), and other data sources to identify 70 cases and 350 controls for a total sample size of 420 patients. The applicant also identified OM1™ data source and noted that the OM1™ data source reflects data from all U.S. States and territories and is representative of the U.S. national population. The applicant used OM1™ data between January 2016 and June 2017, and specifically indicated that these data contain medical and pharmacy claims information, laboratory data, vital signs, problem lists, and other clinical details. The applicant indicated that cases were selected using the ICD–10–PCS Section ''X'' New Technology codes listed above and controls were chosen from fusion spine procedures (Fusion Spine Anterior Cervical, Fusion Spine Anterior Cervical and Discectomy, Fusion Spine Anterior Posterior Cervical, Fusion Spine Transforaminal Interbody Lumbar, Fusion Spine Cervical Thoracic, Fusion Spine Transforaminal Interbody Lumbar with Navigation, and Fusion Spine Transforaminal Interbody Lumber Robot-Assisted). Further, the applicant stated that cases and controls were matched by age (within 5 years), year of surgery, Charlson Comorbidity Index, and gender. According to the applicant, regarding clinical outcomes studied, unlike the case series, the case-control study captured Charlson Comorbidity Index, the average length of stay (ALOS), and 30-day unplanned readmissions; like the case series, this case-control study captured the use of pain medications by assessing the cumulative post-surgical opioid use.

The mean age for all patients in the study was 55 years old, and 47 percent were male. For the clinical length of stay outcome, the applicant noted that the mean length of stay was slightly longer among control patients, 3.9 days (SD=5.4) versus 3.2 days (SD=2.9) for cases, and a larger proportion of patients in the control group had lengths of stay equal to or longer than 5 days (21 percent versus 17 percent). Three control patients (0.8 percent) were readmitted within 30 days compared to zero readmissions among case patients. A slightly lower proportion of case patients were on opioids 3 months post-surgery compared to control patients (15 percent versus 16 percent).

In the proposed rule (83 FR 20318), we stated we were concerned that there may be significant outliers not identified in the case and control arms because for the mean length of stay outcome, the standard deviation for control patients (5.4 days) is larger than the point estimate (3.9 days). Based on the results of this clinical evaluation provided by the applicant, we stated that we were unable to determine whether the findings regarding lengths of stay and cumulative post-surgical opioid use for patients who received treatment involving the nanoLOCK® devices versus conventional intervertebral body fusion devices represent a substantial clinical improvement. We stated that without further information on selection of controls and whether there were adjustments in the statistical analyses controlling for confounding factors (for example, cause of back pain, level of experience of the surgeon, BMI and length of pain), we were concerned that the interpretation of the results may be limited. Finally, we stated we were concerned that the current data does not adequately support a strong association between the outcome measures of length of stay, readmission rates, and use of opioids and the use of nano-surface textures in the manufacturing of the Titan Spine nanoLOCK® device. For these reasons, we stated that we were concerned that the current data do not support a substantial clinical

improvement over the currently available devices used for lumbar and cervical DDD treatment.

In the proposed rule, we noted that the applicant indicated its intent to submit the results of additional ongoing studies to support the evidence of substantial clinical improvement over existing technologies for patients who received treatment involving the nanoLOCK® devices versus patients receiving treatment involving other interbody fusion devices. We invited public comments on whether the Titan Spine nanoLOCK® meets the substantial clinical improvement criterion.

Comment: The applicant submitted a Milligram Morphine Equivalent (MME) analysis. According to the applicant, the purpose of the analysis is to demonstrate support for the ''substantial clinical value'' in the reduction of MME with the implant of a Titan Spine nanoLOCK® device. The applicant indicated that the MME analysis was conducted to assess the impact of nanoLOCK® versus control devices on total MME and narcotic usage. The applicant submitted the results of the MME analysis as additional demonstration to support the representation of a substantial clinical improvement over existing technologies as stated in their application, and indicated that the data will be published soon as a peer-reviewed journal article. The applicant explained that control devices represented a mix of interbody fusion devices, including PEEK and alternative roughened titanium devices without nano-surface technology. The applicant stated that all nanoLOCK® patients were classified as having an interbody fusion device with a nano technology coated surface. The applicant further indicated that all patients received either an allograft or autograft biologic in addition to the implant device. The applicant stated that follow-up time was recorded at 3 points: Follow-up #1—28.71 days (S.D. 20.64); Follow-up #2—65.07 days (S.D. 33.91); and Follow-up #3—104.21 days (S.D. 40.91). According to the applicant, a patient's baseline MME was also a significant predictor of MME at first follow-up when adjusted for all other variables in the model. The applicant stated that, at Follow-up #1, there was a total of 926 patients with data regarding the days from surgery to the first follow-up. The applicant indicated that, according to the MME analysis, of the 926 patients at the time of Follow-up #1, 47 patients had missing data. The applicant further stated that results show there were 873 patients with data on narcotic usage at the time of the first follow-up, with 100 patients with missing data, and 391 patients with data on the total MME, with 582 missing data at the time of final analysis of follow-up #1. The applicant stated that the results from the remaining 391 patients represent only 42 percent of the original study participants. The applicant explained that results indicated the mean total MME of patients was 21.83 units (SD: 42.63). The applicant further stated that there were 349 patients who were using narcotics for pain at the time of their first follow-up. The applicant explained that all missing data was addressed through pairwise deletion. The applicant believed that this analysis further demonstrated that patients who received nanoLOCK® had a significantly lower total MME at first follow-up when compared to control devices patients when adjusted for the following variables: Age, male versus female, history of prior spine surgery, current smoker versus non-smoker, baseline MME, concomitant medical condition, cervical versus lumbar, nanoLOCK® versus control, single versus multi-level surgery, and intra-op complication. The applicant stated that, based on the results of the MME analysis, the use of nanoLOCK® reduced total MME by MME 24.47 units (95 percent CI: 14.42 to 34.52 units) more than patients who received treatment using a control device. The applicant explained that a patient's baseline MME was also a significant predictor of MME at first follow-up when adjusted for all other variables in the model. The applicant noted that the lack of standardized registries to collect spine data, combined with the inability to access CMS registry information in advance, means that the multiple examples provided by the applicant regarding the use of nanoLOCK® are the most robust information available and the consistency in outcomes with statistical significance means the product's attributes generate clinical value.

Response: We appreciate the additional data provided by the applicant. However, we are unable to determine the substantial clinical value based on the analysis' data, due in part to the vast amount of missing data and inconsistencies in the data provided. For example, at each point of follow-up the number of patients in the analysis' cohort is reduced, and ''missing'' numbers of patients in the cohort are listed. Although the analysis attempts to account for the missing patients and patients' data by pairwise deletions, we are unable to determine a consistent cohort of patients for which a possible reduction in MME usage may have occurred. We attempted to assess for a pattern of consistency with the ''missing'' data and have been unable to determine any such pattern. Additionally, while the applicant stated that it used a sample size of n=926 patients, throughout the analyses we noted varying numbers of patients for many of the variables included as covariates, making it difficult to arrive at a meaningful conclusion. We also note that the applicant did not provide further information on our concern for the selection of controls and whether there were adjustments in the statistical analyses controlling for confounding factors (for example, cause of back pain, level of experience of the surgeon, BMI and length of pain).

Comment: One commenter stated that the nanoLOCK® provides a substantial clinical benefit, which is evidenced by multiple third-party analytics evaluations that were performed outside of the manufacturer's control. The commenter stated that these analytic evaluations have found that the nanoLOCK® technology has led to reduced hospital inpatient mean length of stay, fewer total readmissions over 30 days post operation, and decreased use of prescription opioids for post-operative spinal surgery patients. However, the commenter did not provide the specific third-party analytic evaluations with its public comment submission. Several commenters believed that the nanoLOCK® technology represents a substantial clinical improvement over current devices based on personal experience. One commenter stated that within its specific patient population, patients are returning to work faster, participating in more physical therapy, and reducing their use of opiate pain medications. Another commenter with personal experience with the nanoLOCK® technology also stated that substantial improvement within the fusion patient population had been recognized because of the granted access to the nano-surface technology. The commenter noted that patients are back to work earlier, starting physical therapy earlier, and require less narcotic medication after surgery compared to earlier patients who received treatment involving other fusion implants.

Response: We appreciate the input and additional information from the commenters in support for the Titan Spine nanoLOCK® based on personal surgical experience and third party analytics. However, we note that the comments based on personal surgical experience were of a qualitative nature and did not contain objective data to support whether the Titan Spine nanoLOCK® meets the substantial

clinical improvement criterion. We believe that the Titan Spine nanoLock® may potentially be a viable alternative to existing technologies. However, the data provided did not show that use of nanoLock® interbody fusion devices provides a substantial clinical improvement over existing technologies.

After consideration of all the information from the applicant, as well as the public comments we received, we are unable to determine if the Titan Spine nanoLOCK® represents a substantial clinical improvement over the currently available devices used for lumbar and cervical DDD treatment due to a lack of significant and meaningful data. As stated above, we remain concerned that the current data does not adequately support a sufficient association between the outcome measures of length of stay, readmission rates, and use of opioids and the use of nano-surface textures in the manufacturing of the Titan Spine nanoLOCK® device to determine that the technology represents a substantial clinical improvement over existing available options. Therefore, after consideration of all of the new technology add-on payment criteria we are not approving new technology add-on payments for the Titan Spine nanoLock® devices for FY 2019.

f. ZEMDRI™ (Plazomicin)

Achaogen, Inc. submitted an application for new technology add-on payments for Plazomicin for FY 2019. We note that, since the publication of the proposed rule, the applicant has announced that the trade name for Plazomicin is ZEMDRI™. According to the applicant, ZEMDRI™ (Plazomicin) is a next-generation aminoglycoside antibiotic, which has been found in vitro to have enhanced activity against many multi-drug resistant (MDR) gram-negative bacteria. We stated in the proposed rule that the proposed indication for the use of Plazomicin, which had not received FDA approval as of the time of the development of this proposed rule, was for the treatment of adult patients who have been diagnosed with the following infections caused by designated susceptible microorganisms: (1) Complicated urinary tract infection (cUTI), including pyelonephritis; and (2) bloodstream infections (BSIs). We indicated that the applicant stated that it expected that Plazomicin would be reserved for use in the treatment of patients who have been diagnosed with these types of infections who have limited or no alternative treatment options, and would be used only to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms. The applicant received approval from the FDA on June 25, 2018, for Plazomicin with the trade name ZEMDRI™ for use in the treatment of adults with cUTIs, including pyelonephritis.

The applicant stated that there is a strong need for antibiotics that can treat infections caused by MDR Enterobacteriaceae, specifically carbapenem resistant Enterobacteriaceae (CRE). Life-threatening infections caused by MDR bacteria have increased over the past decade, and the patient population diagnosed with infections caused by CRE is projected to double within the next 5 years, according to the Centers for Disease Control and Prevention (CDC). Infections caused by CRE are often associated with poor patient outcomes due to limited treatment options. Patients who have been diagnosed with BSIs due to CRE face mortality rates of up to 50 percent. Patients most at risk for CRE infections are those with CRE colonization, recent hospitalization or stay in a long-term care or skilled-nursing facility, an extensive history of antibacterial use, and whose care requires invasive devices like urinary catheters, intravenous (IV) catheters, or ventilators. The applicant estimated, using data from the Center for Disease Dynamics, Economics & Policy (CDDEP), that the Medicare population that has been diagnosed with antibiotic-resistant cUTI numbers approximately 207,000 and approximately 7,000 for BSIs/sepsis due to CRE.

The applicant noted that due to the public health concern of increasing antibiotic resistance and the need for new antibiotics to effectively treat MDR infections, Plazomicin has received the following FDA designations: Breakthrough Therapy; Qualified Infectious Disease Product, Priority Review; and Fast Track. The applicant noted that Breakthrough Therapy designation was granted on May 17, 2017, for the treatment of bloodstream infections (BSIs) caused by certain Enterobacteriaceae in patients who have been diagnosed with these types of infections who have limited or no alternative treatment options. The applicant noted that Plazomicin is the first antibacterial agent to receive this designation. The applicant noted that on December 18, 2014, the FDA designated Plazomicin as a Qualified Infectious Disease Product (QIDP) for the indications of hospital-acquired bacterial pneumonia (HAPB), ventilator-associated bacterial pneumonia (VABP), and complicated urinary tract infection (cUTI), including pyelonephritis and catheter-related blood stream infections (CRBSI). The applicant noted that Fast Track designation was granted by the FDA on August 12, 2012, for the Plazomicin development program for the treatment of serious and life-threatening infections due to CRE. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20320), we indicated that Plazomicin had not received approval from the FDA as of the time of the development of the proposed rule. However, as noted previously, the applicant received approval from the FDA on June 25, 2018, for Plazomicin with the trade name ZEMDRI™ for use in the treatment of adults with cUTIs, including pyelonephritis. We note that, for the remainder of this discussion in this final rule, the two technology names are referenced interchangeably. The applicant did not receive FDA approval for use in the treatment of BSIs.

The applicant's request for approval for a unique ICD–10–PCS procedure code to identify the use of ZEMDRI™ was granted, and the following procedure codes: XW033G4 (Introduction of Plazomicin anti-infective into peripheral vein, percutaneous approach, new technology group 4) and XW043G4 (Introduction of Plazomicin anti-infective into central vein, percutaneous approach, new technology group 4) are effective October 1, 2018.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that Plazomicin does not use the same or similar mechanism of action to achieve a therapeutic outcome as any other drug assigned to the same or a different MS–DRG. The applicant stated that Plazomicin has a unique chemical structure designed to improve activity against aminoglycoside-resistant bacteria, which also are often resistant to other key classes of antibiotics, including beta-lactams and carbapenems. Bacterial resistance to aminoglycosides usually occurs through enzymatic modification by aminoglycoside modifying enzymes (AMEs) to compromise binding the target bacterial site. According to the applicant, AMEs were found in 98.6 percent of aminoglycoside nonsusceptible E. coli, Klebsiella spp, Enterobacter spp, and Proteus spp collected in 2016 U.S. surveillance

studies. Genes encoding AMEs are typically located on elements that also carry other causes of antibiotic resistance like B-lactamase and/or carbapenemase genes. Therefore, extended spectrum beta-lactamases (ESBL) producing Enterobacteriaceae and CRE are commonly resistant to currently available aminoglycosides. According to the applicant, Plazomicin contains unique structural modifications at key positions in the molecule to overcome antibiotic resistance, specifically at the 6 and N1 positions. These side chain substituents shield Plazomicin from inactivation by AMEs, such that Plazomicin is not inactivated by any known AMEs, with the exception of N-acetyltransferase (AAC) 2′-Ia, -Ib, and -Ic, which is only found in Providencia species. According to the applicant, as an aminoglycoside, Plazomicin also is not hydrolyzed by B-lactamase enzymes like ESBLs and carbapenamases. Therefore, the applicant asserted that Plazomicin is a potent therapeutic agent for treating MDR Enterobacteriaceae, including aminoglycoside-resistant isolates, CRE strains, and ESBL-producers.

The applicant asserted that the mechanism of action is new due to the unique chemical structure. With regard to the general mechanism of action against bacteria, in the proposed rule, we stated we were concerned that the mechanism of action of Plazomicin appeared to be similar to other aminoglycoside antibiotics. As with other aminoglycosides, Plazomicin is bactericidal through inhibition of bacterial protein synthesis. The applicant maintained that the structural changes to the antibiotic constitute a new mechanism of action because it allows the antibiotic to remain active despite AMEs. Additionally, the applicant stated that Plazomicin would be the first, new aminoglycoside brought to market in over 40 years.

We invited public comments on whether Plazomicin's mechanism of action is new, including comments in response to our concern that its mechanism of action to eradicate bacteria (inhibition of bacterial protein synthesis) may be similar to that of other aminoglycosides, even if improvements to its structure may allow Plazomicin to be active even in the presence of common AMEs that inactivate currently marketed aminoglycosides.

Comment: The applicant stated, in response to CMS' concern, that ZEMDRI™'s (Plazomicin's) mechanism of action is not substantially similar to that of existing aminoglycosides because modifications in the chemical structure allow ZEMDRI™ to both withstand resistance and reach the target site of action for antibacterial efficacy. The applicant indicated that ZEMDRI™ is the first intravenous (IV) aminoglycoside approved by the FDA in over 35 years that uses a protein synthesis as its target site, combined with unique structural modifications that withstand bacterial resistance mechanisms that render currently marketed aminoglycosides ineffective. The applicant believed that consideration of the mechanism of action for antibiotics should include how it defends itself against inactivation by the bacteria, in addition to how it kills the bacteria because the increasing emergence of antibiotic resistance requires that new drugs not only exert bactericidal action, but also how the new drugs overcome bacterial resistance. The applicant stated that the ability of an antibiotic to withstand resistance is equally important as the ability to work at the target site because without the first action, the latter would not matter. Therefore, the applicant posited that, while ZEMDRI™'s mechanism of bacterial killing is similar to other aminoglycosides, its ability to withstand antibiotic resistance due to AMEs is substantially different and represents an improvement in the treatment of patients diagnosed with serious gram-negative bacterial infections. The applicant indicated that, in the event of resistance, the antibiotic cannot kill the bacteria without further extension of mechanisms to protect against this resistance, regardless of its site of action. The applicant stated that other aminoglycosides, in contrast to ZEMDRI™, do not have the modifications that allow them to withstand common mechanisms of resistance and, thereby, cannot bind to the target site of antibacterial action and are inactive. The applicant further explained that, specifically, the structural modifications in Plazomicin protects the antibiotic from most AMEs produced by bacteria that inactivates other aminoglycosides including gentamicin, tobramycin, and amikacin. The applicant stated that ZEMDRI™ inhibits 90 percent of the Enterobacteriaceae, including those resistant to one or more aminoglycoside antibiotics at a concentration of ≤4 mcg/mL (the proposed breakpoint for Plazomicin). The applicant also noted that ZEMDRI™ is already protected by at least four issued patents in the U.S., representing the general innovative and novel characteristics of the compound.

Another commenter noted that CMS' concerns focused on commonalities between Plazomicin and other antibiotics in the same general antibiotic class, and stated that the unique benefits of this medicine should not be ignored due to the substantial similarities to other medicines, given the recognized shortage of new antibiotics.

Response: We appreciate the applicant and the commenter's input regarding the technology. After consideration of the comments we received from the applicant regarding ZEMDRI™'s mechanism of action, we agree that ZEMDRI™'s ability to withstand antibiotic resistance is a critical component of its mechanism of action because it enables the antibiotic to effectively inhibit bacterial protein synthesis despite aminoglycoside resistance.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, we believe that potential cases representing patients who may be eligible for treatment involving Plazomicin would be assigned to the same MS–DRGs as cases representing patients who receive treatment for UTI or bacteremia.

Comment: The applicant agreed with CMS and stated that use of ZEMDRI™ will not change the MS–DRG assignment for potential cases representing eligible patients.

Response: We appreciate the applicant's input. We note that, the FDA approval for ZEMDRI™ was only for the treatment of patients 18 years of age or older who have been diagnosed with a cUTI, including pyelonephritis, and not for the other proposed indication of bacteremia/BSI. Therefore, we are only considering the MS–DRG assignment for potential cases representing eligible patients for the approved indication.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, we indicated in the proposed rule that the applicant asserted that Plazomicin is intended for use in the treatment of patients who have been diagnosed with cUTI, including pyelonephritis, and bloodstream infections, who have limited or no alternative treatment options. We stated that because the applicant anticipated that Plazomicin would be reserved for use in the treatment of patients who have limited or no alternative treatment options, the applicant believed that Plazomicin may be indicated to treat a new patient population for which no other technologies are available. However, we stated that it is possible that existing antimicrobials could also be used to treat those same bacteria Plazomicin is

intended to treat. Specifically, we indicated that the applicant was seeking FDA approval for use in the treatment of patients who have been diagnosed with cUTI, including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli* (including cases with concurrent bacteremia), *Klebsiella pneumoniae, Proteus* spp (including *P. mirabilis* and *P. vulgaris*), and *Enterobactercloacae,* and for use in the treatment of patients who have been diagnosed with BSIs caused by the following susceptible microorganisms: *Klebsiella pneumonia* and *Escherichia coli.* We stated that because the susceptible organisms for which Plazomicin was proposed to be indicated include nonresistant strains that existing antibiotics may effectively treat, we were concerned that Plazomicin may not treat a new patient population. Therefore, we invited public comments on whether Plazomicin treats a new type of disease or a new patient population. We also invited public comments on whether Plazomicin is substantially similar to any existing technologies and whether it meets the newness criterion. As noted previously, Plazomicin received approval with the trade name ZEMDRI™ for use in the treatment of patients 18 years of age or older with cUTI, including pyelonephritis.

Comment: The applicant disagreed with CMS' concern that ZEMDRI™ may not treat a new patient population, and stated that most existing antibiotics are *not* effective against MDR strains of bacteria, especially extended spectrum b-lactamase (ESBL)-producing Enterobacteriaceae and CRE. The applicant further stated that, because of the FDA's methodology for determining antibiotic labels and indication of bacteria, ZEMDRI™ is indicated for resistant and also nonresistant strains of bacteria, but the FDA label approving ZEMDRI™ for the treatment of diagnoses of cUTIs, including pyelonephritis, includes the following statement limiting the indication to a new patient population: As only limited clinical safety and efficacy data are available, reserve ZEMDRI™ for use in patients who have limited or no alternative treatment options. The applicant further indicated that ZEMDRI™ treats a new patient population because patients infected with pathogens that are resistant to other antibiotics include patients with infections due to CRE, which is considered ''untreatable'' or ''hard to treat'' by the CDC. The applicant emphasized that the CDC cautions that CRE infections are increasing and resistant to ''all or nearly all'' antibiotics. The applicant stated that ZEMDRI™ meets CMS' criterion for newness by providing, due to its mechanism to withstand resistance and its potent activity against CRE considered by the CDC as ''untreatable'', a new treatment choice for a patient population that may not have a viable option for a cure.

Several other commenters supported the approval of new technology add-on payments for Plazomicin, and believed that Plazomicin treats a new patient population with very limited treatment options. The commenters specifically indicated that there is a need for new antibiotics to combat the crisis of multi-drug resistant bacteria, especially CRE infections. The commenters stated that there at least 70,000 cases of CRE annually in the United States, and the number is expected to double in 4 years. The commenters also noted that the CDC estimates that CRE infections are associated with mortality rates of up to 50 percent and occur in the most medically vulnerable patient populations. The commenters further recommended CMS acknowledge that as these organisms are becoming resistant to last-line antibiotic drugs, clinicians frequently face infections with no realistic treatment options for patients. The commenters also indicated that the CDC identified CRE as one of the three urgent drug-resistant threats to human health, and issued warning that without urgent action more patients will be ''thrust back to a time before we had effective drugs.'' Another commenter also noted that the World Health Organization identified CRE as one of the three pathogens with the highest priority for research and development of novel antimicrobials, and stated that Plazomicin is new because it has demonstrated superiority over historic regimens for the management of invasive CRE infections.

The applicant and other commenters also stated that, even with newly approved antibiotic products with activity against some CRE, development of resistance has already been reported resulting in patients having no other available treatment options. The applicant and other commenters further stated that there is a need for more than one effective antibiotic active against CRE for many reasons, including various patient characteristics such as drug allergies, source location of bacteria, and the need for two active antibiotics given at the same time—a common practice for multi-drug or pan-drug resistance. Therefore, the commenters believed that multiple antibiotic treatment options are necessary and the existence of other effective antibiotics does not preclude a new antibiotic such as ZEMDRI™ from representing an improved benefit for a patient population with limited or no other available treatment options.

Another commenter stated that it, generally, supported CMS' concerns regarding the substantial similarity criteria for Plazomicin.

Response: We appreciate the applicant's and other commenters' input on whether ZEMDRI™ treats a new patient population. We understand that antibiotic resistance poses a significant threat to human health and that clinicians seek new antibiotics to treat multi-drug resistant infections, particularly those caused by CRE. Regarding our concern that ZEMDRI™ is indicated for resistant and also nonresistant strains of bacteria, we believe the FDA label approving ZEMDRI™ for the treatment of adult patients diagnosed with a cUTI, including pyelonephritis, addresses this concern by reserving ZEMDRI™ for use in patients who have limited or no alternative treatment options.

After consideration of the public comments we received, we believe that the mechanism of action for ZEMDRI™ is new, as discussed above. Therefore, we believe that ZEMDRI™ is not substantially similar to any existing technologies and consequently meets the newness criterion. We consider the beginning of the newness period to commence when ZEMDRI™ was approved by the FDA on June 25, 2018.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The analyses submitted by the applicant and presented in the proposed rule and below were for the indications of cUTI and BSI because the applicant was seeking FDA approval for both indications. However, as noted earlier, the technology was only approved for use in the treatment of cUTI, including pyelonephrits. Therefore, while we summarize both analyses below, as presented in the proposed rule, we note that only the cost information related to cUTI is evaluated to demonstrate that the applicant meets the cost criterion. We stated in the proposed rule that in order to identify the range of MS–DRGs that potential cases representing patients who have been diagnosed with the specific types of infections for which the technology had been proposed to be indicated for use in the treatment of and who may be potentially eligible for treatment involving Plazomicin may map to, the applicant identified all MS–DRGs in claims that

included cases representing patients who have been diagnosed with UTI or Septicemia. The applicant searched the FY 2016 MedPAR data for claims reporting 16 ICD–10–CM diagnosis codes for UTI and 45 ICD–10–CM diagnosis codes for Septicemia and identified a total of 2,046,275 cases assigned to 702 MS–DRGs. The applicant also performed a similar analysis based on 75 percent of identified claims, which spanned 43 MS–DRGs. MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC) accounted for roughly 25 percent of all cases in the first analysis of the 702 MS–DRGs identified, and almost 35 percent of the cases in the second analysis of the 43 MS–DRGs identified. Other MS–DRGs with a high volume of cases based on mapping the ICD–10–CM diagnosis codes, in order of number of discharges, were: MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours without MCC); MS–DRG 690 (Kidney and Urinary Tract Infections without MCC); MS–DRG 689 (Kidney and Urinary Tract Infections with MCC); MS–DRG 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC); and MS–DRG 683 (Renal Failure with CC).

For the cost analysis summarized in the proposed rule, the applicant calculated an average unstandardized case-weighted charge per case using 2,046,275 identified cases (100 percent of all cases) and using 1,533,449 identified cases (75 percent of all cases) of $69,414 and $63,126, respectively. The applicant removed 50 percent of the charges associated with other drugs (associated with revenue codes 025x, 026x, and 063x) from the MedPAR data because the applicant anticipated that the use of Plazomicin would reduce the charges associated with the use of some of the other drugs, noting that this was a conservative estimate because other drugs would still be required for these patients during their hospital stay. The applicant then standardized the charges and applied the 2-year inflation factor of 9.357 percent from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to inflate the charges from FY 2016 to FY 2018. No charges for Plazomicin were added in the analysis because the applicant explained that the anticipated price for Plazomicin had yet to be determined. Based on the FY 2018 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $56,996 in the first scenario utilizing 100 percent of all cases, and $55,363 in the second scenario utilizing 75 percent of all cases. The inflated average case-weighted standardized charge per case was $62,511 in the first scenario and $57,054 in the second analysis. Because the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant maintained that the technology met the cost criterion. The applicant noted that the case-weighted threshold amount is met before including the average per patient cost of the technology in both analyses. As such, the applicant anticipated that the inclusion of the cost of Plazomicin, at any price point, would further increase charges above the average case-weighted threshold amount.

The applicant also supplied additional cost analyses that we summarized in the proposed rule, directing attention at each of the two proposed indications individually; the cost analyses considered potential cases representing patients who have been diagnosed with cUTI who may be eligible for treatment involving Plazomicin separately from potential cases representing patients who have been diagnosed with BSI/Bacteremia who may be eligible for treatment involving Plazomicin, with the cost analysis for each considering 100 percent and 75 percent of identified cases using the FY 2016 MedPAR data and the FY 2018 GROUPER Version 36. For the additional cost analyses summarized in the proposed rule, the applicant reported that, for potential cases representing patients who have been diagnosed with Bacteremia and who may be eligible for treatment involving Plazomicin, 100 percent of identified cases spanned 539 MS–DRGs, with 75 percent of the cases mapping to the following 4 MS–DRGs: 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC), 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours without MCC), 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC), and 870 (Septicemia or Severe Sepsis with Mechanical Ventilation 96+ hours).

According to the applicant, for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin, 100 percent of identified cases mapped to 702 MS–DRGs, with 75 percent of the cases mapping to 56 MS–DRGs. Potential cases representing patients who have been diagnosed with cUTIs and who may be eligible for treatment involving Plazomicin assigned to MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC) accounted for approximately 18 percent of all of the cases assigned to any of the identified 56 MS–DRGs (75 percent of cases sensitivity analysis), followed by MS–DRG 690 (Kidney and Urinary Tract Infections without MCC), which comprised almost 13 percent of all of the cases assigned to any of the identified 56 MS–DRGs. Two other common MS–DRGs containing potential cases representing potential patients who may be eligible for treatment involving Plazomicin who have been diagnosed with the specific type of indicated infections for which the technology is intended to be used, using the applicant's analysis approach for UTI based on mapping the ICD–10–CM diagnosis codes were: MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours without MCC) and MS–DRG 689 (Kidney and Urinary Tract Infections with MCC).

According to the applicant's analyses submitted prior to the FDA approval, as stated in the proposed rule, for potential cases representing patients who have been diagnosed with BSI and who may be eligible for treatment involving Plazomicin, the applicant calculated the average unstandardized case-weighted charge per case using 1,013,597 identified cases (100 percent of all cases) and using 760,332 identified cases (75 percent of all cases) of $87,144 and $67,648, respectively. The applicant applied the same methodology as the combined analysis above. Based on the FY 2018 IPPS/LTCH PPS final rule Table 10 thresholds, the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI assigned to the MS–DRGs identified in the sensitivity analysis was $66,568 in the first scenario utilizing 100 percent of all cases, and $61,087 in the second scenario utilizing 75 percent of all cases. The inflated average case-weighted standardized charge per case was $77,004 in the first scenario and $60,758 in the second scenario; in the 100 percent of Bacteremia cases sensitivity analysis, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the sensitivity analysis by $10,436 before including costs of Plazomicin. In the 75 percent of all cases sensitivity analysis scenario, the final inflated case-weighted standardized charge per case did not

exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI assigned to the MS–DRGs identified in the sensitivity analysis, at $329 less than the average case-weighted threshold amount. In the proposed rule, we noted that because the applicant had not yet determined pricing for Plazomicin, however, it is possible that Plazomicin may also exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 75 percent cases sensitivity analysis.

For potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin, the applicant calculated the average unstandardized case-weighted charge per case using 100 percent of all cases and 75 percent of all cases of $59,908 and $48,907, respectively. The applicant applied the same methodology as the combined analysis above. Based on the FY 2018 IPPS/LTCH PPS final rule Table 10 thresholds, the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the first scenario utilizing 100 percent of all cases was $51,308, and $46,252 in the second scenario utilizing 75 percent of all cases. The inflated average case-weighted standardized charge per case was $53,868 in the first scenario and $45,185 in the second scenario. In the 100 percent of cUTI cases sensitivity analysis, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 100 percent of all cases sensitivity analysis by $2,560 before including costs of Plazomicin. In the 75 percent of all cases scenario, the final inflated case-weighted standardized charge per case did not exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 75 percent sensitivity analysis, at $1,067 less than the average case-weighted threshold amount. In the proposed rule, we noted that because the applicant had not yet determined pricing for Plazomicin, however, it is possible that Plazomicin may also exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 75 percent of all cases sensitivity analysis if charges for Plazomicin are more than $1,067. We invited public comments on whether Plazomicin meets the cost criterion.

We note that the FDA approval for ZEMDRI™ was only for the treatment of adults with complicated urinary tract infections cUTI, including pyelonephritis, and not for the other proposed indication of BSI. Therefore, we are only considering the cost analysis supplied by the applicant which considered potential cases representing patients who have been diagnosed with cUTI who may be eligible for treatment involving Plazomicin.

Comment: The applicant believed that ZEMDRI™ met the cost criterion, but supplied additional information that included the pricing for ZEMDRI™ to update the cost threshold analyses presented in the proposed rule. The applicant noted in supplemental information submitted to CMS the WAC of ZEMDRI™ (which is supplied as 500mg/10ml (50mg/mL) solution in a single dose vial) is $330 per vial. The applicant indicated that the recommended dosage for ZEMDRI™ is 15mg/kg, every 24 hours administered as an IV infusion based on patient weight. The applicant stated that, because each vial contains 1,000 mg of ZEMDRI™, a single vial provides the complete recommended dose for a single patient who weighs 100 kg or less. The applicant predicted that patients will typically require 3 vials for the course of treatment with ZEMDRI™ per day, and the average duration of ZEMDRI™ therapy is 5.5 days. Therefore, the applicant stated that the total cost of ZEMDRI™ per patient is $5,445. The applicant utilized the national CCR for ''Drugs'' as listed in the FY 2018 IPPS/LTCH PPS final rule to estimate hospital charges by dividing the total cost per patient by the CCR ($5,445/0.194).

The applicant also updated the cost threshold analysis including hospital charges for ZEMDRI™. The applicant's updated analysis applied only to those ICD–10–CM diagnosis codes used to identify cases representing patients who have been diagnosed with a cUTI and who may be eligible for treatment involving ZEMDRI™. The applicant included two scenarios considering 100 percent of identified cases mapping to 702 MS–DRGs and 75 percent of identified cases mapping to 56 MS–DRGs using the FY 2016 MedPAR data and the FY 2018 GROUPER Version 36. The applicant stated that, as discussed in the FY 2019 IPPS/LTCH PPS proposed rule, potential cases representing patients who have been diagnosed with cUTIs and who may be eligible for treatment involving Plazomicin assigned to MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC) accounted for approximately 18 percent of all of the cases assigned to any of the identified 56 MS–DRGs (75 percent of cases sensitivity analysis), followed by MS–DRG 690 (Kidney and Urinary Tract Infections without MCC), which comprised almost 13 percent of all of the cases assigned to any of the identified 56 MS–DRGs. The applicant further stated that the two other common MS–DRGs containing potential cases representing potential patients who may be eligible for treatment involving Plazomicin who have been diagnosed with the specific type of indicated infections for which the technology is intended to be used, using the applicant's analysis approach for UTI based on mapping the ICD–10–CM diagnosis codes were: MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours without MCC) and MS–DRG 689 (Kidney and Urinary Tract Infections with MCC).

Consistent with the analysis submitted for the proposed rule, the applicant calculated the average unstandardized case-weighted charge per case using 100 percent of all cases and 75 percent of all cases of $59,908 and $48,907, respectively. Consistent with the analysis submitted for the proposed rule, based on the FY 2018 IPPS/LTCH PPS final rule Table 10 thresholds, the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with a cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the first scenario utilizing 100 percent of all cases was $51,308, and $46,252 in the second scenario utilizing 75 percent of all cases. The applicant utilized the same methodology described in the FY 2019 IPPS/LTCH PPS proposed rule with the exception of adding charges for Plazomicin. The applicant removed 50 percent of the charges associated with other drugs (associated with revenue

codes 025x, 026x, and 063x), then standardized the charges and applied the 2-year inflation factor of 9.357 percent from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to inflate the charges from FY 2016 to FY 2018. After adding the charges for Plazomicin, the inflated average case-weighted standardized charge per case was $81,935 in the first scenario and $73,252 in the second scenario. The applicant indicated that, in the 100 percent of cUTI cases sensitivity analysis, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with a cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 100 percent of all cases sensitivity analysis by $30,627 after including the cost of Plazomicin. The applicant further stated that, in the 75 percent of all cases scenario, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with a cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 75 percent sensitivity analysis by $27,000 after including the cost of Plazomicin. In both scenarios, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount and, therefore, the applicant believed that ZEMDRI™ continued to meet the cost criterion.

Response: We appreciate the additional information received from the applicant regarding the cost of ZEMDRI™ and whether the technology meets the cost criterion. After consideration of the public comments we received, we agree that ZEMDRI™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Plazomicin is a next generation aminoglycoside that offers a treatment option for a patient population who have limited or no alternative treatment options. Patients who have been diagnosed with BSI or cUTI caused by MDR Enterobacteria, particularly CRE, are difficult to treat because carbapenem resistance is often accompanied by resistance to additional antibiotic classes. For example, CRE may be extensively drug resistant (XDR) or even pandrug resistant (PDR). CRE are resistant to most antibiotics, and sometimes the only treatment option available to health care providers is a last-line antibiotic (such as colistin and tigecycline) with higher toxicity. According to the applicant, Plazomicin would give the clinician an alternative treatment option for patients who have been diagnosed with MDR bacteria like CRE because it has demonstrated activity against clinical isolates that possess a broad range of resistance mechanisms, including ESBLs, carbapenemases, and aminoglycoside modifying enzymes that limit the utility of different classes of antibiotics. Plazomicin also can be used to treat patients who have been diagnosed with BSI caused by resistant pathogens, such as ESBL-producing Enterobacteriaceae, CRE, and aminoglycoside-resistant Enterobacteriaceae. The applicant maintained that Plazomicin is a substantial clinical improvement because it offers a treatment option for patients who have been diagnosed with serious bacterial infections that are resistant to current antibiotics. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20322), we noted that Plazomicin is not indicated exclusively for resistant bacteria, but rather for certain susceptible organisms of gram-negative bacteria, including resistant and nonresistant strains for which existing antibiotics may be effective. We stated we were concerned that the applicant focused solely on Plazomicin's activity for resistant bacteria and did not supply information demonstrating substantial clinical improvement in treating nonresistant strains in the bacteria families for which Plazomicin is indicated. We note that because the FDA approval was for the cUTI indication only, and not the BSI proposed indication, we are only summarizing comments pertaining to the cUTI indication and evaluating whether ZEMDRI™ meets the substantial clinical improvement criterion for use in the treatment of cUTI.

Comment: The applicant stated in response to CMS' concerns that the EPIC study evaluated the efficacy of ZEMDRI™ against both susceptible and resistant organisms (ESBLs) in cUTIs against a highly potent antibiotic, meropenem. The applicant noted that, although in this study approximately 25 percent of the isolates were beta-lactamase producers (ESBL), which are resistant to commonly used antibiotics such as penicillins and cephalosporins, the remaining 75 percent were susceptible to beta-lactam antibiotics (non-ESBL). Therefore, the applicant indicated that, while ZEMDRI™'s substantial clinical benefit was particularly differentiated in patients with infections due to MDR pathogens where limited or no alternative therapies are available, ZEMDRI™ also demonstrated a clinical improvement in patients diagnosed with a cUTI, including acute pyelonephritis, against pathogens that are susceptible to other antibiotics. The applicant emphasized that the approved FDA label fully addresses this concern because it restricts the use of ZEMDRI™ to patients diagnosed with a cUTI, including pyelonephritis, who have limited or no alternative treatment options. The applicant stated that the FDA labeling ensures that ZEMDRI™ is used exclusively to treat patients diagnosed with infections due to resistant bacteria and will result in ZEMDRI™'s use in the treatment of patients where the benefit outweighs the risk, which includes patients with infections due to resistant pathogens such as ESBL-producing Enterobacteriaceae, non-susceptible to other currently marketed aminoglycosides, and CRE when other antibiotics cannot be used.

Response: We agree with the applicant that the FDA label addresses this concern because it restricts the use of ZEMDRI™ to patients diagnosed with a cUTI, including pyelonephritis, who have limited or no alternative treatment options.

The applicant stated that Plazomicin also meets the substantial clinical improvement criterion because it significantly improves clinical outcomes for a patient population compared to currently available treatment options. Specifically, the applicant asserted that Plazomicin has: (1) A mortality benefit and improved safety profile in treating patients who have been diagnosed with BSI due to CRE; and (2) statistically better outcomes at test-of-cure in patients who have been diagnosed with cUTI, including higher eradication rates for ESBL-producing pathogens, and lower rate of subsequent clinical relapses. The applicant conducted two Phase III studies, CARE and EPIC. The CARE trial compared Plazomicin to colistin, a last-line antibiotic that is a standard of care agent for patients who have been diagnosed with BSI when caused by CRE. The EPIC trial compared Plazomicin to meropenem for the treatment of patients who have been diagnosed with cUTI/acute pyelonephritis.

The CARE clinical trial was a randomized, open label, multi-center Phase III study comparing the efficacy of Plazomicin against colistin in the treatment of patients who have been diagnosed with BSIs or hospital-acquired bacterial pneumonia (HABP)/ventilator-acquired bacterial pneumonia

(VABP) due to CRE. Due to the small number of enrolled patients with HAPB/VABP, however, results were only analyzed for patients who had been diagnosed with BSI due to CRE. The primary endpoint was day 28 all-cause mortality or significant disease complications. Patients were randomized to receive 7 to 14 days of IV Plazomicin or colistin, along with an adjunctive therapy of meropenem or tigecycline. All-cause mortality and significant disease complications were consistent regardless of adjunctive antibiotics received, suggesting that the difference in outcomes was driven by Plazomicin and colistin, with little impact from meropenem and tigecycline. Follow-up was done at test-of-cure (TOC; 7 days after last dose of IV study drug), end of study (EOS; day 28), and long-term follow-up (LFU; day 60). Safety analysis included all patients; microbiological modified intent-to-treat (mMITT) analysis included 17/18 Plazomicin and 20/21 colisitin patients. Baseline characteristics like age, gender, APACHE II score, infection type, baseline pathogens, creatinine clearance, and adjunctive therapy with either meropenem or tigecycline were comparable in the Plazomicin and colistin groups.

According to the applicant, the following results demonstrate a reduced mortality benefit in the patients who had been diagnosed with BSI subset. All-cause mortality at day 28 in the Plazomicin group was more than 5 times less than in the colistin group and all-cause mortality or significant complications at day 28 was reduced by 39 percent in the Plazomicin group compared to the colistin group. There was a large sustained 60-day survival benefit in the patients who had been diagnosed with BSI subset, with survival approximately 70 percent in the Plazomicin group compared to 40 percent in the colistin group. Additionally, according to the applicant, faster median time to clearance of CRE bacteremia of 1.5 versus 6 days for Plazomicin versus colistin and higher rate of documented clearance by day 5 (86 percent versus 46 percent) supported the reduced mortality benefit due to faster and more sustained clearance of bacteremia and also demonstrated clinical improvement in terms of more rapid beneficial resolution of the disease.

The applicant maintained that Plazomicin also represents a substantial clinical improvement in improved safety outcomes. Patients treated with Plazomicin had a lower incidence of renal events (10 percent versus 41.7 percent when compared to colistin), fewer Treatment Emergent Adverse Events (TEAEs), specifically blood creatinine increases and acute kidney injury, and approximately 30 percent fewer serious adverse events were in the Plazomicin group. According to the applicant, other substantial clinical improvements demonstrated by the CARE study for use of Plazomicin in patients who had been diagnosed with BSI included lower rate of superinfections or new infections, occurring in half as many patients treated with Plazomicin versus colistin (28.6 percent versus 66.7 percent).

According to the applicant, the CARE study demonstrates decreased all-cause mortality and significantly reduced disease complications at day 28 (EOS) and day 60 for patients who had been diagnosed with BSI, in addition to a superior safety profile to colistin. However, the applicant stated that, with the achieved enrollment, this study was not powered to support formal hypothesis testing and p-values and 90 percent confidence intervals are provided for descriptive purposes. The total number of patients who had been diagnosed with BSI was 29, with 14 receiving Plazomicin and 15 receiving colistin. While we understand the difficulty enrolling a large number of patients who have been diagnosed with BSI caused by CRE due to severity of the illness and the need for administering treatment promptly, we stated in the proposed rule we were concerned that results indicating reduced mortality and treatment advantages over existing standard of care for patients who have been diagnosed with BSI due to CRE are not statistically significant due to the small sample size. Therefore, we stated that we were concerned that the results from the CARE study cannot be used to support substantial clinical improvement.

Comment: A commenter agreed with CMS' assessment that results of the CARE study are not statistically significant due to the small sample size of 29 patients.

Response: We appreciate the commenter's input. However, we note that, we are no longer evaluating whether ZEMDRI™ meets the substantial clinical improvement criterion for use in the treatment of patients diagnosed with BSI because the FDA did not approve ZEMDRI™ for that proposed indication.

The EPIC clinical trial was a randomized, multi-center, multi-national, double-blind study evaluating the efficacy and safety of Plazomicin compared with meropenem in the treatment of patients who have been diagnosed with cUTI based on composite cure endpoint (achieving both microbiological eradication and clinical cure) in the microbiological modified intent-to-treat (mMITT) population. Patients received between 4 to 7 days of IV therapy, followed by optional oral therapy like levofloxacin (or any other approved oral therapy) as step down therapy for a total of 7 to 10 days of therapy. Test-of-cure (TOC) was done 15 to 19 days and late follow-up (LFU) 24 to 32 days after the first dose of IV therapy. Six hundred nine patients fulfilled inclusion criteria, and were randomized to receive either Plazomicin or meropenem, with 306 patients receiving Plazomicin and 303 patients receiving meropenem. Safety analysis included 303 (99 percent) Plazomicin patients and 301 (99.3 percent) meropenem patients. mMITT analysis included 191 (62.4 percent) Plazomicin patients and 197 (65 percent) meropenem patients; exclusion from mMITT analysis was due to lack of study-qualifying uropathogen, which were pathogens susceptible to both Plazomicin and meropenem. In the mMITT population, both groups were comparable in terms of gender, age, percentage of patients who had been diagnosed with cUTI/acute pyelonephritis (AP)/urosepsis/bacteremia/moderate renal impairment at baseline.

According to the applicant, Plazomicin successfully achieved the primary efficacy endpoint of composite cure (combined microbiological eradication and clinical cure). At the TOC visit, 81.7 percent of Plazomicin patients versus 70.1 percent of meropenem patients achieved composite cure; this was statistically significant with a 95 percent confidence interval. Plazomicin also demonstrated higher eradication rates for key resistant pathogens than meropenem at both TOC (89.4 percent versus 75.5 percent) and LFU (77 percent versus 60.4 percent), suggesting that the Plazomicin treatment benefit observed at TOC was sustained. Specifically, Plazomicin demonstrated higher eradication rates, defined as baseline uropathogen reduced to less than 104, against the most common gram-negative uropathogens, including ESBL producing (82.4 percent Plazomicin versus 75.0 percent meropenem) and aminoglycoside resistant (78.8 percent Plazomicin versus 68.6 percent meropenem) pathogens. This was statistically significant, although of note, as total numbers of Enterobacteriaceae exceeded population of mMITT (191 Plazomicin, 197 meropenem) this presumably

included patients who were otherwise excluded from the mMITT population.

According to the applicant, importantly, higher microbiological eradication rates at the TOC and LFU visits were associated with a lower rate of clinical relapse at LFU for Plazomicin treated patients (3 versus 14, or 1.8 percent Plazomicin versus 7.9 percent meropenem), with majority of the meropenem failures having had asymptomatic bacteriuria; that is, positive urine cultures without clinical symptoms, at TOC (21.1 percent), suggesting that the higher microbiological eradication rate at the TOC visit in Plazomicin-treated patients decreased the risk of subsequent clinical relapse. Plazomicin decreased recurrent infection by four-fold compared to meropenem, suggesting improved patient outcomes, such as reduced need for additional therapy and re-hospitalization for patients who have been diagnosed with cUTI. The safety profile of Plazomicin compared to meropenem was similar. The applicant noted that higher bacteria eradication results for Plazomicin were not due to meropenem resistance, as only patients with isolates susceptible to both drugs were included in the study. According to the applicant, the EPIC clinical trial results demonstrate clear differentiation of Plazomicin from meropenem, an agent considered by some as a gold-standard for treatment of patients who have been diagnosed with cUTI in cases due to resistant pathogens.

While the EPIC clinical trial was a non-inferiority study, the applicant contended that statistically significant improved outcomes and lower clinical relapse rates for patients treated with Plazomicin demonstrate that Plazomicin meets the substantial clinical improvement criterion for the cUTI indication. Specifically, according to the applicant, the efficacy results for Plazomicin combined with a generally favorable safety profile provide a compelling benefit-risk profile for patients who have been diagnosed with cUTI, and particularly those with infections due to resistant pathogens. Most patients enrolled in the EPIC clinical trial were from Eastern Europe. We expressed in the proposed rule that it is unclear how generalizable these results would be to patients in the United States as the susceptibilities of bacteria vary greatly by location. The applicant maintained that this is consistent with prior studies and is unlikely to have affected the results of the study because the pharmacokinetics of Plazomicin and meropenem are not expected to be affected by race or ethnicity. However, bacterial resistance can vary regionally and, in the proposed rule, we expressed that we are interested in how this data can be extrapolated to a majority of the U.S. population.

Comment: A commenter agreed with CMS' concern that results from the EPIC clinical trial are predominately based on patients enrolled in trials in Eastern Europe, and it is not clear how generalizable their results would be to patients in the United States. The applicant stated that the representation of the patients enrolled in the EPIC trial was similar to other recent cUTI studies for drugs approved in the U.S., and the spectrum of diagnoses and bacteriology in these studies were representative of the epidemiology and standard-of-care used in the United States. The applicant further noted that the primary analysis excluded pathogens resistant to either study drugs (ZEMDRI™ or meropenem) and, therefore, avoided imbalances due to geographic differences in resistance. The applicant also provided additional data to demonstrate that the results from the EPIC trial are generalizable to patients treated in the U.S. because the susceptibilities of bacteria to ZEMDRI™ do not vary between patients in the U.S. versus patients in Eastern Europe, and the pharmacokinetic profile of ZEMDRI™ or meropenem are not affected by race because ZEMDRI™ and meropenem are cleared almost entirely by the kidneys rather than metabolized. The applicant further indicated that, in the Phase II study of ZEMDRI™ in patients diagnosed with a cUTI (ACHN–490–009), a larger number of patients from the U.S. were enrolled and outcomes were similar to those observed in the EPIC trial.

Response: We appreciate the commenter's input and the applicant's additional explanation demonstrating the results from the EPIC trial.

We also stated that it is also unknown how quickly resistance to Plazomicin might develop. Additionally, we stated that the microbiological breakdown of the bacteria is unknown without the full published results, and patients outside of the mMITT population were included when the applicant reported the statistically superior microbiological eradication rates of Enterobacteriaceae at TOC. In the FY 2019 IPPS/LTCH PPS proposed rule, we stated we were concerned whether there is still statistical superiority of Plazomicin in the intended bacterial targets in the mMITT.

Comment: Regarding our concern about how quickly resistance to ZEMDRI™ might develop, the applicant stated that ZEMDRI™'s limited use indication, the short duration of therapy, and oversight by the antimicrobial stewardship team will prevent development of resistance, which is often associated with widespread use of antibiotics. Specifically, the applicant indicated that, unlike broad spectrum antibacterial drugs, the FDA restrictions of ZEMDRI™'s use helps to reduce development of resistance and is consistent with antimicrobial stewardship programs recommended by the CDC. The applicant also explained that the clinical dose of 15 mg/kg administered daily was selected to reduce the risk of emergence of resistance to ZEMDRI™. The applicant further stated that, because Plazomicin is generally not inactivated by common AMEs, the primary mechanism of resistance to Plazomicin in Enterobacteriaceae is target-site modification in isolates containing 16S–RMTases, which are rarely encountered in the U.S. and do not appear to be increasing in prevalence despite decades of clinical use of aminoglycoside class; 16S–RMTases were found in only 0.08 percent or 5 of approximately 6,500 U.S. Enterobacteriaceae isolates collected during a 2014 through 2016 surveillance study.

The applicant also provided data presenting the breakdown of the uropathogens identified from baseline urine cultures in the mMITT population in the EPIC study, and clarified that statistically superior microbiological eradication rates observed with ZEMDRI™ compared to meropenem at TOC (Table 2) were achieved in the same mMITT population used for the primary endpoint.

Response: We appreciate the additional information received from the applicant explaining why ZEMDRI™ has a low potential for development of resistance and demonstrating ZEMDRI™'s statistical superiority in the intended bacterial targets in the mMITT population.

Finally, because both Plazomicin and meropenem were also utilized in conjunction with levofloxacin, we stated in the proposed rule that it is unclear to us whether combined antibiotic therapy will continue to be required in clinical practice, and how levofloxacin activity or resistance might affect the clinical outcome in both patient groups.

Comment: The applicant clarified that levofloxacin was provided only as an optional oral step-down therapy after pre-specified criteria in the protocol were met, consistent with recent trials of other antibiotics that have been evaluated for diagnoses of cUTIs. The

applicant explained that optional oral step-down therapy is commonly used in clinical trials of cUTIs to increase study participation by allowing patients to be discharged from the hospital following favorable response to IV therapy, rather than staying in the hospital for 10 days to receive the IV study drug. With regard to clinical practice, the applicant noted that the FDA label does not require patients to receive oral therapy following administration of ZEMDRI™, and it would be the decision of the treating physician if a patient may be switched to an oral agent following IV infusion of ZEMDRI™ and the physician would determine the appropriate oral therapy, if applicable. The applicant indicated that levofloxacin did not influence the outcome of the study because it was used for a similarly short course in both the ZEMDRI™ and meropenem group, and the TOC visit outcomes continued to favor ZEMDRI™ in both patients who received the IV study drug only and those who received the IV study drug followed by oral therapy.

Response: We appreciate the applicant's clarification regarding levoflaxin's use in clinical practice, and agree that the use of levoflaxin did not negate the study results favoring ZEMDRI™ because it was used similarly in both groups and the TOC visit demonstrated improved outcomes for patients receiving only ZEMDRI™, as well as patients receiving ZEMDRI™ followed by oral antibiotic therapy.

We invited public comments on whether Plazomicin meets the substantial clinical improvement criterion for patients who have been diagnosed with BSI and cUTI, including with respect to whether Plazomicin constitutes a substantial clinical improvement for the treatment of patients who have been diagnosed with BSI who have limited or no alternative treatment options, and whether statistically better outcomes at test-of-cure visit, including higher eradication rates for ESBL-producing pathogens, and lower rate of subsequent clinical relapses constitute a substantial clinical improvement for patients who have been diagnosed with cUTI.

Comment: The applicant and other commenters believed that ZEMDRI™ represents a substantial clinical improvement for patients who have been diagnosed with a cUTI. The commenters stated that ZEMDRI™ offers a substantial clinical improvement over existing aminoglycosides, both in having a higher degree of susceptibility against CRE and enhanced potency, which potentially allows safer exposures of the drug. Another commenter described some of the complications and limitations of existing therapies, including colistin, polymyxin, tigecycline, ceftolozane/tazobactam, and ceftazidime/avibactam, and the limited effectiveness of antibiotics like amikacin, and noted that ZEMDRI™ provides an exciting option for transitions of care because it can be utilized in the outpatient setting and administered once-daily by IV infusion. Another commenter, generally, supported granting approval of new technology add-on payments for ZEMDRI™ and stated that this next-generation aminoglycoside is a substantial innovation and advancement in the treatment of serious bacterial infections due to MDR enterobacteriaceae that commonly occur in the hospital setting.

Response: We appreciate the applicant's and other commenters' input on whether ZEMDRI™ offers a substantial clinical improvement over current therapies for patients who have been diagnosed with a cUTI. We believe that ZEMDRI™ offers a substantial clinical improvement for patients who have limited or no alternative treatment options because it is a new antibiotic that offers a treatment option for a patient population unresponsive to currently available treatments. After consideration of the public comments we received, we have determined that ZEMDRI™ meets all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for ZEMDRI™ for FY 2019. Cases involving ZEMDRI™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033G4 and XW043G4.

In its application, the applicant estimated that the average Medicare beneficiary would require a dosage of 15 mg/kg administered as an IV infusion as a single dose. According to the applicant, the WAC for one dose is $330, and patients will typically require 3 vials for the course of treatment with ZEMDRI™ per day for an average duration of 5.5 days. Therefore, the total cost of ZEMDRI™ per patient is $5,445. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of ZEMDRI™ is $2,722.50 for FY 2019. In accordance with the current ZEMDRI™ label, CMS expects that ZEMDRI™ will be prescribed for adult patients diagnosed with cUTIs, including pyelonephritis, who have limited or no alternative treatment options.

g. GIAPREZA™

The La Jolla Pharmaceutical Company submitted an application for new technology add-on payments for GIAPREZA™ for FY 2019. GIAPREZA™, a synthetic human angiotensin II, is administered through intravenous infusion to raise blood pressure in adult patients who have been diagnosed with septic or other distributive shock.

The applicant stated that shock is a life-threatening critical condition characterized by the inability to maintain blood flow to vital tissues due to dangerously low blood pressure (hypotension). Shock can result in organ failure and imminent death, such that mortality is measured in hours and days rather than months or years. Standard therapy for shock currently uses fluid and vasopressors to raise the mean arterial pressure (MAP). The two classes of standard of care (SOC) vasopressors are catecholamines and vasopressins. Patients do not always respond to existing standard of care therapies. Therefore, a diagnosis of shock can be a difficult and costly condition to treat. According to the applicant, 35 percent of patients who are diagnosed with shock fail to respond to standard of care treatment options using catecholamines and go on to second-line treatment, which is typically vasopressin. Eighty percent of patients on vasopressin fail to respond and have no other alternative treatment options. The applicant estimated that CMS covered charges to treat patients who are diagnosed with vasodilatory shock who fail to respond to standard of care therapy are approximately 2 to 3 times greater than the costs of other conditions, such as acute myocardial infarction, heart failure, and pneumonia. According to the applicant, one-third of patients in the intensive care unit are affected by vasodilatory shock, with 745,000 patients who have been diagnosed with shock being treated annually, of whom approximately 80 percent are septic.

With respect to the newness criterion, according to the applicant, the expanded access program (EAP), or FDA authorization for the ''compassionate use'' of an investigational drug outside of a clinical trial, was initiated August 8, 2017. GIAPREZA™ was granted Priority Review status and received FDA approval on December 21, 2017, for the use in the treatment of adults who have been diagnosed with septic or other distributive shock as an intravenous infusion to increase blood pressure. The

applicant submitted a request for approval for a unique ICD–10–PCS code for the administration of GIAPREZA™ beginning in FY 2019 and was granted approval for the following procedure codes effective October 1, 2018: XW033H4 (Introduction of synthetic human angiotensin II into peripheral vein, percutaneous approach, new technology, group 4) and XW043H4 (Introduction of synthetic human angiotensin II into central vein, percutaneous approach, new technology group 4).

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, GIAPREZA™ is the first synthetic formulation of human angiotensin II, a naturally occurring peptide hormone in the human body. Angiotensin II is one of the major bioactive components of the renin-angiotensin-aldosterone system (RAAS), which serves as one of the body's central regulators of blood pressure. Angiotensin II increases blood pressure through vasoconstriction, increased aldosterone release, and renal control of fluid and electrolyte balance. Current therapies for the treatment of patients who have been diagnosed with shock do not leverage the RAAS. The applicant asserted that GIAPREZA™ is a novel treatment with a unique mechanism of action relative to SOC treatments for patients who have been diagnosed with shock, which is adequate fluid resuscitation and vasopressors. Specifically, the two classes of SOC vasopressors are catecholamines like Norepinephrine, epinephrine, dopamine, and phenylephrine IV solutions, and vasopressins like Vasostrict® and vasopressin-sodium chloride IV solutions. Catecholamines leverage the sympathetic nervous system and vasopressin leverages the arginine-vasopressin system to regulate blood pressure. However, the third system that works to regulate blood pressure, the RAAS, is not currently leveraged by any available therapies to raise mean arterial pressure in the treatment of patients who have been diagnosed with shock. The applicant maintained that GIAPREZA™ is the first synthetic human angiotensin II approved by the FDA and the only FDA-approved vasopressor that leverages the RAAS and, therefore, GIAPREZA™ utilizes a different mechanism of action than currently available treatment options.

The applicant explained that GIAPREZA™ leverages the RAAS, which is a body system not used by existing vasopressors to raise blood pressure through inducing vasoconstriction. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20325), we stated we were concerned that GIAPREZA™'s general mechanism of action, increasing blood pressure by inducing vasoconstriction through binding to certain G-protein receptors to stimulate smooth muscle contraction, may be similar to that of norepinephrine, albeit leveraging a different body system. We invited public comments on whether GIAPREZA™ uses a different mechanism of action to achieve a therapeutic outcome with respect to currently available treatment options, including comments or additional information regarding whether the mechanism of action used by GIAPREZA™ is different from that of other treatment methods of stimulating vasoconstriction.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, we stated in the proposed rule that we believe that potential cases representing patients who may be eligible for treatment involving GIAPREZA™ would be assigned to the same MS–DRGs as cases representing patients who receive SOC treatment for a diagnosis of shock. As explained below in the discussion of the cost criterion, the applicant believed that potential cases representing patients who may be eligible for treatment involving GIAPREZA™ would be assigned to MS–DRGs that contain cases representing patients who have failed to respond to administration of fluid and vasopressor therapies.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, once patients have failed treatment using catecholamines, treatment options for patients who have been diagnosed with severe septic or other distributive shock are limited. According to the applicant, agents that were previously available are each associated with their own adverse events (AEs). The applicant noted that primary options that have been investigated include vasopressin, corticosteroids, methylene blue, and blood purification techniques. Of these options, the applicant stated that only vasopressin has a recommendation as add on vasopressor therapy in current treatment guidelines, but the recommendations are listed as weak with moderate quality of evidence. According to the applicant, there is uncertainty regarding vasopressin's effect on mortality due to mixed clinical trial results, and higher doses of vasopressin have been associated with cardiac, digital, and splanchnic ischemia. Therefore, the applicant asserted that there is a significant unmet medical need for treatments for patients who have been diagnosed with septic or distributive shock who remain hypotensive, despite adequate fluid and vasopressor therapy and for medications that can provide catecholamine-sparing effects.

The applicant also noted that there is currently no standard of care for addressing the clinical state of septic or other distributive shock experienced by patients who fail to respond to fluid and available vasopressor therapy. Additionally, according to the applicant, no clinical evidence or consensus for treatments is available.

Based on the applicant's statements as summarized above, we stated in the proposed rule that it appears that the applicant is asserting that GIAPREZA™ provides a new therapeutic treatment option for critically-ill patients who have been diagnosed with shock who have limited options and worsening prognosis. However, we further stated we were concerned that GIAPREZA™ may not offer a treatment option to a new patient population, specifically because the FDA approval for GIAPREZA™ does not reserve the use of GIAPREZA™ only as a last-line drug or adjunctive therapy for a subset of the patient population who have been diagnosed with shock who have failed to respond to standard of care treatment options. According to the FDA-approved labeling, GIAPREZA™ is a vasoconstrictor to increase blood pressure in adult patients who have been diagnosed with septic or other distributive shock. Patients who have been diagnosed with septic or other distributive shock are not a new patient population. Therefore, we stated that it appears that GIAPREZA™ is used to treat the same or similar type of disease (a diagnosis of shock) and a similar patient population receiving SOC therapy for the treatment of shock.

In the proposed rule, we invited public comments on whether GIAPREZA™ meets the substantial similarity criteria and the newness criterion.

Comment: The applicant indicated that GIAPREZA™ is not substantially similar to existing treatment options

because it is the sole member of a new class of vasopressor peptide, and the only one that acts to leverage the renin-angiotensin-aldosterone (RAAS) system. The applicant stated that GIAPREZA™'s mechanism of action is unique because GIAPREZA™ operates in a fundamentally different manner than norepinephrine, in addition to leveraging a different body system. The applicant noted, specifically, that GIAPREZA™ causes vasoconstriction of the smooth muscles and stimulates the release of aldosterone from the adrenal cortex to promote sodium retention by the kidneys, both of which lead to increased blood pressure. The applicant explained that, although catecholamines, vasopressin, and angiotensin II all engage G-coupled protein receptors for their function, they engage entirely different G-coupled receptors subtypes and engage different receptor targets. The applicant further described the biochemical pathways unique to angiotensin, and recommended that CMS consider the feedback mechanisms present in the classical RAAS,[123] which enable GIAPREZA™ to be more effective in the treatment of diagnosis of shock than standard-of-care vasopressors. The applicant provided literature and specific citations that suggested ACE activity is diminished in conditions associated with vasodilatory shock, which would result in a state of relative angiotensin II deficiency, that is, excess angiotensin I, similar to a state induced by ACE inhibitor treatment in patients who have been diagnosed with essential hypertension.[124] [125] According to the applicant, in vasodilatory shock syndromes, the addition of exogenous angiotensin II attenuates production of angiotensin I by suppressing release of renin at the juxtaglomerular apparatus, and potentially reduces angiotensin (1–7) levels, resulting in a more normalized angiotensin I to/angiotensin II ratio and a reduced endogenous vasodilator drive. In contrast, the applicant asserted that norepinephrine is a catecholamine that functions as a peripheral vasoconstrictor by acting on alpha-adrenergic receptors and an inotropic stimulator of the heart and a dilator of coronary arteries, a result of its activity at the beta-adrenergic receptors. The applicant stated that, GIAPREZA™, however, has a non-adrenergic mechanism of action that contributes to its catecholamine-sparing effect. The applicant indicated that GIAPREZA™ can be administered in combination with norepinephrine because GIAPREZA™ affects vasoconstriction not by augmentation of norepinephrine, but by way of an entirely novel mechanism.

One commenter pointed out that vasoconstriction is a very general and fundamental physiologic mechanism by which blood pressure is regulated, such that it would occur with any regimen for treating patients who have been diagnosed with shock.

Other commenters stated that current standard-of-care treatment options only target two of the three major biological systems regulating MAP, which makes GIAPREZA™ the first and only FDA-approved synthetic human angiotensin II treatment option that activates the RAAS to increase MAP. The commenters believed that GIAPREZA ™'s unique mechanism of action supports a multi-modal approach to the treatment of patients who have been diagnosed with shock that mimics the body's natural response to hypotension, and offers physicians a critical new tool for saving lives.

With respect to the second criterion, the applicant indicated that there are inherent difficulties in capturing specific patient types for a condition such as a diagnosis of shock, and explained that the current structure of the MS–DRG payment system does not yet have the refined elements necessary to identify those patients likely to respond to treatment involving GIAPREZA ™. The applicant emphasized that the MS–DRGs for Septicemia or Severe Sepsis with or without Mechanical Ventilation >96 Hours are MS–DRGs that are noted frequently as being in the top 10 highest volume Medicare MS–DRGs reported overall each year. The applicant believed that medical DRGs that are driven by complications have an inherently more challenging time demonstrating uniqueness as a function of Medicare's MS–DRG GROUPER approach than the medical device population. However, the applicant stated that as the ICD–10–CM/PCS system continues to evolve and new MS–DRGs are added to capture new technologies, there will be additional opportunities to better highlight certain products' use, like GIAPREZA™, in key populations.

Regarding the third criterion, the applicant contended that although the FDA approval for GIAPREZA™ is not reserved exclusively for patients diagnosed with shock who have failed to respond to standard-of-care treatment options, GIAPREZA™ still treats a new patient population that is a significant subset of the larger patient population for which GIAPREZA™ has received FDA approval. Specifically, the applicant emphasized that, of approximately 1.12 million hypotensive patients, greater than 50 percent fail the standard-of-care treatment practice and, therefore, have no other available treatment options. The applicant believed that GIAPREZA™ provides a new treatment option for Medicare beneficiaries that can be started immediately and can benefit the patient within only approximately 5 minutes.

Other commenters similarly stated that GIAPREZA™ fills an unmet need for new treatment options for patients who have been diagnosed with shock, considering that more than 50 percent of patients who have been diagnosed with distributive shock fail to meet MAP goals using the standard-of-care treatment options. The commenters emphasized that mortality from shock remains high, especially in patients who have been diagnosed with refractory shock, primarily due to progressive hypotension and resulting organ failure and limited treatment options. The commenters believed that GIAPREZA™ offers a breakthrough treatment option that promises to save lives by providing an alternative treatment option for a subset of the shock patient population for whom there was previously no other treatment options available.

In addition to the public comments summarized above regarding mechanism of action, MS–DRG assignment of potential cases eligible for treatment involving use of GIAPREZA™, and the treatment of the intended patient population, the applicant stated that prior to approval of GIAPREZA™, only two classes of vasopressors were available: Catecholamines and vasopressin, both of which have narrow therapeutic windows and significant toxic effects when administered at higher doses. The applicant further stated that catecholamines are correlated to serious complications, such as increased digital and limb necrosis [126] and kidney injury.[127] The applicant explained that

[123] Sparks MA, Crowley SD, Gurley SB, Mirotsou M, Coffman TM. Classical renin-angiotensin system in kidney physiology. *Comprehensive Physiology*. 2014;4(3):1201–1228. doi:10.1002/cphy.c130040.

[124] Luque M, Martin P, Martell N, Fernandez C, Brosnihan KB, Ferrario CM. Effects of captopril related to increased levels of prostacyclin and angiotensin-(1–7) in essential hypertension. J Hypertens. 1996;14:799–805.

[125] Balakumar P, Jagadeesh G. A century-old renin–angiotensin system still grows with endless possibilities: AT1 receptor signaling cascades in cardiovascular physiopathology. Cell Signal. 2014;26(10):2147–60.

[126] Brown SM, Lanspa MJ, Jones JP, et al. Survival After Shock Requiring High-Dose Vasopressor Therapy. *Chest*. 2013;143(3):664–671. doi:10.1378/chest.12–1106.

[127] Gordon AC, Mason AJ, Thirunavukkarasu N, et al. Effect of Early Vasopressin vs Norepinephrine

vasopressin was the only non-catecholamine vasopressor available to clinicians, but it fails to improve blood pressure in the majority of patients, therefore, making its impact quite limited.[128] Additionally, the applicant indicated that vasopressin is also slow to take effect (peak effect at 15 minutes) and, therefore, is difficult to titrate, to achieve and maintain the desired MAP, which further complicates its use and leaves patients hypotensive for longer.[129] [130] The applicant further explained that last-resort adjuvant non-vasopressor therapies such as corticosteroids, ascorbic acid, thiamine, and methylene blue are still used in desperation, but none have been shown to reliably improve blood pressure or survival. Therefore, the applicant suggested that CMS recognize that GIAPREZA™ answers an unmet need for a safe, effective, fast-acting, alternative therapy.[131] With regard to newness, a couple of commenters stated that GIAPREZA™ is the first new vasopressor approved by the FDA in over 40 years. To the contrary, another commenter stated that it, generally, supported CMS' concerns about GIAPREZA™.

Response: After review of the information provided by the applicant and consideration of the public comments we received, we believe that GIAPREZA™ has a unique mechanism of action to achieve a therapeutic outcome because it leverages the RAAS system to increase blood pressure. Therefore, GIAPREZA™ is not substantially similar to existing treatment options and meets the newness criterion.

With regard to the cost criterion, the applicant conducted an analysis for a narrower indication, patients who have been diagnosed with refractory shock who have failed to respond to standard of care vasopressors, and an analysis for a broader indication of all patients who have been diagnosed with septic or other distributive shock. In the FY 2019 IPPS/LTCH PPS proposed rule (82 FR 20325), we stated we believed that only this broader analysis, which reflects the patient population for which the applicant's technology is approved by the FDA, is relevant to demonstrate that the technology meets the cost criterion and, therefore, we only summarized this broader analysis in the proposed rule (and below). In order to identify the range of MS–DRGs that potential cases representing potential patients who may be eligible for treatment using GIAPREZA™ may map to, the applicant used two separate analyses to identify the MS–DRGs for patients who have been diagnosed with shock or related diagnoses. The applicant also performed three sensitivity analyses on the MS–DRGs for each of the two selections: 100 percent of the MS–DRGs, 80 percent of the MS–DRGs, and 25 percent of the MS–DRGs. Therefore, a total of six scenarios were included in the cost analysis.

The first analysis (Scenario 1) selected the MS–DRGs most representative of the potential patient cases where treatment involving GIAPREZA™ would have the greatest clinical impact and outcomes of improvement over present treatment options. The applicant searched for 28 different ICD–9–CM codes under this scenario. The second analysis (Scenario 2) used the 80 most relevant ICD–9–CM diagnosis codes based on the inclusion criteria of the GIAPREZA™ Phase III clinical trial, ATHOS–3, and an additional 8 ICD–9–CM diagnosis codes for clinical presentation associated with vasodilatory or distributive shock patients failing fluid and standard of care therapy to capture any additional potential cases that may be applicable based on clinical presentations associated with this patient population.

Among only the top quartile of potential patient cases, the single MS–DRG representative of most potential patient cases was MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC) for both ICD–9–CM diagnosis code selection scenarios, and in both selections, it accounted for a potential patient case percentage surpassing 25 percent. Because GIAPREZA™ is not reserved exclusively as a last-line drug based on the FDA indication, the applicant removed 50 percent of drug charges for prior technologies or other charges associated with prior technologies from the unstandardized charges before standardization in order to account for other drugs that may be replaced by the use of GIAPREZA™. At the time of development of the proposed rule, the applicant had not yet supplied CMS with pricing for GIAPREZA™ and did not include charges for the new technology when conducting this analysis. For all analyses' scenarios, the applicant standardized charges using the FY 2015 impact file and then inflated the charges to FY 2019 using an inflation factor of 15.4181 percent (or 1.154181) by multiplying the inflation factor of 1.098446 in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286) by the inflation factor of 1.05074 in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524). The final inflated average case-weighted standardized charge per case was calculated for each scenario and compared with the average case-weighted threshold amount for each group of MS–DRGs based on the thresholds in Table 10.

Results of the analyses for each of the two code selection scenarios, each with three sensitivity analyses for a total of six analyses, are summarized in the tables below:

	Number of MS–DRGs assessed	Number of Medicare cases	Case-weighted new technology add-on payment threshold	Final average inflated standardized charge per case	Amount exceeded threshold
Cost Analysis Based on ICD–9–CM Diagnosis Code Scenario 1					
ICD–9–CM Diagnosis Code Selection (28 Codes):					
100 Percent	439	120,966	$77,427	$111,522	$34,095
80 Percent	10	96,102	77,641	100,167	22,526
25 Percent	1	66,980	53,499	71,951	18,452

on Kidney Failure in Patients With Septic Shock. *Jama.* 2016;316(5):509. doi:10.1001/jama.2016.10485.

[128] Sacha GL, Lam SW, Duggal A, Torbic H, Reddy AJ, et al, Hypotension risk based on vasoactive agent discontinuation order in patients in the recovery phase of septic shock. Pharmacotherapy. 2018 Mar;38(3):319–326. doi: 10.1002/phar.2082. Epub 2018 Feb 8.

[129] Vasostrict [Package Insert]. Chestnut Ridge, NY. Par Pharmaceutical; 2016.

[130] Malay MB, Ashton JL, Dahl K, Savage EB, Burchell SA, Ashton RC Jr, et al. Heterogeneity of the vasoconstrictor effect of vasopressin in septic shock. Crit Care Med. 2004;32(6):1327 31.

[131] Andreis DT, Singer M. Catecholamines for inflammatory shock: a Jekyll-and-Hyde conundrum. Intensive Care Med. 2016;42(9):1387–97.

	Number of MS–DRGs assessed	Number of Medicare cases	Case-weighted new technology add-on payment threshold	Final average inflated standardized charge per case	Amount exceeded threshold
Cost Analysis Based on ICD–9–CM Diagnosis Code Scenario 2					
ICD–9–CM Diagnosis Code Selection (88 Codes):					
100 Percent	466	164,892	78,675	112,174	33,499
80 Percent	52	131,690	79,732	108,396	28,664
25 Percent	1	67,016	53,499	71,688	18,189

The applicant maintained that, based on the Table 10 thresholds, the inflated average case-weighted standardized charge per case in the analyses exceeded the average case-weighted threshold amount. The applicant noted that the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount by at least $18,189, without the average per patient cost of the technology. As such, the applicant anticipated that the inclusion of the cost of GIAPREZA™, at any price point, would further increase charges above the average case-weighted threshold amount. Therefore, the applicant stated that the technology met the cost criterion. We noted in the proposed rule that we were unsure whether the selection in both scenarios fully captures the broader indication for which the FDA approved the use of GIAPREZA™. We invited public comments on whether GIAPREZA™ meets the cost criterion, including with respect to the concern we had raised.

Comment: The applicant provided an updated cost analysis to broaden the patient cases according to the expanded FDA-approved indication. Specifically, the applicant stated that it removed the original exclusion criteria, which previously limited the patient cases used in the cost analysis to vasopressor-unresponsive patient cases, subjected all three ICD–9–CM code selections to a broader procedure code inclusion list, and additionally adjusted codes based on the clinical profile of diagnoses of distributive/septic shock.

The applicant noted, as noted in the proposed rule, that the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount before including the average per patient cost of the technology. The applicant also added charges for the cost of the technology to its updated analysis. The applicant indicated that the WAC of GIAPREZA™ (which is supplied as a 2.5mg/1mL vial) is $1,500 per vial. The applicant stated that, according to the FDA-approved labeling, the recommended dosage of GIAPREZA™ is 20 nanograms (ng)/kg/min administered as an IV infusion, titrated as frequently as every 5 minutes by increments of up to 15 ng/kg/min, as needed. The applicant stated that, because each vial contains 2.5 mg of GIAPREZA™, a patient weighing 70 kg infused for 48 hours at a constant dose of 20ng/kg/min would use 1.6 vials of GIAPREZA™. The applicant explained that, as vials will be used in whole integers, each episode-of-care would require 2 vials and consequently would cost $3,000 per patient, per episode-of-care, at the current WAC of $1,500.

To estimate the anticipated average charge submitted by hospitals for use of GIAPREZA™, the applicant stated that it used a conservative CCR of 0.5, which equated to the lower hospital markups for similar drugs. The applicant subtracted 50 percent of the costs of prior technology charges, which resulted in the final inflated average standardized charge per case, which exceeded the Table 10 average case-weighted threshold amounts by an average of $40,011, after the outlined changes were made. The applicant submitted the following table summarizing the updated cost threshold analysis:

SUMMARY OF CASE-WEIGHTED COST-THRESHOLD ANALYSIS USING FY 2015 MEDPAR DATA (50 PERCENT OF PHARMACY CHARGES) POST ISSUANCE OF THE FY 2019 IPPS/LTCH PPS PROPOSED RULE

	Number of MS–DRGs assessed	Number of Medicare cases	Case-weighted new technology add-on payment threshold	Final inflated average case-weighted standardized charge per case	Amount exceeded threshold
Cost Analysis Based on ICD–9–CM Diagnosis Code Scenario 1					
ICD–9–CM Diagnosis Code Selection (41 Codes):					
100 Percent	711	816,386	$93,312	$134,127	$40,815
80 Percent	55	652,298	97,759	134,733	36,974
25 Percent	1	145,043	53,499	82,947	29,448
Cost Analysis Based on ICD–9–CM Diagnosis Code Scenario 2					
ICD–9–CM Diagnosis Code Selection (28 Codes):					
100 Percent	499	318,168	93,324	148,143	54,819
80 Percent	8	251,694	96,337	139,486	43,149
25 Percent	1	145,345	53,499	82,900	29,401
Cost Analysis Based on ICD–9–CM Diagnosis Code Scenario 3					
ICD–9–CM Diagnosis Code Selection (99 Codes):					

SUMMARY OF CASE-WEIGHTED COST-THRESHOLD ANALYSIS USING FY 2015 MEDPAR DATA (50 PERCENT OF PHARMACY CHARGES) POST ISSUANCE OF THE FY 2019 IPPS/LTCH PPS PROPOSED RULE—Continued

	Number of MS–DRGs assessed	Number of Medicare cases	Case-weighted new technology add-on payment threshold	Final inflated average case-weighted standardized charge per case	Amount exceeded threshold
100 Percent	685	487,091	97,294	147,388	50,094
80 Percent	45	388,622	103,664	149,700	46,036
25 Percent	1	145,472	53,499	82,866	29,367

Response: After consideration of the public comments we received, we agree that GIAPREZA™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant summarized that it believes that GIAPREZA™ represents a substantial clinical improvement because it: (1) Addresses an unmet medical need for patients who have been diagnosed with septic or distributive shock that, despite standard of care vasopressors, are unable to maintain adequate mean arterial pressure; (2) is the only agent shown in randomized clinical trial to rapidly and sustainably achieve or maintain target blood pressure in patients who do not respond adequately to fluid and vasopressor therapy; (3) although not powered for mortality, the ATHOS–3 trial demonstrated a strong trend to reduce the risk of death in adults from septic or distributive shock who remain hypotensive despite fluid therapy and vasopressor therapy, a severe, life-threatening condition, for which there are no other therapies; (4) provides a catecholamine-sparing effect; and (5) is generally safe and well-tolerated, with no significant differences in the percentages of patients with any grade adverse events or serious adverse events when compared to placebo.

Expanding on the statements above, we stated in the proposed rule that the applicant believes that the use of GIAPREZA™ offers clinicians a significant new tool to manage and treat severe hypotension in all adult patients who have been diagnosed with septic or other distributive shock who are unresponsive to existing vasopressor therapies. The applicant also stated that the use of GIAPREZA™ provides a new therapeutic option for critically-ill adult patients who have been diagnosed with septic or other distributive shock who have limited options and worsening prognoses.

The applicant maintained that GIAPREZA™ was shown to be an effective treatment option for critically-ill patients who have been diagnosed with refractory shock. The applicant reported that a randomized, double-blind placebo controlled trial called ATHOS–3 [132] examined the ability of GIAPREZA™ to increase mean arterial pressure (MAP), with the primary endpoint being achievement of a MAP of greater than or equal to 75 mmHg (the research-backed guideline set by the Surviving Sepsis Campaign) or a 10 mmHg increase in baseline MAP. Significantly more patients in the treatment arm met the primary endpoint (69.9 percent versus 23.4 percent, P<0.001). The applicant asserted that this MAP improvement constitutes a significant substantial clinical improvement because patients treated with GIAPREZA™ were three times more likely to achieve acceptable blood pressure than patients receiving the placebo. The MAP significantly and rapidly increased in patients treated with GIAPREZA™ and was sustained over 48 hours consistent across subgroups and the treatment effect of GIAPREZA™ was confirmed using multivariate analysis. The group treated with GIAPREZA™ also experienced a greater mean increase in MAP; the MAP increased by a mean of 12.5 mmHg for the GIAPREZA™ group compared to a mean of 2.9 mmHg for the placebo group.

Second, the applicant maintained that GIAPREZA™ demonstrated potential improvement in organ function by lowering the cardiovascular sequential organ failure assessment (SOFA) scores of patients at 48 hours (−1.75 GIAPREZA™ group versus −1.28 placebo group). However, we stated in the proposed rule we were concerned that lower cardiovascular SOFA scores may not demonstrate substantial clinical improvement because there was no difference in the improvement of other components of the SOFA score or the overall SOFA score.

Third, the applicant asserted that GIAPREZA™ represents a substantial clinical improvement because the use of GIAPREZA™ reduced the need to increase overall doses of catecholamine vasopressors. The applicant stated that patients receiving higher doses of catecholamine vasopressors suffer from cardiac toxicity, organ dysfunction, and other metabolic complications that are associated with higher mortality. According to the applicant, by decreasing the overall dosage of catecholamine vasopressors, GIAPREZA™ potentially reduces the adverse effects of vasopressors. The mean change in catecholamine vasopressors in patients receiving GIAPREZA™ versus patients receiving the placebo at 3 hours was −0.03 versus 0.03 (P<0.001), showing that GIAPREZA™ allowed for catecholamines to be titrated down, while patients not receiving GIAPREZA™ required additional catecholamine doses. The vasopressor mean doses were consistently lower in the GIAPREZA™ group, and at 48 hours, vasopressors had been discontinued in 28.5 percent of patients in the placebo group versus 40.5 percent of the GIAPREZA™ group. We noted in the proposed rule that, while GIAPREZA™ may potentially reduce certain adverse effects associated with SOC treatments, the FDA-approved labeling cautions that the use of GIAPREZA™ can cause dangerous blood clots with serious consequences (clots in arteries and veins, including deep venous thrombosis); according to the FDA-approved label, prophylactic treatment for blood clots should be used.

In the proposed rule, we noted that the applicant stated that while the study was not powered to detect mortality effects, there was a nonsignificant trend toward longer survival in the GIAPREZA™ group. Overall mortality rates at 7 days and 8 days in the modified intent to treat (MITT) population were 22 percent less in the GIAPREZA™ group than in the placebo

[132] Khanna, A., English, S.W., Wang, X.S., et al., ''Angiotensin II for the treatment of vasodilatory shock,'' [supplementary appendix] [published online ahead of print May 21, 2017], *N Engl J Med.,* 2017, doi: 10.1056/NEJMoa1704154.

group. At 28 days, the mortality rate in the placebo group was 54 percent versus 46 percent in the GIAPREZA™ group. However, the p-values for the decrease in mortality with GIAPREZA™ at 7 days, 8 days, and 28 days did not demonstrate statistical significance.

The applicant concluded that GIAPREZA™ is the first commercial product to increase blood pressure in adults who have been diagnosed with septic or other distributive shock that leverages the renin-angiotensin-aldosterone system. The applicant stated that the results of the ATHOS–3 study provide support for a well-tolerated new therapeutic agent that demonstrates significant improvements in mean arterial pressure. Additionally, the applicant noted that hypotension in adults who have been diagnosed with septic or other distributive shock is a prevalent life-threatening condition where therapeutic options are limited and a high unmet medical need exists. The applicant stated that the use of GIAPREZA™ will represent a safe and effective new therapy that not only leverages a system that current therapies are not utilizing, but also offers a viable alternative where one does not exist.

We stated in the proposed rule that we understood that, in this heterogeneous and difficult to treat patient population, studies assessing mortality as a primary endpoint are difficult, and as such, surrogate endpoints (that is, achieving baseline MAP) have been explored to assess the efficacy of treatments. While the outcomes presented by the applicant, such as achieving target MAP, lower SOFA scores, and reduced catecholamine usage, could be surrogates for clinical outcomes in these patients, we stated that there is not a strong pool of evidence connecting these single data points directly with morbidity and mortality. Therefore, in the proposed rule, we stated that we were unsure whether achieving target MAP, lower SOFA scores, and reduced catecholamine usage represents a substantial clinical improvement or instead short-term, temporary improvements without a change in overall patient prognosis.

In response to this concern about MAP constituting a meaningful measure for substantial clinical improvement, the applicant supplied additional information from the current Surviving Sepsis guidelines, which recommend an initial target MAP of 65 mmHg. The applicant explained that as MAP falls below a critical threshold, inadequate tissue perfusion occurs, potentially resulting in multiple organ dysfunction and death. Therefore, early and adequate hemodynamic support and treatment of hypotension is critical to restore adequate organ perfusion and prevent worsening organ dysfunction and failure. In diagnoses of septic or distributive shock, the goal of treatment is to increase and maintain a threshold MAP in order to improve tissue perfusion. According to the applicant, tissue perfusion becomes linearly dependent on arterial pressure below a threshold MAP. In patients who have been diagnosed with septic shock requiring vasopressors, the current Surviving Sepsis guidelines are based on available evidence that demonstrates that adequate MAP is important to clinical outcomes and that prolonged decreases in MAP below 65 mmHg is associated with poor outcome. According to information supplied by the applicant, even short durations like less than 5 minutes of low MAP have been associated with severe outcomes, such as myocardial infarction, stroke, and acute kidney injury. The applicant stated that a retrospective study [133] found that MAP was independently related to ICU and hospital mortality in patients with severe sepsis or septic shock.

Finally, we stated in the proposed rule that we were concerned that the study results may demonstrate substantial clinical improvement only for patients who are unresponsive to the administration of fluids and vasopressors because patients were only included in the ATHOS–3 study if they failed fluids and vasopressors, rather than for the broader patient population of adult patients who have been diagnosed with septic or other distributive shock for which GIAPREZA™ was approved by the FDA for use as an available treatment option. We stated in the proposed rule that the applicant continues to maintain that the use of GIAPREZA™ has significant efficacy in improving blood pressure for patients who have been diagnosed with distributive shock, while decreasing adrenergic vasopressor usage, thereby, providing another avenue for therapy in this difficult to treat patient population. However, we stated we were still concerned that the results from the clinical trial may be too narrow to accurately represent the entire patient population that has been diagnosed with septic or other distributive shock and, therefore, we were concerned that the clinical trial's results may not adequately demonstrate that GIAPREZA™ is a substantial clinical improvement over existing therapies for all the patients for whom the treatment option is indicated. We invited public comments on whether GIAPREZA™ meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments addressing the concerns raised by CMS in the proposed rule regarding whether GIAPREZA™ meets the substantial clinical improvement criterion. With respect to the concern regarding the SOFA scores, the applicant stated that the data results, which it believes demonstrate that GIAPREZA™ delivers substantial clinical improvement, are not based solely upon the observed improvements in the SOFA score. Rather, the applicant explained that SOFA is used to identify patients at a greater risk of poor outcomes. The applicant stated that the mean cardiovascular SOFA score at hour 48 showed that there was significant improvement in the GIAPREZA™ group (−1.75) versus the placebo group (−1.28) (p=0.01), reflecting a higher incidence of vasopressor discontinuation prior to hour 48 and a reduced catecholamine dose in the GIAPREZA™ group.

The applicant also reiterated that clinical data showing GIAPREZA™'s proven benefit of reducing the need for background vasopressors constitutes a substantial clinical improvement, considering the significant toxic effects of catecholamines and vasopressin administered at higher doses, including cardiac and digital ischemia; tachyarrhythmias with norepinephrine; cardiac, digital, and splanchnic ischemia; and ischemic skin lesions with vasopressin.[134] [135] [136] [137] [138] [139] The applicant further stated that norepinephrine (a catecholamine) is

[133] Walsh, M., Devereaux, P.J., Garg, A.X., et al., ''Relationship between Intraoperative Mean Arterial Pressure and Clinical Outcomes after Noncardiac Surgery Toward an Empirical Definition of Hypotension,'' *Anesthesiology,* 2013, vol. 119(3), pp. 507–515.

[134] Dünser MW, Meier J. Vasopressor hormones in shock–noradrenaline, vasopressin or angiotensin II: which one will make the race? J Thorac Dis. 2017;9(7):1843–7.

[135] Dünser MW, Hasibeder WR. Sympathetic overstimulation during critical illness: adverse effects of adrenergic stress. J Intensive Care Med. 2009;24(5):293–316.

[136] Russell JA, Rush B, Boyd J. Pathophysiology of septic shock. Crit Care Clin. 2018;34(1):43 61.

[137] Asfar P, Meziani F, Hamel JF, Grelon F, Megarbane B, Anguel N, et al. High versus low blood-pressure target in patients with septic shock. N Engl J Med. 2014;370(17):1583–93.

[138] Schmittinger CA, Torgersen C, Luckner G, Schroder DC, Lorenz I, and Dunser MW. Adverse cardiac events during catecholamine vasopressor therapy: a prospective observational study. Intensive Care Med. 2012;38(6):950–8.

[139] Russell JA, Walley KR, Singer J, Gordon AC, Hébert PC, Cooper DJ, et al. VASST Investigators. Vasopressin versus norepinephrine infusion in patients with septic shock. N Engl J Med. 2008;358(9):877–87.

also associated with immunosuppression, which may predispose the patient to a higher risk of secondary infections.[140] Other commenters similarly stated that use of GIAPREZA™ reduces the need for administration of these high-dose vasopressors and helps patients achieve MAP, with a significant reduction in adverse effects, unlike with the use of other vasopressors which fail to raise a patient's MAP and are associated with increases in mortality when administered at high doses; including cardiac toxicity, necrosis of the skin and distal extremities, and metabolic dysfunction. Regarding the risk of thrombosis, the applicant stated that most of the thromboembolic adverse events were of lower severity and assigned to Grade I or Grade II. The applicant further pointed out that patients who are diagnosed with vasodilatory shock are, generally, at a high risk for thrombosis, and that the FDA labeling and the immediate availability of blood-thinning agents fully address this potential safety concern.

In response to our concern that the mortality benefit was not statistically significant, the applicant stated that the p-values for the decrease in mortality rates with use of GIAPREZA™ may not demonstrate statistical significance because the clinical trial was not powered to definitively prove a decrease in mortality rate. The applicant also contended that the substantial clinical improvement criterion described in the September 7, 2001 final rule (66 FR 46902) identifies only a ''reduced mortality rate'' as one of a multitude of different standards and does not restrict p-values cited to a certain range to support a new technology add-on payment application determination. Therefore, the applicant believed that the p-values support the validity of the new technology add-on payment application for GIAPREZA™; they do not detract from it. Similarly, other commenters stated that GIAPREZA™ is the only vasopressor to show a strong trend towards a survival benefit.

The applicant also disagreed with CMS regarding our statement in the proposed rule that there is not a strong pool of evidence directly connecting target MAP, lower SOFA scores, and reduced catecholamine usage with morbidity and mortality. The applicant submitted additional evidence from the Surviving Sepsis Campaign and international and European consensus guidelines to demonstrate that maintaining an adequate MAP is a clinically meaningful benefit affecting morbidity and mortality. The applicant reiterated that when MAP drops below 60 mmHg, the human body loses autoregulatory control of blood supply to key organs,[141] and even short durations of hypotension (<5 minutes) are associated with increased serious adverse outcomes, such as myocardial ischemia and acute kidney injury.[142] Furthermore, the applicant cited research demonstrating that a low MAP is associated with an increased 28-day mortality, and stated that an analysis of outcomes in patients who have been diagnosed with distributive shock demonstrated a clear relationship between duration and extent of hypotension and ICU mortality.[143] [144]

The applicant also stated that clinical data show reduced catecholamine use, a benefit of treatment involving GIAPREZA™, is associated with less mortality and less morbidity. The applicant further stated that, according to an analysis conducted by the applicant of outcomes based on a 50 percent reduction of the administration of catecholamine doses at 24 hours, those patients with a 50 percent reduction of administration of catecholamines doses at 24 hours had a statistically significant improved survival benefit. Additionally, the applicant indicated that the catecholamine-sparing effect resulted in significantly fewer patients experiencing a serious adverse event or a fatal event.

Finally, in response to our concern that the results from the clinical trial may be too narrow to accurately represent the entire patient population that has been diagnosed with septic or other distributive shock and, therefore, may not adequately demonstrate that GIAPREZA™ is a substantial clinical improvement over existing therapies for all the patients for whom the treatment option is indicated, the applicant posited that CMS' definition of substantial clinical improvement in the September 7, 2001 final rule (66 FR 46902) does not refer to the scope of FDA approval or the patient populations that that were enrolled in the clinical trial. The applicant asserted that the multitude of benefits that GIAPREZA™ delivers directly pertaining to the substantial clinical improvement criterion cannot be assumed to be restricted solely to patients who have been diagnosed with refractory shock. The applicant specifically summarized the following improved outcomes:

- *Reduced mortality rate with use of the device:* A promising trend toward lower mortality was observed in the GIAPREZA™ arm, and more generally, MAP ≥65 mmHg is associated with decreased mortality.[145]
- *Reduced rate of device-related complications:* GIAPREZA™ reduced the need for background vasopressors, the utilization of which is correlated to serious complications such as increased digital and limb necrosis,[146] and kidney injury.[147]
- *Decreased rate of subsequent diagnostic or therapeutic interventions:* In a sub-population analysis of patients suffering from acute kidney injury, it was found that GIAPREZA™-treated patients had fewer ICU days, shorter dialysis days, reduced ventilation usage, and longer survival, compared to placebo.[148] [149]
- *More rapid beneficial resolution of the disease process treatment:* Whereas SOC vasopressors are administered for extended periods (days), GIAPREZA™ has a much shorter time to effect of only five minutes.
- *Reduced recovery time:* Since low MAP is associated with high ICU and 28-day mortality and GIAPREZA™ achieved target MAP of 75 mmHg by hour 3 in significantly more patients than the standard-of-care, while

[140] Stolk RF, van der Poll T, Angus DC, van der Hoeven JG, Pickkers P, Kox M. Potentially inadvertent immunomodulation: Norepinephrine use in sepsis. Am J Respir Crit Care Med. 2016;194(5):550–8.

[141] LeDoux D, Astiz ME, Carpati CM, Rackow EC. Effects of perfusion pressure on tissue perfusion in septic shock. Crit Care Med. 2000;28(8):2729–32.

[142] Walsh M, Devereaux PJ, Garg AX, Kurz A, Turan A, Rodseth RN, et al. Relationship between intraoperative mean arterial pressure and clinical outcomes after noncardiac surgery: toward an empirical definition of hypotension. Anesthesiology. 2013;119(3):507–15.

[143] Johnson AE, Pollard TJ, Shen L, et al. MIMIC–III, a freely accessible critical care database. Sci data 2016;3:160035.

[144] Nielsen ND, Zeng F, Gerbasi ME, Oster G, Grossman A, Shapiro NI. Blood pressure control and clinical outcomes in patients with distributive shock in an academic intensive care setting. 2018 ISICEM Annual Meeting, Brussels, Belgium (March 20–23, 2018); Abstract No. A516.

[145] Nielsen ND, Zeng F, Gerbasi ME, Oster G, Grossman A, Shapiro NI. Blood pressure control and clinical outcomes in patients with distributive shock in an academic intensive care setting. 2018 ISICEM Annual Meeting, Brussels, Belgium (March 20–23, 2018); Abstract No. A516.

[146] Brown SM, Lanspa MJ, Jones JP, et al. Survival After Shock Requiring High-Dose Vasopressor Therapy. *Chest.* 2013;143(3):664–671. doi:10.1378/chest.12–1106.

[147] Gordon AC, Mason AJ, Thirunavukkarasu N, et al. Effect of Early Vasopressin vs Norepinephrine on Kidney Failure in Patients With Septic Shock. *Jama.* 2016;316(5):509. doi:10.1001/jama.2016.10485.

[148] Khanna A, et al. Angiotensin II for the Treatment of Vasodilatory Shock Suppl: S14. *NEJM.* 2017. DOI: 10.1056/NEJMoa1704154.

[149] Tumlin JA, Murugan R, Deane AM, et al. Outcomes in Patients with Vasodilatory Shock and Renal Replacement Therapy Treated with Intravenous Angiotensin II. *Critical Care Medicine.* 2018;46(6):949–957. doi:10.1097/ccm.3092.

reducing the need for other vasopressors, GIAPREZA™ may result in a shorter ICU length of stay and a faster recovery.

Other commenters supported the clinical results and evidence of GIAPREZA™'s meeting the substantial clinical improvement criterion, and explained that not only did the ATHOS–3 study provide compelling support for a well-tolerated new therapeutic agent that demonstrated significant improvements in MAP, it also demonstrated a strong trend toward improved survival benefit, a catecholamine-sparing effect, an increase in ICU free days, and a reduction in patients requiring renal replacement therapy (RRT). To the contrary, another commenter stated that it, generally, supported CMS' concerns.

Response: We appreciate the additional information and analysis provided by the applicant and the commenters' input in response to our concerns regarding substantial clinical improvement. After reviewing the information submitted by the applicant addressing our concerns raised in the proposed rule, we agree that GIAPREZA™ more rapidly allows for beneficial resolution of the disease process treatment with its shorter time to effect of only five minutes, and that GIAPREZA™ has a reduced rate of device-related complications by reducing the need for background vasopressors, the utilization of which is correlated to serious complications. Specifically, we agree with the commenters and the applicant that a reduction in high-dose SOC catecholamines and vasopressin, which can be toxic and have numerous adverse effects, constitutes a substantial clinical improvement. We also agree with the applicant that the FDA-approved label, which cautions that prophylactic treatment for blood clots should be used, addresses the potential safety concern of thrombosis for patients treated with GIAPREZA™. Based on the data provided by the applicant and consideration of the public comments we received, we agree with the applicant and the commenters that GIAPREZA™ represents a substantial clinical improvement over existing technologies because it quickly and effectively raises MAP while allowing for a reduction in other vasopressors.

After consideration of the public comments we received, we have determined that GIAPREZA™ meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for GIAPREZA™ for FY 2019. Cases involving the use of GIAPREZA™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033H4 and XW043H4.

In its application, the applicant estimated that the average Medicare beneficiary would require a dosage of 20ng/kg/min administered as an IV infusion over 48 hours, which would require 2 vials. The applicant explained that the WAC for one vial is $1,500, with each episode-of-care costing $3,000 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of GIAPREZA™ is $1,500 for FY 2019.

h. Cerebral Protection System (Sentinel® Cerebral Protection System)

Claret Medical, Inc. submitted an application for new technology add-on payments for the Cerebral Protection System (Sentinel® Cerebral Protection System) for FY 2019. According to the applicant, the Sentinel Cerebral Protection System is indicated for the use as an embolic protection (EP) device to capture and remove thrombus and debris while performing transcatheter aortic valve replacement (TAVR) procedures. The device is percutaneously delivered via the right radial artery and is removed upon completion of the TAVR procedure. The De Novo request for the Sentinel® Cerebral Protection System was granted by FDA on June 1, 2017 (DEN160043).

Aortic stenosis (AS) is a narrowing of the aortic valve opening. AS restricts blood flow from the left ventricle to the aorta and may also affect the pressure in the left atrium. The most common presenting symptoms of AS include dyspnea on exertion or decreased exercise tolerance, exertional dizziness (presyncope) or syncope and exertional angina. Symptoms experienced by patients who have been diagnosed with AS and normal left ventricular systolic function rarely occur until stenosis is severe (defined as valve area is less than 1.0 cm2, the jet velocity is over 4.0 m/sec, and/or the mean transvalvular gradient is greater than or equal to 40 mmHg).[150] AS is a common valvular disorder in elderly patients. The prevalence of AS increases with age, and some degree of valvular calcification is present in 75 percent of patients who are 85 to 86 years old.[151] TAVR procedures are the standard of care treatment for patients who have been diagnosed with severe AS. Patients undergoing TAVR procedures are often older, frail, and may be affected by multiple comorbidities, implying a significant risk for thromboembolic cerebrovascular events.[152] Embolic ischemic strokes can occur in patients undergoing surgical and interventional cardiovascular procedures, such as stenting (carotid, coronary, peripheral), catheter ablation for atrial fibrillation, endovascular stent grafting, left atrial appendage closure (LAAO), patent formal ovale (PFO) closure, balloon aortic valvuloplasty, surgical valve replacement (SAVR), and TAVR. Clinically overt stroke, or silent ischemic cerebral infarctions, associated with the TAVR procedure, may result from a variety of causes, including mechanical manipulation of instruments or other interventional devices used during the procedure. These mechanical manipulations are caused by, but not limited to, the placement of a relatively large bore delivery catheter in the aortic arch, balloon valvuloplasty, valve positioning, valve re-positioning, valve expansion, and corrective catheter manipulation, as well as use of guidewires and guiding or diagnostic catheters required for proper positioning of the TAVR device. The magnitude and timing of embolic activity resulting from these manipulations was studied by Szeto, et al.[153] using a transcranial Doppler, and it was found that embolic material is liberated throughout the TAVR procedure with some of the emboli reaching the central nervous system leading to cerebral ischemic infarctions. Some of the cerebral ischemic infarctions lead to neurologic injury and clinically apparent stroke. Szeto, et al. also noted that the rate of silent ischemic cerebral infarctions following TAVR procedures is estimated to be between 68 and 91 percent.[154] [155]

[150] Otto, C., Gaasch, W., ''Clinical manifestations and diagnosis of aortic stenosis in adults,'' In S. Yeon (Ed.), 2016, Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnosis-of-aortic-stenosis-in-adults.*

[151] Lindroos, M., et al., ''Prevalence of aortic valve abnormalities in the elderly: An echocardiographic study of a random population sample,'' *J Am Coll Cardio,* 1993, vol. 21(5), pp. 1220–1225.

[152] Giustino, G., et al., ''Neurological Outcomes With Embolic Protection Devices in Patients Undergoing Transcatheter Aortic Valve Replacement,'' *J Am Coll Cardio,* CARDIOVASCULAR INTERVENTIONS, 2016, vol. 9(20).

[153] Szeto, W.Y., et al., ''Cerebral Embolic Exposure During Transfemoral and Transapical Transcatheter Aortic Valve Replacement,'' *J Card Surg,* 2011, vol. 26, pp. 348–354.

[154] Gupta, A., Giambrone, A.E., Gialdini, G., et al., ''Silent brain infarction and risk of future stroke: a systematic review and meta-analysis,'' *Stroke,* 2016, vol. 47, pp. 719–25.

The TAVR procedure is a minimally invasive procedure that does not involve open heart surgery. During a TAVR procedure the prosthetic aortic valve is placed within the diseased native valve. The prosthetic valve then becomes the functioning aortic valve. As previously outlined, stroke is one of the risks associated with TAVR procedures. According to the applicant, the risk of stroke is highest in the early post-procedure period and, as previously outlined, is likely due to mechanical factors occurring during the TAVR procedure.[156] Emboli can be generated as wire-guided devices are manipulated within atherosclerotic vessels, or when calcified valve leaflets are traversed and then crushed during valvuloplasty and subsequent valve deployment.[157] Stroke rates in patients evaluated 30 days after TAVR procedures range from 1.0 percent to 9.6 percent [158], and have been associated with increased mortality. Additionally, new ''silent infarcts,'' assessed via diffusion-weighted magnetic resonance imaging (DW–MRI), have been found in a majority of patients after TAVR procedures.[159]

As stated earlier, the De Novo request for the Sentinel® Cerebral Protection System was granted by FDA on June 1, 2017. The FDA concluded that this device should be classified into Class II (moderate risk). Effective October 1, 2016, ICD–10–PCS Section ''X'' code X2A5312 (Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach) was approved to identify cases involving TAVR procedures using the Sentinel® Cerebral Protection System.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, the Sentinel® Cerebral Protection System device is inserted at the beginning of the TAVR procedure, via a small tube inserted through a puncture in the right wrist. Next, using a minimally invasive catheter, two small filters are placed in the brachiocephalic and left common carotid arteries. The filters collect debris, preventing it from becoming emboli, which can travel to the brain. These emboli, if left uncaptured, can cause cerebral ischemic lesions, often referred to as silent ischemic cerebral infarctions, potentially leading to cognitive decline or clinically overt stroke. At the completion of the TAVR procedure, the filters, along with the collected debris, are removed. The applicant stated that there are no other similar products for commercial sale available in the United States for cerebral protection during TAVR procedures. Two neuroprotection devices, the Triguard™ Cerebral Protection Device (Keystone Heart, Herzliya Pituach, Israel) and the Embrella Embolic Deflector™ System (Edwards Lifesciences, Irvine, CA) are used in Europe. These devices work by deflecting embolic debris distally, rather than capturing and removing debris with filters.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, as stated earlier, the Sentinel® Cerebral Protection System is an EP device used to capture and remove thrombus and debris while performing TAVR procedures. Therefore, potential cases representing patients who may be eligible for treatment involving this device would map to the same MS–DRGs as cases involving TAVR procedures.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, this technology will be used to treat patients who have been diagnosed with severe aortic valve stenosis who are eligible for a TAVR procedure. The applicant asserted that there are currently no approved alternative treatment options for cerebral protection during TAVR procedures, and the Sentinel® Cerebral Protection System is the first and only embolic protection device for use during TAVR procedures and, therefore, meets the newness criterion. The applicant also asserted that the device meets the newness criterion, as evidenced by the FDA's granting of the De Novo request and there was no predicate device.

Based on the above, we stated in the proposed rule that it appears that the Sentinel® Cerebral Protection System is not substantially similar to other existing technologies. We invited public comments on whether the Sentinel® Cerebral Protection System is substantially similar to any existing technology and whether it meets the newness criterion.

Comment: Several commenters agreed with CMS' assessment that the Sentinel® Cerebral Protection System is not substantially similar to other existing technologies.

Response: After consideration of the public comments we received, we believe the Sentinel® Cerebral Protection System is not substantially similar to other existing technologies because it is the only neuro protective device available in the U.S. that has been granted a De Novo request by the FDA. Therefore, we believe that the Sentinel® Cerebral Protection System meets the newness criterion.

The applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2016 MedPAR file for cases with the following ICD–10–CM procedure codes to identify cases involving TAVR procedures, which are potential cases representing patients who may be eligible for treatment involving use of the Sentinel® Cerebral Protection System: 02RF37Z (Replacement of aortic valve with autologous tissue substitute, percutaneous approach); 02RF38Z (Replacement of aortic valve with zooplastic tissue, percutaneous approach); 02RF3JZ (Replacement of aortic valve with synthetic substitute, percutaneous approach); 02RF3KZ (Replacement of aortic valve with nonautologous tissue substitute, percutaneous approach); 02RF37H (Replacement of aortic valve with autologous tissue substitute, transapical, percutaneous approach); 02RF38H (Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach); 02RF3JH (Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach); and 02RF3KH (Replacement of aortic valve with nonautologous tissue substitute, transapical, percutaneous approach). This process resulted in 26,012 potential cases. The applicant limited its search to MS–DRG 266 (Endovascular Cardiac Valve Replacement with MCC) and MS–DRG

[155] Mokin, M., Zivadinov, R., Dwyer, M.G., Lazar, R.M., Hopkins, L.N., Siddiqui, A.H., ''Transcatheter aortic valve replacement: perioperative stroke and beyond,'' *Expert Rev Neurother,* 2017, vol. 17, pp. 327–34.

[156] Nombela-Franco, L., et al., ''Timing, predictive factors, and prognostic value of cerebrovascular events in a large cohort of patients undergoing transcatheter aortic valve implantation,'' *Circulation,* 2012, vol. 126(25), pp. 3041–53.

[157] Freeman, M., et al., ''Cerebral events and protection during transcatheter aortic valve replacement,'' *Catheterization and Cardiovascular Interventions,* 2014, vol. 84(6), pp. 885–896.

[158] Haussig, S., Linke, A., ''Transcatheter aortic valve replacement indications should be expanded to lower-risk and younger patients,'' *Circulation,* 2014. vol. 130(25), pp. 2321–31.

[159] Kahlert, P., et al., ''Silent and apparent cerebral ischemia after percutaneous transfemoral aortic valve implantation: a diffusion-weighted magnetic resonance imaging study,'' *Circulation,* 2010, vol. 121(7), pp. 870–8.

267 (Endovascular Cardiac Valve Replacement without MCC) because these two MS–DRGs accounted for 97.4 percent of the total cases identified.

Using the 26,012 identified cases, the applicant determined that the average unstandardized case-weighted charge per case was $211,261. No charges were removed for the prior technology because the device is used to capture and remove thrombus and debris while performing TAVR procedures. The applicant then standardized the charges, but did not inflate the charges. The applicant then added charges for the new technology to the average case-weighted standardized charges per case by taking the cost of the device and dividing the amount by the CCR of 0.332 for implantable devices from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38103). The applicant calculated a final inflated average case-weighted standardized charge per case of $187,707 and a Table 10 average case-weighted threshold amount of $170,503. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology met the cost criterion. We invited public comments on whether the Sentinel® Cerebral Protection System meets the cost criterion.

Comment: The applicant reiterated that the Sentinel® Cerebral Protection System meets the cost criterion.

Response: We appreciate the applicant's input. After consideration of the public comment we received and reviewing the cost data and data analysis submitted by the applicant, we agree that the Sentinel® Cerebral Protection System meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the Sentinel® Cerebral Protection System represents a substantial clinical improvement over existing technologies because it is the first and only cerebral embolic protection device commercially available in the United States for use during TAVR procedures. The applicant stated that the data below shows that the Sentinel® Cerebral Protection System effectively captures brain bound embolic debris and significantly improves clinical outcomes (that is, stroke) beyond the current standard of care, that is, TAVR procedures with no embolic protection.

The applicant provided the results of four key studies: (1) The SENTINEL® study[160] conducted by Claret Medical, Inc.; (2) the CLEAN–TAVI trial [161]; (3) the Ulm real-world registry [162]; and (4) the MISTRAL–C study.[163] The applicant reported that the SENTINEL® study was a prospective, single blind, multi-center, randomized study using the Sentinel® Cerebral Protection System which enrolled patients who had been diagnosed with severe symptomatic calcified native aortic valve stenosis indicated for a TAVR procedure. A total of 363 patients at 19 centers in the United States and Germany were randomized across 3 arms (Safety, Test, and Control) in a 1:1:1 fashion. According to the applicant, evaluations performed for patients in each arm were as follows:

- Safety Arm patients who underwent a TAVR procedure involving the Sentinel® Cerebral Protection System—Patients enrolled in this arm of the study received safety follow-up at discharge, at 30 days and 90 days post-procedure; and neurological evaluation at baseline, discharge, 30 days and 90 days (only in the case of a stroke experienced less than or equal to 30 days) post-procedure. The Safety Arm patients did not undergo MRI or neurocognitive assessments.
- Test Arm patients who underwent a TAVR procedure involving the Sentinel® Cerebral Protection System—Patients enrolled in this arm of the study underwent safety follow-up at discharge, at 30 days and 90 days post-procedure; MRI assessment for efficacy at baseline, 2 to 7 days and 30 days post-procedure; neurological evaluation at baseline, discharge, 30 days and 90 days (only in the case of a stroke experienced less than or equal to 30 days) post-procedure; neurocognitive evaluation at baseline, 2 to 7 days (optional), 30 days and 90 days post-procedure; Quality of Life assessment at baseline, 30 days and 90 days; and histopathological evaluation of debris captured in the Sentinel® Cerebral Protection System's device filters.
- Control Arm patients who underwent a TAVR procedure only—Patients enrolled in this arm of the study underwent safety follow-up at discharge, at 30 days and 90 days post-procedure; MRI assessment for efficacy at baseline, 2 to 7 days and 30 days post-procedure; neurological evaluation at baseline, discharge, 30 days and 90 days (only in the case of a stroke experienced less than or equal to 30 days) post-procedure; neurocognitive evaluation at baseline, 2 to 7 days (optional), 30 days and 90 days post-procedure; and Quality of Life assessment at baseline, 30 days and 90 days.

The primary safety endpoint was occurrence of major adverse cardiac and cerebrovascular events (MACCE) at 30 days compared with a historical performance goal. MACCE was defined as follows: All causes of death; all strokes (disabling and nondisabling, Valve Academic Research Consortium-2 (VARC–2)); and acute kidney injury (stage 3, VARC–2). The point estimate for the historical performance goal for the primary safety endpoint at 30 days post-TAVR procedure was derived from a review of published reports of 30-day TAVR procedure outcomes. The VARC–2 established an independent collaboration between academic research organizations and specialty societies (cardiology and cardiac surgery) in the United States and Europe to create consistent endpoint definitions and consensus recommendations for implementation in TAVR procedure clinical research.[164]

The applicant reported that results of the SENTINEL® study demonstrated the following:

- The rate of MACCE was numerically lower than the control arm, 7.3 percent versus 9.9 percent, but was not statistically significant from that of the control group (p=0.41).
- New lesion volume was 178.0 mm^3 in control patients and 102.8 mm^3 in the Sentinel® Cerebral Protection System device arm (p=0.33). A post-hoc multivariable analysis identified preexisting lesion volume and valve type as predictors of new lesion volume.
- Strokes experienced at 30 days were 9.1 percent in control patients and 5.6 percent in patients treated with the Sentinel® Cerebral Protection System devices (p=0.25). Neurocognitive function was similar in control patients

[160] Kapadia, S., Kodali, S., Makkar, R., et al., ''Protection against cerebral embolism during transcatheter aortic valve replacement,'' *JACC,* 2017, vol. 69(4), pp. 367–377.

[161] Haussig, S., Mangner, N., Dwyer, M.G., et al., ''Effect of a Cerebral Protection Device on Brain Lesions Following Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Stenosis: The CLEAN–TAVI Randomized Clinical Trial,'' *JAMA,* 2016, vol. 316, pp. 592–601.

[162] Seeger, J., et al., ''Cerebral Embolic Protection During Transfemoral Aortic Valve Replacement Significantly Reduces Death and Stroke Compared With Unprotected Procedures,'' *JACC Cardiovasc Interv,* 2017.

[163] Mieghem, Van, et al., ''Filter-based cerebral embolic protection with transcatheter aortic valve implantation: the randomized MISTRAL–C trial,'' *Eurointervention,* 2016, vol. 12(4), pp. 499–507.

[164] Leon, M.B., Piazza, N., Nikolsky, E., et al., ''Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium,'' *European Heart Journal,* 2011, vol. 32(2), pp. 205–217, doi:10.1093/eurheartj/ehq406.

and patients treated with the Sentinel® Cerebral Protection System devices, but there was a correlation between lesion volume and neurocognitive decline (p=0.0022).

- Debris was found within filters in 99 percent of patients and included thrombus, calcification, valve tissue, artery wall, and foreign material.
- The applicant also noted that the post-hoc analysis of these data demonstrated that there was a 63 percent reduction in 72-hour stroke rate (compared to control), p=0.05.

According to the applicant, the CLEAN–TAVI (Claret Embolic Protection and TAVI) trial, was a small, randomized, double-blind, controlled trial. The trial consisted of 100 patients assigned to either EP (n=50) with the Claret Medical, Inc. device (the Sentinel® Cerebral Protection System) or to no EP (n=50). Patients were all treated with femoral access and self-expandable (SE) devices. The study endpoint was the number of brain lesions at 2 days post-procedure versus baseline. Patients were evaluated with DW–MRI at 2 and 7 days post-TAVR procedure. The mean age of patients was 80 years old; 43 percent were male. The study results showed that patients treated with the Sentinel® Cerebral Protection System had a lower number of new lesions (4.00) than patients in the control group (10.0); (p<0.001).

According to the applicant, the single-center Ulm study, a large propensity matched trial, with 802 consecutive patients, occurred at the University of Ulm between 2014 and 2016. The first 522 patients (65.1 percent of patients) underwent a TAVR procedure without EPs, and the subsequent 280 patients (34.9 percent of patients) underwent a TAVR procedure with EP involving the Sentinel® Cerebral Protection System. For both arms of the study, a TAVR procedure was performed in identical settings except without cerebral EP, and neurological follow-up was performed within 7 days post-procedure. The primary endpoint was a composite of all-cause mortality or all-stroke according to the VARC–2 criteria within 7 days. The authors who documented the study noted the following:

- Patient baseline characteristics and aortic valve parameters were similar between groups, that both filters of the device were successfully positioned in 280 patients, all neurological follow-up was completed by the 7th post-procedure date, and that propensity score matching was performed to account for possible confounders.
- Results indicated a decreased rate of disabling and nondisabling stroke at 7 days post-procedure was seen in those patients who were treated with the Sentinel® Cerebral Protection System device versus control patients (1.6 percent versus 4.6 percent, p=0.03).
- At 48 hours, stroke rates were lower with patients treated with the Sentinel® Cerebral Protection System device versus control patients (1.1 percent versus 3.6 percent, p=0.03).
- In multi-variate analysis, TAVR procedures performed without the use of a EP device was found to be an independent predictor of stroke within 7 days (p=0.04).

The aim of the MISTRAL–C study was to determine if the Sentinel® Cerebral Protection System affects new brain lesions and neurocognitive performance after TAVR procedures. The study was designed as a multi-center, double-blind, randomized trial enrolling patients who were diagnosed with symptomatic severe aortic stenosis and 1:1 randomization to TAVI patients treated with or without the Sentinel® Cerebral Protection System. From January 2013 to August 2015, 65 patients were enrolled in the study. Patients ranged in age from 77 years old to 86 years old, 15 (47 percent) were female and 17 (53 percent) were male patients randomized to the Sentinel® Cerebral Protection System group and 16 (49 percent) were female and 17 (51 percent) were male patients randomized to the control group. There were 3 mortalities between 5 days and 6 months post-procedure for the Sentinel® Cerebral Protection System group. There were no strokes reported for the Sentinel® Cerebral Protection System group. There were 7 mortalities between 5 days and 6 months post-procedure for the control group. There were 2 strokes reported for the control group. Patients underwent DW–MRI and neurological examination, including neurocognitive testing 1 day before and 5 to 7 days after TAVI. Follow-up DW–MRI and neurocognitive testing was completed in 57 percent of TAVI patients treated with the Sentinel® Cerebral Protection System and 80 percent for the group of TAVI patients treated without the Sentinel® Cerebral Protection System. New brain lesions were found in 78 percent of the patients with follow-up MRI. According to the applicant, patients treated with the Sentinel® Cerebral Protection System had numerically fewer new lesions and a smaller total lesion volume (95 mm3 versus 197 mm3). Overall, 27 percent of the patients treated with the Sentinel® Cerebral Protection System and 13 percent of the patients treated in the control group had no new lesions. Ten or more new brain lesions were found only in the patients treated in the control group (20 percent in the control group versus 0 percent in the Sentinel® Cerebral Protection System group, p=0.03). Neurocognitive deterioration was present in 4 percent of the patients treated with the Sentinel® Cerebral Protection System versus 27 percent of the patients treated without (p=0.017). The filters captured debris in all of the patients treated with Sentinel® Cerebral Protection System device.

In the Ulm study, the primary outcome was a composite of all-cause mortality or stroke at 7 days, and occurred in 2.1 percent of the Sentinel® Cerebral Protection System group versus 6.8 percent of the control group (p=0.01, number needed to treat (NNT)=21). Use of the Sentinel® Cerebral Protection System device was associated with a 2.2 percent absolute risk reduction in mortality with NNT 45. Composite endpoint of major adverse cardiac and cerebrovascular events (MACCE) was found in 2.1 percent of those patients undergoing a TAVR procedure with the use of the Sentinel® Cerebral Protection System device versus 7.9 percent in the control group (p=0.01). Similar but statistically nonsignificant trends were found in the SENTINEL® study, with rate of MACCE of 7.3 percent in the Sentinel® Cerebral Protection System group versus 9.9 percent in the control group (p=0.41).

The applicant reported that the four studies discussed above that evaluated the Sentinel® Cerebral Protection System device have limitations because they are either small, nonrandomized and/or had significant loss to follow-up. In the proposed rule, we stated that a meta-analysis of EP device studies, the majority of which included use of the Sentinel® Cerebral Protection System device, found that use of cerebral EP devices was associated with a nonsignificant reduction in stroke and death.[165] After further review, we realize we misquoted the statement made in the study. The meta-analysis from 2016 actually concluded the following: ''Although the differences in overt stroke were not significant, use of intraoperative EP was associated with a numeric stroke reduction, which may become significant in larger RCTs powered for hard endpoints.'' We note that we provide an updated discussion of this meta-analysis in our response to comments below.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20338), we stated

[165] Giustino, G., et al., ''Neurological Outcomes With Embolic Protection Devices in Patients Undergoing Transcatheter Aortic Valve Replacement,'' *Journal of the American College of Cardiology: Cardiovascular Interventions,* 2016, vol. 9(20), pp. 2124–2133.

we were concerned that the use of cerebral protection devices may not be associated with a significant reduction in stroke and death. We noted that the SENTINEL® study, although a randomized study, did not meet its primary endpoint, as illustrated by nonstatistically significant reduction in new lesion volume on MRI or nondisabling strokes within 30 days (5.6 percent stroke rate in the Sentinel® Cerebral Protection System device group versus a 9.1 percent stroke rate in the control group at 30 days; p=0.25). We also noted that only with a post-hoc analysis of the SENTINEL® study data were promising trends noted, where the device use was associated with a 63 percent reduction in stroke events at 72 hours (p=0.05). Additionally, although there was a statistically significant difference between the patients treated with and without cerebral embolic protection in the composite of all-cause mortality or stroke at 7 days, the Ulm study was a nonrandomized study and propensity matching was performed during analyses. We stated we are concerned that studies involving the Sentinel® Cerebral Protection System may be inconclusive regarding whether the device represents a substantial clinical improvement for patients undergoing TAVR procedures. We also stated we are concerned that the SENTINEL® studies did not show a substantial decrease in neurological complications for patients undergoing TAVR procedures. We invited public comments on whether the Sentinel® Cerebral Protection System meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments in response to the concerns we raised in the proposed rule. Specifically, in the proposed rule, we noted the following:

- The SENTINEL® study, although a randomized study, did not meet its primary endpoint as illustrated by non-statistically significant reduction in new lesion volume on MRI or non-disabling strokes within 30 days (5.6 percent stroke rate in the Sentinel® Cerebral Protection System device group versus a 9.1 percent stroke rate in the control group at 30 days; p=0.25).
- Only with a post-hoc analysis of the SENTINEL® study data were promising trends noted where the device use was associated with a 63 percent reduction in stroke events at 72 hours (p=0.05).

With regard to the above, the applicant responded and explained the following with respect to the SENTINEL® trial:

- The SENTINEL® trial's success criteria were designed with two primary efficacy endpoints that were a surrogate imaging endpoint combination of: (1) Observed reduction of 30 percent in new lesion volume on MRI; and (2) statistical reduction in new lesion volume on MRI. The applicant indicated that the trial was successful in demonstrating a 42 percent reduction in new lesion volume, but as CMS pointed out, it did not, on its own, reach statistical significance, which the applicant stated was because of, in part, the surrogate nature of the endpoint as well as the higher than expected variability. The applicant noted that the variability resulted from the following sources: (1) Variability in the MRI data, in part due to the variability in the allowed time window of 2 to 7 days, logistics of scheduling follow-up MRIs within this time window for elderly patients, and the transient nature of the DW–MRI signal over time which made the signal decay rate very noisy; (2) variability due to multiplicity (total of four types) of TAVR valve types (including balloon expandable and self-expanding) introduced mid-course into the trial (the trial was powered for only two types of TAVR valves originally), which behaved differently and required different procedural parameters in terms of pre-dilatation or post-dilatation and repositioning; and (3) variability in the patient baseline lesion volumes burden or white matter disease, which was unaccounted for because this was new science generated as a result of this trial [166] that has now been published, and a related manuscript [167] submitted and in review.
- In retrospect, the SENTINEL® trial was underpowered for the surrogate efficacy endpoint. However, according to the applicant, a meta-analysis of all three randomized trials of Claret dual-filter technology in TAVR using MRI endpoints by Latib, et al. (2017), which had an increased number of patients available for analysis, did show statistically significant reduction in new lesion volume.
- The primary safety endpoint for the SENTINEL® trial was occurrence of all Major Adverse Cardiac and Cerebrovascular Events (MACCE) at 30 days compared to a historical performance goal, and the Sentinel® Cerebral Protection System met this endpoint for noninferiority (p<0.001) and superiority (p=0.0026)
- The SENTINEL® trial was not designed to be powered to show a statistically significant reduction in procedural stroke between trial arms at 30-days; therefore, it did not reach statistical significance. However, according to the applicant, investigators were encouraged by the trend to lower rates of stroke in the Sentinel® arms (5.6 percent) as compared to Control (9.1 percent) at 30-days. Additionally, more than 60 percent of ischemic neurological events in TAVR occur during the acute peri procedural phase as a result of thromboembolic debris released from manipulation of TAVR and accessory devices in a heavily atherosclerotic vascular and valvular structures.[168] As a result, the SENTINEL® investigators and FDA Advisory Panel at large were, according to the applicant, keen to temporally analyze the stroke data in two phases (acute and subacute). The applicant stated that this post-hoc analysis demonstrated that the acute phase is the critical period where cerebral protection offers the most protection against any incidence of stroke by demonstrating a significant treatment effect of 63 percent at <72 hours. This window was less confounded by events that may occur later in the subacute phase after a TAVR procedure as a result of new onset AF or suboptimal anticoagulation/antiplatelet regimens.

Response: We appreciate the applicant's input and have considered this information in our determination below.

Comment: With regard to CMS' concern in the proposed rule that the use of cerebral protection devices may not be associated with a significant reduction in stroke and death (as noted previously, we have corrected our statement from the proposed rule on the findings of the meta-analysis on which this statement was based), the applicant stated that the meta-analysis of 180 randomized patients from 3 small randomized trials from 2016 did not include the results from the SENTINEL® randomized trial, which were not available at the time, but the authors of this study (Giustino, G., et al.[169]) subsequently published in 2017 an updated systematic review and meta-analysis of 5 randomized trials totaling 625 patients (in which the SENTINEL® trial contributed 363 patients to the 625

[166] Lazar, R., et al., ''Neurocognition and Cerebral Lesion Burden in High-Risk Patients Before Undergoing Transcatheter Aortic Valve Replacement: Insights From the SENTINEL Trial,'' *J Cardiovasc Interv,* February 26, 2018, vol. 11(4), pp. 384–392.

[167] Dwyer, M., et al., ''Pre-procedural white matter lesion burden predicts MRI outcomes in transcatheter aortic valve replacement (TAVR): The SENTINEL Trial.''

[168] Kapadia, S., et al., *Circ Cardiovasc Interv,* September 2016, vol. 9(9), pp. 1–10.

[169] Giustino, G., Sabato, S., Mehran, R., Faggioni, M., and Dangas, G., ''Cerebral Embolic Protection During TAVR, A Clinical Event Meta-Analysis,'' *JACC,* 2017, vol. 69, pp. 465–66.

patients in the 2017 meta-analysis). The 2017 Guistino, G., et al. meta-analysis evaluated EP during TAVR, including SENTINEL®, and showed that at 30 days EP was associated with a lower risk of death or stroke on relative (6.4 percent versus 10.8 percent; RR: 0.57; 95 percent CI: 0.33 to 0.98; p=0.04; I2=0 percent) and absolute (ARD: −4.4 percent; 95 percent CI: −9.0 percent to −0.1 percent; NNT=22) terms (that is, for every 22 patients assigned to an EP device, 1 death or stroke event may be averted). According to the applicant, these findings suggest that EP may be a clinically relevant adjunctive strategy in patients undergoing TAVR procedures. The applicant noted that in the updated analysis, the authors of Giustino, G., et al. stated that, in conclusion, the totality of the data suggests that use of EP during TAVR appears to be associated with a significant reduction in death or stroke.

The applicant stated that an independent group recently published a similar meta-analysis of the same 5 randomized trials in the *Journal of Thoracic Disease* [170] and reached the same conclusion as Giustino, G., et al. The applicant indicated that a third meta-analysis has been accepted that is in press, which includes 5 randomized and prospective observational studies, totaling 1,160 TAVR patients, in which cerebral embolic protection was used in 661.[171] According to the applicant, the authors found that the risk of strokes within the first week of TAVR was significantly lower in the CPD group [0.56(95 percent CI 0.33–0.96)]; p=0.034. The authors concluded that TAVR with CPD is associated with decreased strokes within 1 week of follow-up and not associated with an increase in peri-procedural adverse events. The applicant stated that it is important to note that the effectiveness of cerebral protection devices is during the procedure and best measured within a week or less of the procedure. The applicant further noted that events occurring after 1 week, up to and beyond 30 days are often associated with new-onset atrial fibrillation associated with the valve implant, inadequate anticoagulation regimen, and unrelated background risk.

Response: In the comment above, the applicant focused on the 2017 meta-analysis from Giustino, G., et al.[172] and stated, as indicated in the summary above, that the authors concluded that the totality of the data suggests that use of EP during TAVR appears to be associated with a significant reduction in death or stroke.

However, in April 2018, based on updated data, the authors for the 2017 Giustino, G., et al. publication updated their conclusion of the 2017 meta-analysis and stated the following: ''In conclusion, the totality of the data suggests that use of EP during TAVR appears to be associated with a nonsignificant trend towards reduction in death or stroke.'' Therefore, we continue to be concerned that the use of cerebral protection devices may not be associated with a significant reduction in stroke and death beyond 7 days (which is the focus of the meta-analysis). However, we note, as discussed below, the applicant has responded with additional information regarding the reduction in death or stroke within 7 days.

Comment: In response to CMS' concerns as indicated in the proposed rule that the studies involving the Sentinel® Cerebral Protection System may be inconclusive regarding whether the device represented a substantial clinical improvement for patients undergoing TAVR procedures, the applicant referenced the academic study from the University of Ulm in Germany, which was independently funded and conducted, and published by Seeger, J., et al.[173] The applicant stated that this study is an example of performance in routine clinical use, as investigators used the Sentinel® Cerebral Protection System in 280 consecutive TAVR patients and compared results in a propensity-score analysis to recent unprotected patients from the same institution, with the same operators, and the same independent neurologist who adjudicated all the neurological events. According to the applicant, this approach gives information about performance in a broad set of patients seen in clinical practice, unrestricted by inclusion and exclusion criteria of randomized trials. The applicant further explained that the academic study from the University of Ulm used propensity-score analysis based on an optimal matching attempt by adjusting/matching up to 14 key confounders after performing a comprehensive multivariable analysis by stepwise forward regression to evaluate independent predictors of clinical events. The applicant explained that propensity-score analyses are well accepted in the interventional cardiology and medical device community at large. The applicant further stated that propensity-score analyses are an alternative when randomized trials are not possible, practical, or ethical. For example, according to the applicant, in the case of cerebral embolic protection, investigators have struggled with ethical and moral imperatives of randomizing when many patients do not want to enter a randomized trial when they know that the device is already commercially available.

The applicant added that it believed that the 1 to 7 day time period is the most appropriate for evaluation of cerebral protection efficacy because it is difficult to accurately diagnose neurological impairment immediately post-operatively when the patient is recovering from the effects of anesthesia and some sequelae of embolic events can take time to evolve and be diagnosed, and conversely time points later than a week or so are confounded by strokes unrelated to embolic events during the index procedure, such as New Onset of Atrial Fibrillation (NOAF), suboptimal concomitant anti-platelet/anticoagulation medication, and other comorbid history of the patients.

The applicant noted that, in the past few months, a number of TAVR centers have begun to share their data from routine practice using the Sentinel® Cerebral Protection System in TAVR procedures, which are in line with the clinical event reductions seen in the aforementioned trials. The applicant provided information from the following TAVR centers:

- Erasmus Medical Center (Rotterdam, The Netherlands) demonstrated comprehensive and systematic analysis of 747 TAVR patients treated with or without the use of the Sentinel® EP with independent neurological adjudication of the events. The applicant noted that, as presented by Nicolas van Mieghem, MD at the Joint Interventional Meeting (JIM) 2018 and Cardiovascular Research Technologies (CRT) 2018 conferences in February and March, there was an 80 percent relative risk reduction from 5 percent (23/453) to 1 percent (3/294) for all-stroke + TIA at 3 days with use of Sentinel® (p<0.01).
- Data from Cedars-Sinai Medical Center in Los Angeles, CA from a

[170] Wang N and Phan K, ''Cerebral protection devices in transcatheter aortic valve replacement: a clinical meta-analysis of randomized controlled trials'', *J Thorac Dis,* 2018;10(3):1927–1935.

[171] Mohananey D, et al. ''Safety and Efficacy of Cerebral Protection Devices in Transcatheter Aortic Valve Replacement: A Clinical End-points Meta-analysis.'' *Cardiovasc Revasc Med,* 2018 Feb 16.

[172] Giustino, G., Sabato, S., Mehran, R., Faggioni, M., and Dangas, G., ''Cerebral Embolic Protection During TAVR, A Clinical Event Meta-Analysis,'' *JACC,* 2017, vol. 69, pp. 465–66.

[173] Seeger, J., et al., ''Cerebral Embolic Protection During Transfemoral Aortic Valve Replacement Significantly Reduces Death and Stroke Compared With Unprotected Procedures,'' *JACC Cardiovasc Interv,* 2017.

comprehensive and systematic analysis of 419 TAVR patients treated with or without the use of the Sentinel® EP results show: 78 percent relative risk reduction from 6.3 percent (8/128) to 1.4 percent (4/291) for all-stroke at 7 days with use of Sentinel® (HR 0.22 (95 percent CI: 0.06 to 0.74, p=0.01).

- Data from Pinnacle Health (Harrisburg, PA) as presented by Hemal Gada, MD at the CMS New Technology Town Hall meeting, February 2018, demonstrated a reduction from 10 percent (7/69) 7-day stroke rate without the use of the Sentinel® to 0 percent (0/53) with the use of the Sentinel®, as of the time at the Town Hall presentation in February.

The applicant concluded that the clinical evidence is robust, consistent, reliable, and repeatable and that the totality of the data shows that Sentinel® Cerebral Protection System represents a substantial clinical improvement for patients undergoing TAVR procedures.

Response: We appreciate the applicant's response to our concerns and its additional input. We agree with the applicant that the 1 to 7 day time period is the most appropriate for evaluation of cerebral protection efficacy. Specifically, as the commenter noted, it is difficult to accurately diagnose neurological impairment immediately post-operatively when the patient is recovering from the effects of anesthesia and some sequelae of embolic events can take time to evolve and be diagnosed. Conversely, time points later than 7 days are confounded by strokes unrelated to embolic events during the index procedure, such as NOAF, suboptimal concomitant anti-platelet/anticoagulation medication, and other comorbid history of the patients. We believe that the use of propensity matching in the Ulm study supports the statistical difference of all-cause mortality or stroke at 7 days. Specifically, as stated above, in the Ulm study, the primary outcome was a composite of all-cause mortality or stroke at 7 days, and occurred in 2.1 percent of the Sentinel® Cerebral Protection System group versus 6.8 percent of the control group (p=0.01, number needed to treat (NNT)=21). Use of the Sentinel® Cerebral Protection System device was associated with a 2.2 percent absolute risk reduction in mortality with NNT=45. Composite endpoint of major adverse cardiac and cerebrovascular events (MACCE) was found in 2.1 percent of those patients undergoing a TAVR procedure with the use of the Sentinel® Cerebral Protection System device versus 7.9 percent in the control group (p=0.01). Therefore, we believe the data provided by the applicant showing reduced mortality and stroke within 7 days of a TAVR procedure as compared to patients undergoing a TAVR procedure without a cerebral protection device demonstrate that the Sentinel® Cerebral Protection System represents a substantial clinical improvement.

After consideration of the public comments we received, we have determined that the Sentinel® Cerebral Protection System meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2019. Cases involving the use of the Sentinel® Cerebral Protection System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code X2A5312. In its application, the applicant estimated that the cost of the Sentinel® Cerebral Protection System is $2,400. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the Sentinel® Cerebral Protection System is $1,400 for FY 2019.

i. The AquaBeam System (Aquablation)

PROCEPT BioRobotics Corporation submitted an application for new technology add-on payments for the AquaBeam System (Aquablation) for FY 2019. According to the applicant, the AquaBeam System is indicated for the use in the treatment of patients experiencing lower urinary tract symptoms caused by a diagnosis of benign prostatic hyperplasia (BPH). The AquaBeam System consists of three main components: a console with two high-pressure pumps, a conformal surgical planning unit with trans-rectal ultrasound imaging, and a single-use robotic hand-piece.

The applicant reported that The AquaBeam System provides the operating surgeon a multi-dimensional view, using both ultrasound image guidance and endoscopic visualization, to clearly identify the prostatic adenoma and plan the surgical resection area. Based on the planning inputs from the surgeon, the system's robot delivers Aquablation, an autonomous waterjet ablation therapy that enables targeted, controlled, heat-free and immediate removal of prostate tissue used for the purpose of treating lower urinary tract symptoms caused by a diagnosis of BPH. The combination of surgical mapping and robotically-controlled resection of the prostate is designed to offer predictable and reproducible outcomes, independent of prostate size, prostate shape or surgeon experience.

In its application, the applicant indicated that benign prostatic hyperplasia (BPH) is one of the most commonly diagnosed conditions of the male genitourinary tract [174] and is defined as the ''. . . enlargement of the prostate due to benign growth of glandular tissue . . .'' in older men.[175] BPH is estimated to affect 30 percent of males that are older than 50 years old.[176] [177] BPH may compress the urethral canal possibly obstructing the urethra, which may cause symptoms that effect the lower urinary tract, such as difficulty urinating (dysuria), hesitancy, and frequent urination.[178] [179] [180]

The initial treatment for a patient who has been diagnosed with BPH is watchful waiting and medications.[181] Symptom severity, as measured by one test, the International Prostate Symptom Score (IPSS), is the primary measure by which surgery necessity is decided.[182]

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[174] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

[175] Gilling, P., Anderson, P., and Tan, A., ''Aquablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: 1-Year results,'' *The Journal of Urology,* 2017, vol. 197, pp. 156–1572.

[176] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[177] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[178] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[179] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[180] Roehrborn, C., Gilling, P., Cher, D., and Templin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue),'' Redwood City: PROCEPT BioRobotics Corporation, 2017.

[181] Ibid.

[182] Cunningham, G.R., Kadmon, D., 2017, ''Clinical manifestations and diagnostic evaluation

Many techniques exist for the surgical treatment of patients who have been diagnosed with BPH, and these surgical treatments differ primarily by the method of resection: electrocautery in the case of Transurethral Resection of the Prostate (TURP), laser enucleation, plasma vaporization, photoselective vaporization, radiofrequency ablation, microwave thermotherapy, and transurethral incision [183] are among the primary methods. TURP is the primary reference treatment for patients who have been diagnosed with BPH.[184] [185] [186] [187] [188].

According to the applicant, while the TURP procedure achieves alleviation of the symptoms that affect the lower urinary tract associated with a diagnosis of BPH, morbidity rates caused by adverse events are high following the procedure. The TURP procedure has a well-documented history of associated adverse effects, such as hematuria, clot retention, bladder wall injury, hyponatremia, bladder neck contracture, urinary incontinence, and retrograde ejaculation.[189] [190] [191] [192] [193] The likelihood of both adverse events and long-term morbidity related to the TURP procedure increase with the size of the prostate.[194]

The applicant asserted that the AquaBeam System provides superior safety outcomes as compared to the TURP procedure, while providing non-inferior efficacy in treating the symptoms that affect the lower urinary tract associated with a diagnosis of BPH. The applicant further stated that the AquaBeam System yields consistent and predictable procedure and resection times regardless of the size and shape of the prostate and the surgeon's experience. Lastly, according to the applicant, the AquaBeam System provides increased efficacy and safety for larger prostates as compared to the TURP procedure.

With respect to the newness criterion, FDA granted the applicant's *De Novo* request on December 21, 2017, for use in the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. The applicant stated that the AquaBeam System was made available on the U.S. market immediately after the FDA granted the *De Novo* request. Therefore, we stated in the proposed rule that if approved for new technology add-on payments, the newness period is considered to begin on December 21, 2017. CMS has approved the use of ICD–10–PCS code XV508A4 (Destruction of prostate using robotic waterjet ablation, via natural or artificial opening endoscopic, new technology group 4), effective October 1, 2018, to uniquely identify procedures involving the AquaBeam System.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that the AquaBeam System is the first technology to deliver treatment to patients who have been diagnosed with BPH for the symptoms that effect the lower urinary tract caused by BPH via Aquablation therapy. The AquaBeam System utilizes intra-operative image guidance for surgical planning and then Aquablation therapy to robotically resect tissue utilizing a high-velocity waterjet. According to the applicant, all other BPH treatment procedures only utilize cystoscopic visualization, whereas the AquaBeam System utilizes Aquablation therapy, a combination of cystoscopic visualization and intra-operative image guidance. According to the applicant, the AquaBeam System's use of Aquablation therapy qualifies it as the only technology to utilize a high-velocity room temperature waterjet for tissue resection, while most other BPH surgical procedures utilize thermal energy to resect prostatic tissue, or require the implantation of clips to pull back prostatic tissue blocking the urethra. Lastly, according to the applicant, all other surgical modalities are executed by the operating surgeon, while the AquaBeam System allows planning by the surgeon and utilization of Aquablation therapy ensures accurate and efficient tissue resection is autonomously executed by the robot.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that potential cases representing potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy technique will ultimately map to the same MS–DRGs as cases for existing BPH treatment options.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant

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of benign prostatic hyperplasia,'' 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnostic-evaluation-of-benign-prostatic-hyperplasia?search=cunningham%20kadmon%202017%20benign%20prostatic&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2.*

[183] Ibid.

[184] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

[185] Cunningham, G.R., Kadmon, D.,''Clinical manifestations and diagnostic evaluation of benign prostatic hyperplasia,'' 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnostic-evaluation-of-benign-prostatic-hyperplasia?search=cunningham%20kadmon%202017%20benign%20prostatic&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2.*

[186] Mamoulakis, C., Efthimiou, I., Kazoulis, S., Christoulakis, I., and Sofras, F., ''The Modified Clavien Classification System: A standardized platform for reporting complications in transurethral resection of the prostate,'' *World Journal of Urology,* 2011, vol. 29, pp. 205–210.

[187] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[188] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[189] Roehrborn, C., Gilling, P., Cher, D., and Templin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue), Redwood City: PROCEPT BioRobotics Corporation, 2017.

[190] Cunningham, G.R., & Kadmon, D., 2017, ''Clinical manifestations and diagnostic evaluation of benign prostatic hyperplasia,'' 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnostic-evaluation-of-benign-prostatic-hyperplasia?search=cunningham%20kadmon%202017%20benign%20prostatic&source=search_result&selected Title=2~150&usage_type=default&display_rank=2.*

[191] Mamoulakis, C., Efthimiou, I., Kazoulis, S., Christoulakis, I., Sofras, F., ''The Modified Clavien Classification System: A standardized platform for reporting complications in transurethral resection of the prostate,'' *World Journal of Urology,* 2011, vol. 29, pp. 205–210.

[192] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[193] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[194] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

stated that the AquaBeam System's Aquablation therapy will ultimately treat the same patient population as other available BPH treatment options. The applicant asserted that the AquaBeam System's Aquablation therapy has been shown to be more effective and safer than the TURP procedure for patients with larger prostate sizes. The applicant stated that prostates 80 ml or greater in size are not appropriate for the TURP procedure and, therefore, more intensive procedures such as surgery are required. Furthermore, the applicant claimed that the AquaBeam System's Aquablation therapy is particularly appropriate for smaller prostate sizes, ~30 ml, due to increased accuracy provided by both the computer assistance and ultrasound visualization.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20346), we stated we had the following concerns regarding whether the AQUABEAM System meets the newness criterion. Currently, there are many treatment options that utilize varying forms of ablation, such as mono and bipolar TURP procedures, laser, microwave, and radiofrequency, to treat the symptoms associated with a diagnosis of BPH. We stated that we were concerned that, while this device utilizes water to perform any tissue removal, its mechanism of action may not be different from that of other forms of treatment for patients who have been diagnosed with BPH. Further, the use of water to perform tissue removal in the treatment of associated symptoms in patients who have been diagnosed with BPH has existed in other areas of surgical treatment prior to the introduction of this product (for example, endometrial ablation and wound debridement). In addition, the standard operative treatment, such as with the TURP procedure, for patients who have been diagnosed with BPH is to widen the urethra compressed by an enlarged prostate in an effort to alleviate the negative effects of an enlarged prostate. Like other existing methods, the AQUABEAM System's Aquablation therapy also ablates tissue to relieve compression of the urethra. Additionally, while the robotic arm and computer programing may result in different outcomes for patients, we stated we were uncertain that the use of the robotic hand and computer programming result in a new mechanism of action. We invited public comments on this issue.

We also invited public comments on whether the AQUABEAM System's Aquablation therapy is substantially similar to existing technologies and whether it meets the newness criterion.

Comment: The applicant stated in regard to the beginning of the newness period that, while the AQUABEAM System received approval from the FDA for its *De Novo* request on December 21, 2017, local non-coverage determinations in the Medicare population resulted in the first case being delayed until April 19, 2018. Therefore, the applicant believed that the beginning date of the newness period should begin on April 9, 2018, instead of the date FDA granted the *De Novo* request.

Response: With regard to the beginning of the technology's newness period, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data begin to become available. While local non-coverage determinations may limit the use of a technology in different regions in the country, a technology may be available in regions where no local non-coverage decision existed (with data beginning to become available). Additionally, similar to the discussion in the FY 2006 IPPS final rule (70 FR 47349), we do not consider how frequently the medical service or technology has been used in the Medicare population in our determination of newness. We welcome further information from the applicant for consideration in future rulemaking regarding the beginning of the newness period.

Comment: The applicant reiterated in response to CMS' concerns regarding the mechanism of action of the AquaBeam System that it is novel because of: (1) The real-time multi-dimensional imaging which enables improved clinical decision-making and personalized treatment planning; (2) the accuracy of the autonomous robotic hand piece which autonomously executes the surgeon's treatment plan for controlled and precise tissue removal; and (3) the heat free submerged waterjet used to resect prostatic tissue which avoids the possibility of complications arising from thermal injury, and that these qualities result in consistently safe and effective outcomes for patients and greatly reduced chances of side effects when compared to TURP and further provide a minimally invasive transurethral alternative to open prostatectomy (OP) in large prostates. The applicant further indicated that each of the three components, individually, are unique to existing BPH surgical options and the combination of the three further represents the novelty of the technology's mechanism of action in the treatment of BPH.

The applicant also believed that CMS' concerns that the use of water to perform tissue removal may not be different than other forms of tissue removal in treating BPH, the use of water has been used in other areas such as endometrial ablation and wound debridement, and there is uncertainty that the use of a robotic hand and computer programming result in a new mechanism of action reflect a broad interpretation of mechanism of action. The applicant stated that the notion that all ablation techniques are similar ignores the fact that ablation is used to treat a variety of illnesses and conditions throughout the body using a variety of technological approaches with varying effectiveness. The applicant reiterated that it believed the three mechanisms of action of the AquaBeam System are unique in prostate treatment when compared to all other existing prostate treatments, and the AquaBeam System is the only ablation technique that utilizes room-temperature water whereas other ablative approaches such as TURP, laser vaporization (PVP), laser resection (HoLEP/ThuLEP), microwave necrosis (TUMT), and mechanical radio-frequency resection (open simple prostatectomy) utilize heat as the primary mechanism of action. The applicant explained that the waterjet mechanism of action has the advantage of sparing sensitive tissues around the prostate like the bladder neck, verumontanum, and nerve and vascular tissues, whereas other ablative approaches are tissue agnostic. The applicant also disagreed with CMS' comparison of Aquablation therapy to wound debridement and tissue dissection because the surgical goals are different. The applicant stated that, in the application of wound debridement the surgical goal is wound cleansing and debris removal using a waterjet, and in tissue dissection, the goal is tissue separation or disassociating the parenchymal connective tissue. The applicant further stated, in contrast, the goal of all BPH surgical procedures is to remove excessive prostatic tissue. The applicant reiterated that the use of the robotic handpiece and computer programming is the essence of the AquaBeam System to deliver Aquablation therapy, and these components allow the surgeon to visualize the prostate in a way that was previously unavailable in BPH surgery to precisely determine the specific prostatic tissue to resect, which is not possible with existing technologies. The applicant further indicated that the

robotic handpiece autonomously executes the tissue resection, which has been clinically shown to provide consistent results, regardless of the prostate size or surgeon experience. The applicant believed that this differs from other treatment modalities, which rely on surgeon experience that introduces more variability into the procedure. The applicant stated that the robotic handpiece also facilitates the use of a minimally invasive transurethral approach to treat large prostates in which the vast majority of other transurethral technologies are not recommended.

The applicant also stated that CMS has not historically applied such a broad definition when defining and evaluating mechanism of action, as in example, for new technology add-on payments for the INTUITY and Perceval valves that are aortic valve replacements that share the surgical goal of providing the patient with a functioning aortic valve. The applicant noted that, CMS determined the mechanisms of action of the INTUITY and Perceval valves in achieving the surgical goal were not substantially similar to treatments that were available at the time, and both technologies were approved for new technology add-on payments. In addition, the applicant stated that drug-coated balloons (a new combination of existing balloon and existing drugs) have a surgical goal similar to non-drug coated balloons of creating a lumen in the artery, and CMS determined that the drug-coated balloons used a different mechanism of action and similarly approved both applications for new technology add-on payments. The applicant explained that, in the case of Aquablation therapy, the surgical goal is similar to other BPH technologies in creating an opening in the prostatic urethra. However, the applicant indicated, as described above, the mechanism of action is different from any other technologies currently available. The applicant believed that, applying the same criterion as applied in the historical examples, the AquaBeam System meets the criteria for approval of new technology add-on payments.

The applicant also stated that for large prostates, the MS–DRG assignment for potential cases representing patients eligible for treatment involving the AquaBeam System would be similar to normal transurethral prostate treatments, which is different than the MS–DRG assignment for open prostatectomy (OP). The applicant believed that potential cases involving Aquablation therapy would group to MS–DRGs 713 and 714 (Transurethral Prostatectomy) and open simple prostatectomy procedures would group to MS–DRGs 707 and 708 (Major Male Pelvic Procedures). The applicant stated that, for prostates sized less than 80 ml, potential cases involving Aquablation therapy would map to the same MS–DRGs as other transurethral procedures, and for large prostates greater than 80 ml in size, procedures involving Aquablation therapy in lieu of an open prostatectomy would result in a different MS–DRG assignment. Therefore, the applicant believed AquaBeam System's Aquablation therapy meets this criterion under substantial similarity.

Other commenters believed that the AquaBeam System met the newness criterion. The commenters stated that the use of imaging and ultrasound, the autonomous robotic execution of the procedure, and the use of room temperature water rather than heat, combined make the AquaBeam System a novel treatment for BPH. Another commenter further indicated that many other technologies are surgeon- and experience-dependent, whereas the AquaBeam System's image guided procedure with robotic execution allows for a greater degree of precision and monitoring of the treatment independent of experience or expertise. The commenter believed that the addition of image guidance and robotic execution of the procedure leads to consistent results independent of surgeon experience.

Response: We appreciate the commenters' input. After consideration of these comments, we agree that the AquaBeam System has a unique mechanism of action because it is the first to use waterjet ablation therapy that enables targeted, controlled, heat-free and immediate removal of prostate tissue used for the purpose of treating lower urinary tract symptoms caused by a diagnosis of BPH. Therefore, after consideration of the public comments we received, we agree that the AquaBeam System meets the newness criterion and the newness period beginning date is April 19, 2018.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. Given that at the time of the analysis, the AquaBeam System's Aquablation therapy procedure did not have a unique ICD–10–PCS procedure code, the applicant searched the FY 2016 MedPAR data file for cases with the following current ICD–10–PCS codes describing other BPH minimally invasive procedures to identify potential cases representing potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy: 0V507ZZ (Destruction of prostate, via natural or artificial opening), 0V508ZZ (Destruction of prostate, via natural or artificial opening endoscopic), 0VT07ZZ (Resection of prostate, via natural or artificial opening), and 0VT08ZZ (Resection of prostate, via natural or artificial opening endoscopic). The applicant identified a total of 133 MS–DRGs using these ICD–10–PCS codes.

In order to calculate the standardized charges per case, the applicant conducted two analyses, based on 100 percent and 75 percent of identified claims in the FY 2016 MedPAR data file. The applicant based its analysis on 100 percent of claims mapping to 133 MS–DRGs, and 75 percent of claims mapping to 6 MS–DRGs. The cases identified in the 75 percent analysis mapped to MS–DRGs 665 (Prostatectomy with MCC), 666 (Prostatectomy with CC), 667 (Prostatectomy without CC/MCC), 713 (Transurethral Prostatectomy with CC/MCC), 714 (Transurethral Prostatectomy without CC/MCC), and 988 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC). In situations in which there were fewer than 11 cases for individual MS–DRGs in the MedPAR data file, a value of 11 was imputed to ensure confidentiality for patients. When evaluating 100 percent of the cases identified, the applicant included low-volume MS–DRGs that had equal to or less than 11 total cases to represent potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy in order to calculate the average case-weighted unstandardized and standardized charge amounts. The 75 percent analysis removed those MS–DRGs with 11 cases or less representing potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy, resulting in only 6 of the 133 MS–DRGs remaining for analysis. A total of 8,449 cases were included in the 100 percent analysis and 6,285 cases were included in the 75 percent analysis.

Using the 100 percent and 75 percent samples, the applicant determined that the average case-weighted unstandardized charge per case was $69,662 and $47,475, respectively. The applicant removed 100 percent of total charges associated with the service category ''Medical/Surgical Supply Charge Amount'' (which includes revenue centers 027x and 062x) because the applicant believed that it was the most conservative choice, as this

amount varies by MS–DRG. The applicant stated that the financial impact of utilizing the AquaBeam System's Aquablation therapy on hospital resources other than on ''Medical Supplies'' is unknown at this time. Therefore, a value of $0 was used for charges related to the prior technology.

The applicant standardized the charges, and inflated the charges using an inflation factor of 1.09357, from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524). The applicant then added the charges for the new technology. The applicant computed a final inflated average case-weighted standardized charge per case of $69,588 for the 100 percent sample, and $51,022 for the 75 percent sample. The average case-weighted threshold amount was $59,242 for the 100 percent sample, and $48,893 for the 75 percent sample. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for both analyses, the applicant maintained that the technology met the cost criterion.

We invited public comment regarding whether the technology meets the cost criterion.

Comment: The applicant reiterated the results of the cost analysis detailed in the FY 2019 IPPS/LTCH PPS proposed rule, and believed that the AquaBeam System meets the cost criterion.

Response: We appreciate the applicant's input and agree that the AquaBeam System meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the Aquablation therapy provided by the AquaBeam System represents a substantial clinical improvement over existing treatment options for symptoms associated with the lower urinary tract for patients who have been diagnosed with BPH. Specifically, the applicant stated that the AquaBeam System's Aquablation therapy provides superior safety outcomes compared to the TURP procedure, while providing non-inferior efficacy in treating the symptoms that effect the lower urinary tract associated with a diagnosis of BPH; the AquaBeam System's delivery of Aquablation therapy yields consistent and predictable procedure and resection times regardless of the size and shape of the prostate or the surgeon's experience; and the AquaBeam System's Aquablation therapy demonstrated superior efficacy and safety for larger prostates (that is, prostates sized 50 to 80 ml) as compared to the TURP procedure.

The applicant provided the results of one Phase I and one Phase II trial published articles, the WATER Study Clinical Study Report, and a meta-analysis of current treatments with its application as evidence for the substantial clinical improvement criterion.

According to the applicant, the first study [195] enrolled 15 nonrandomized patients with a prostate volume between 25 to 80 ml in a Phase I trial testing the safety and feasibility of the AquaBeam System's Aquablation therapy; all patients received the AquaBeam System's Aquablation therapy. This study, a prospective, nonrandomized study, enrolled men who were 50 to 80 years old who were affected by moderate to severe lower urinary tract symptoms, who did not respond to standard medical therapy.[196] Follow-up assessments were conducted at 1, 3, and 6 months and included information on adverse events, serum PSA level, uroflowmetry, PVR, quality of life, and the International Prostate Symptom Score (IPSS) and International Index of Erectile Function (IIEF) scores. The primary outcome was the assessment of safety as measured by adverse event reporting; secondary endpoints focused on alleviation of BPH symptoms.[197]

The applicant indicated that 8 of the 15 patients who were enrolled in the trial had at least 1 procedure-related adverse event (for example, catheterization, hematuria, dysuria, pelvic pain, bladder spasms), which the authors reported to be consistent with outcomes from minimally-invasive transurethral procedures.[198] There were no occurrences of incontinence, retrograde ejaculation, or erectile dysfunction at 30 days.[199] Statistically significant improvement on all outcomes occurred over the 6-month period. Average IPSS scores showed a negative slope with scores of 23.1, 11.8, 9.1, and 8.6 for baseline, 1 month, 3 months, and 6 months ($p<0.01$ in all cases). Average quality of life scores, which range from 1 to 5, where 1 is better and 5 is worse, decreased from 5.0 at baseline to 2.6 at 1 month, 2.2 at 3 months, and 2.5 at 6 months. Average maximum urinary flow rate increased steadily across time points from 8.6 ml/s at baseline to 18.6 ml/s at 6 months. Lastly, average post-void residual urine volume decreased from 91 ml at baseline to 38 ml at 1 month, 60 ml at 3 months, and 30 ml at 6 months.[200]

The second study [201] presents results from a Phase II trial involving 21 men with a prostate volume between 30 to 102 ml who received treatment involving the AquaBeam System's Aquablation therapy with follow-up at 1 year. This prospective study enrolled men between the ages of 50 and 80 years old who were effected by moderate to severe symptomatic BPH.[202] The primary end point was the rate of adverse events; the secondary end points measured alleviation of symptoms associated with a diagnosis of BPH. Data was collected at baseline and at 1 month, 3 months, 6 months, and 12 months; 1 patient withdrew at 3 months. The authors asserted that the occurrence of post-operative adverse events (urinary retention, dysuria, hematuria, urinary tract infection, bladder spasm, meatal stenosis) were consistent with other minimally-invasive transurethral procedures; [203] 6 patients had at least 1 adverse event, including temporary urinary symptoms and medically-treated urinary tract infections.[204] The mean IPSS scores decreased from the baseline of 22.8 with 11.5 at 1 month, 7 at 3 months, 7.1 at 6 months, and 6.8 at 12 months and were statistically significantly different. Similarly, quality of life decreased from a mean score of 5 at baseline to 1.7 at 12 months, all time points were statistically significantly different from the baseline.

The third document provided by the applicant is the Clinical Study Report: WATER Study,[205] a prospective multi-center, randomized, blinded study. The WATER Study compared the AquaBeam System's Aquablation therapy to the TURP procedure for the treatment of lower urinary tract symptoms associated with a diagnosis of BPH. One hundred eighty one (181) patients with prostate volumes between 30 and 80 ml were randomized, 65 patients to the TURP procedure group and the other 116 to

[195] Gilling, P., Reuther, R., Kahokehr, A., Fraundorfer, M., ''Aquablation—Image-guided Robot-assisted Waterjet Ablation of the Prostate: Initial clinical experience,'' *British Journal of Urology International,* 2016, vol. 117, pp. 923–929.

[196] Ibid.

[197] Ibid.

[198] Gilling, P., Anderson, P., and Tan, A., ''Aquablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: 1-Year results,'' *The Journal of Urology,* 2017, vol. 197, pp. 156–1572.

[199] Ibid.

[200] Gilling, P., Anderson, P., and Tan, A., ''Aquablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: 1-Year results,'' *The Journal of Urology,* 2017, vol. 197, pp. 156–1572.

[201] Ibid.

[202] Ibid.

[203] Ibid.

[204] Ibid.

[205] Roehrborn, C., Gilling, P., Cher, D., Templin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue),'' Redwood City: PROCEPT BioRobotics Corporation, 2017.

the AquaBeam System's Aquablation therapy group, with 176 (97 percent of patients) continuing at 3 and 6 month follow-up, where 2 missing patients received treatment involving the AquaBeam System's Aquablation therapy and 3 received treatment involving the TURP procedure; randomization efficacy was assessed and confirmed with findings of no statistical differences between cases and controls among all characteristics measures, specifically prostate volume. Two primary endpoints were identified: (1) The safety endpoint was the proportion of patients with adverse events rates as ''probably or definitely related to the study procedure'' also classified as the Clavien-Dindo (CD) Grade 2 or higher or any Grade 1 resulting in persistent disability; and (2) the primary efficacy endpoint was a change in the IPSS score from baseline to 6 months. Three secondary endpoints were based on perioperative data and were: length of hospital stay, length of operative time, and length of resection time. The occurrences of three secondary endpoints during the 6-month follow-up were: (1) Reoperation or reintervention within 6 months; (2) evaluation of proportion of sexually active patients; and (3) evaluation of proportion of patients with major adverse urologic events.

At 3 months, 25 percent of the patients in the AquaBeam System's Aquablation therapy group and 40 percent of the patients in the TURP group had an adverse event. The difference of −15 percent has a 95 percent confidence interval of −29.2 and −1.0 percent. At 6 months, 25.9 percent of the patients in the AquaBeam System's Aquablation therapy group and 43.1 percent of the patients in the TURP group had an adverse event. The difference of −17 percent has a 95 percent confidence interval of −31.5 to −3.0 percent. An analysis of safety events classified with the CD system as possibly, probably or definitely related to the procedure resulted in a CD Grade 1 persistent event difference between −17.7 percent (favoring the AquaBeam System's Aquablation therapy) with 95 percent confidence interval of −30.1 to −7.2 percent and a CD Grade 2 or higher event difference of −3.3 percent with 95 percent confidence interval of −16.5 to 8.7 percent.

The applicant indicated that the primary efficacy endpoint was assessed by a change in IPSS score over time. While change in score and change in percentages are generally higher for the AquaBeam System's Aquablation therapy, no statistically significant differences occurred between the AquaBeam System's Aquablation therapy and the TURP procedure over time. For example, the AquaBeam System's Aquablation therapy group experienced changes in IPSS mean score by visit of 0, −3.8, −12.5, −16.0, and −16.9 at baseline, 1 week, 1 month, 3 months, and 6 months, respectively, while the TURP group had mean scores of 0, −3.6, −11.1, −14.6, and −15.1 at baseline, 1 week, 1 month, 3 months, and 6 months, respectively.

Lastly, the applicant indicated that secondary endpoints were assessed. A mean length of stay for both the AquaBeam System's Aquablation therapy and the TURP procedure groups of 1.4 was achieved. While the mean operative times were similar, the hand piece in and out time was statistically significantly shorter for the AquaBeam System's Aquablation therapy group at 23.3 minutes as compared to 34.2 in the TURP procedure group. The mean resection time was 23 minutes shorter for the AquaBeam System's Aquablation therapy group at 3.9 minutes. No statistically significant difference was seen between the AquaBeam System's Aquablation therapy and the TURP procedure groups on the outcomes of re-intervention and worsening sexual function; 32.9 percent of the AquaBeam System's Aquablation therapy group had worsening sexual function as compared to 52.8 percent of the TURP procedure group. While statistically significant differences occurred across groups for change in ejaculatory function, the difference no longer remained at 6 months. While a greater proportion of the TURP procedure group patients experienced a negative change in erectile function as compared to the AquaBeam System's Aquablation therapy group patients (10 percent versus 6.2 percent at 6 months), no statistically significant differences occurred. No statistically significant differences between groups occurred for major adverse urologic events.

The applicant provided a meta-analysis of landmark studies regarding typical treatments for patients who have been diagnosed with BPH in order to provide supporting evidence for the assertion of superior outcomes achieved with the use of the AquaBeam System's Aquablation therapy. The applicant cited four ''landmark clinical trials,'' which report on the AquaBeam System's Aquablation therapy,[206] the TURP procedure, Green light laser versus the TURP procedure,[207] and Urolift.[208] Comparisons are made between performance outcomes on three separate treatments for patients who have been diagnosed with BPH: the AquaBeam System's Aquablation therapy, the TURP procedure, and Urolift. The applicant stated that all three clinical trials included men with average IPSS baseline scores of 21 to 23 points. The applicant stated that, while total procedure times are similar across all three treatment options, the AquaBeam System's Aquablation therapy has dramatically less time and variability associated with the tissue treatment. The applicant further stated that the differences between treatment options were not assessed for statistical significance. The applicant indicated that the AquaBeam System's Aquablation therapy, with an approximate score of 17, had the largest improvement in IPSS scores at 6 months as compared to 16 for the TURP procedure and 11 for Urolift. Compared to 46 percent in the TURP group, the applicant found that the AquaBeam System's Aquablation therapy and Urolift had much lower percentages, 4 percent and 0 percent, respectively, of an ejaculation-related consequence in patients. Lastly, the applicant stated that safety events, as measured by the percentage of CD Grade 2 or higher events, were lower in the AquaBeam System's Aquablation therapy (19 percent) and Urolift (14 percent) than in TURP (29 percent).

In the FY 2019 IPPS/LTCH proposed rule (83 FR 20349), we stated that we have several concerns related to the substantial clinical improvement criterion. The applicant performed a meta-analysis comparing results from three separate studies, which tested the effects of three separate treatment options. According to the applicant, the results provided consistently show the AquaBeam System's Aquablation therapy and Urolift as being superior to the standard treatment of the TURP procedure. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20349), we stated we have concerns with the

[206] Roehrborn, C., Gilling, P., Cher, D., Templin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue),'' Redwood City: PROCEPT BioRobotics Corporation, 2017.

[207] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

[208] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

interpretation of these results that the applicant provided. We noted that the comparison of multiple clinical studies is a difficult issue, and it was not clear if the applicant took into account the varying study designs, sample techniques, and other study specific issues, such as physician skill and patient health status. For instance, the applicant stated that a comparison of Urolift and the AquaBeam System's Aquablation therapy may not be appropriate due to the differing indications of the procedures; the applicant indicated that Urolift is primarily used for the treatment of patients who have been diagnosed with BPH who have smaller prostate volumes, whereas the AquaBeam System's Aquablation therapy procedure may be used in all prostate sizes. Similarly, the applicant stated that the TURP procedure is generally not utilized in patients with prostates larger than 80 ml, whereas such patients may be eligible for treatment involving the AquaBeam System's Aquablation therapy.

We noted that the applicant submitted a meta-analysis in an effort to compare currently available therapies to the AquaBeam System's Aquablation therapy. We stated that the possibility of the heterogeneity of samples and methods across studies leads to the possible introduction of bias, which results in the difficulty or inability to distinguish between bias and actual outcomes. We invited public comments on the applicability of this meta-analysis.

Comment: The applicant stated in response to CMS' concerns in regard to the meta-analysis that the meta-analysis was performed with the cited studies because of the similarities in geography where enrolled, inclusion of similar prostate size (30 to 80 ml), and the randomization against the same control of TURP. The applicant indicated that the objective of the analysis was to compare the reduced safety profile in ejaculatory dysfunction of Aquablation therapy compared to TURP as demonstrated in the WATER study, as well as to compare the safety profile of Aquablation therapy to the UroLift procedure.

Response: We appreciate the applicant's response and have taken this new information into consideration in making a final determination, as indicated below.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20349), we indicated that we had a concern that the differences between the AquaBeam System's Aquablation therapy and standard treatment options may not be as impactful and confined to safety aspects. We stated that it appears that the data on efficacy supported the equivalence of the AquaBeam System's Aquablation therapy and the TURP procedure based upon noninferiority analysis. In the proposed rule, we stated we agree with the applicant that the safety data were reported as showing superiority of the AquaBeam System's Aquablation therapy over the TURP procedure, although the data were difficult to track because adverse consequences were combined into categories; the AquaBeam System's Aquablation therapy was reportedly better in terms of ejaculatory function. It was noted in the application that, while the AquaBeam System's Aquablation therapy was statistically superior to the TURP procedure in the CD Grade 1 + adverse events, it was not statistically different in the CD Grade 2 or greater category. The applicant stated that regardless of the method, the urethra is typically used as the means for performing the BPH treatment procedure, which necessarily increases the likelihood of CD Grade 2 adverse events in all transurethral procedures.

In addition, the applicant noted that the treatment option may depend on the size of the prostate. The applicant stated that the AquaBeam System's Aquablation therapy is appropriate for small and large prostate sizes as a BPH treatment procedure. The AquaBeam System's Aquablation therapy has been shown to have limited positive outcomes as compared to the TURP procedure for prostates sized greater than 50 grams to 80 grams in each of the studies provided by the applicant. However, the applicant noted that the TURP procedure would not be used for prostates larger than 80 grams in size. Therefore, we stated in the proposed rule that we believe that another proper comparator for the AquaBeam System's Aquablation therapy may be laser or radical/open surgical procedures given their respective indication for small and large prostate sizes.

Lastly, the applicant compared AquaBeam System's Aquablation therapy and the standard of care TURP procedure to support a finding of improved safety. We stated that there are other treatment modalities available that may have a similar safety profile as the AquaBeam System's Aquablation therapy and we are interested in information that compares the AquaBeam System's Aquablation therapy to other treatment modalities.

We invited public comments on whether the AquaBeam System's Aquablation therapy meets the substantial clinical improvement criterion.

Comment: In response to CMS' concerns from the proposed rule that, while the WATER safety data showed superiority, adverse consequences were difficult to track because the data were combined into a composite endpoint, the applicant explained that in the WATER study a CD1+ event was defined as involving persistent bladder spasms, bleeding, dysuria, pain, retrograde ejaculation, urethral damage, urinary retention, urinary tract infection, and urinary urgency/frequency/difficulty/leakage. The applicant stated that data from the WATER study show Aquablation therapy was statistically superior to TURP in CD Grade 1+ adverse events. The applicant indicated that CD2 and above events are defined as those requiring pharmacological treatment, blood transfusions, endoscopic, surgical, or radiological interventions. The applicant stated that, after removal of the ejaculatory dysfunction events from the composite safety endpoint, the rate of CD2 and above adverse events for Aquablation therapy as compared to TURP was 19.8 percent and 23.1 percent, respectively.

In response to CMS' concern with regard to the WATER study finding of Aquablation's improved safety relative to TURP and that other treatment modalities demonstrate safety profiles similar to Aquablation, the applicant stated that, while this may be true, treatment modalities such as TUIP, TUNA/RF, Microwave, and PUL have inferior efficacy to TURP in a variety of objective and subjective measures including peak urine flow, PVR reduction and BPH symptom reduction.[209] However, the applicant indicated that, because the WATER study showed Aquablation efficacy similar to TURP for all prostate sizes and superiority in prostates sized 50 to 80 ml in volume, and that TURP shows superior efficacy to these other treatment modalities, Aquablation therapy offers an overall clinical improvement relative to these alternative treatment modalities.

In response to CMS' concern that Aquablation has limited positive outcomes for prostates sized 50 to 80 ml, the applicant stated that in a pre-specified subgroup analysis the WATER study showed superior safety and efficacy in prostates sized 50 to 80 ml

[209] Christidis, D., McGrath, S., Perera, M., Manning, T., Bolton, D., & Lawrentschuk, N., ''Minimally invasive surgical therapies for benign prostatic hypertrophy: The rise in minimally invasive surgical therapies,'' *Prostate International,* 2017, pp. 41–46.

compared to TURP. The applicant indicated that, in fact, because the subset analysis of men with prostates sized 50 to 80 ml in volume demonstrated Aquablation's superior outcomes over the TURP arm of the WATER study, the applicant sought to assess the efficacy and safety of the procedure in men with even larger prostates in the follow up WATER II study, which included prostates in sizes greater than 80 ml.

In response to CMS' concern that Aquablation therapy performed on larger prostates should be compared with laser (that is, HoLEP) and open simple prostatectomy procedures, the applicant stated that between September and December 2017, 101 men (67 percent were Medicare eligible) with moderate-to-severe BPH symptoms and prostates sized 80 to 150 ml in volume underwent Aquablation therapy in the prospective multi-center international WATER II clinical trial. The applicant indicated that, as noted above, the American Urological Association (AUA) BPH surgical guidelines recommend open simple prostatectomy or laser enucleation for the treatment of large prostates (>80 ml in volume). The applicant explained that the primary purpose of the WATER II was to assess the safety profile for Aquablation therapy in larger prostates. The applicant stated that the overall CD Grades 2, 3, and 4 complications were recorded in 19 percent, 11 percent, and 5 percent, respectively.[210] The applicant further stated that postoperative bleeding after Aquablation therapy that required transfusion (N=6, 5.9 percent) and/or cystoscopy with clot evacuation/fulguration (N=2, 2.0 percent) was observed in 8 patients during the procedural hospitalization.[211] The applicant stated that these results compare favorably to simple prostatectomy because the severe hemorrhage rate (defined as patients with a diagnosis related to hemorrhage and those who underwent transfusion) has been reported as high as 29 percent (range 12 to 29 percent) based on a claims analysis of 35,171 patients [212] who underwent the procedure. The applicant stated that Aquablation therapy has an average length of stay of 1.6 days compared to an average length of state of 5 days for prostatectomy. The applicant further indicated that transfusion rates for the AquaBeam System were less than those for the simple prostatectomy procedure. The applicant explained that the AquaBeam procedure is technically feasible even for surgeons with low or no prior experience, and open prostatectomy has higher morbidity rates, longer hospital stays, and longer catheter times than those for the AquaBeam System.

In response to CMS' concern regarding the appropriateness of the AquaBeam System for prostates of smaller sizes (for example, <30 mls), the applicant apologized for any inference in its application regarding smaller prostate sizes because it was not its intention to make any specific claims regarding smaller prostates.

Other commenters also believed that the AquaBeam System represented a substantial clinical improvement. Another commenter stated that all of its treated patients experienced improved urinary flow and decreased BPH symptoms following treatment with the AquaBeam System. The commenter further stated that treated patients appreciated the preservation of ejaculatory function and indicated they would undergo the procedure again. Two commenters summarized results from the WATER II study, a single-arm study of the AquaBeam System in patients diagnosed with BPH with >80 ml prostate volumes, and stated that the AquaBeam System decreases operative time, time under anesthesia, decreases the length of inpatient stays, and has fewer complications as compared to open prostatectomy, which is the standard treatment for large prostates greater than 80 ml in volume. Another commenter with an interest in providing the AquaBeam therapy at its facility stated that, if an adequate payment is provided for the therapy, increased volume will most likely reduce the cost of this method of treatment.

Response: We appreciate the additional information provided by the applicant and the commenters' input. We agree that the results of the WATER study are statistically significant (95 percent confidence interval of the difference between AquaBeam and TURP) and superior to TURP in safety as evidenced by a lower proportion of persistent CD Grade 1 adverse events at 3 months (which measured in totality Bladder spasm, Bleeding, Dysuria, Pain, Retrograde ejaculation, Urethral damage, Urinary retention, Urinary tract infection, Urinary urgency/frequency/difficulty/leakage). Additionally, patients enrolled in the WATER study with prostate sizes greater than 50 ml in volume and treated with Aquablation therapy had superior IPSS improvement than those treated with TURP, as well as better peak urinary flow rates (Qmax) at 6 months, and improved ejaculatory function and incontinence scores at 3 months. Results from the WATER II study for patients with large prostate volumes demonstrate better outcomes of the AquaBeam System over the standard-of-care, the open prostatectomy, regarding less operative time, decreased length of stay, and decreased rates of severe hemorrhage and transfusions. Based on the results above, we have determined the AquaBeam System represents a substantial clinical improvement for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms due to benign prostatic hyperplasia.

After consideration of the public comments we received, we have determined that the AquaBeam System's Aquablation therapy meets all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for the AquaBeam System for FY 2019. Cases involving the AquaBeam System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XV508A4 (Destruction of prostate using robotic waterjet ablation, via natural or artificial opening endoscopic, new technology group 4).

In its application, the applicant estimated that the average Medicare beneficiary would require the transurethral procedure of one AQUABEAM System per patient. According to the application, the cost of the AQUABEAM System is $2,500 per procedure. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology, or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the AQUABEAM System's Aquablation System is $1,250 for FY 2019. In accordance with the current indication for the AQUABEAM System, CMS expects that the AQUABEAM System will be used in the treatment for adult patients experiencing lower urinary tract symptoms caused by a diagnosis of BPH.

j. AndexXa™ (Andexanet alfa)

Portola Pharmaceuticals, Inc. (Portola) submitted an application for new technology add-on payments for FY 2019 for the use of AndexXa™ (Andexanet alfa). (We note that the

[210] Mihir, D., Bidar, M., Bhojani, N., Trainer, A., Arther, A., Kramolowsky, E., Doumanian, L., et al., ''WATER II (80–150 mL) Procedureal Outcomes,'' 2018, *BJU International.*

[211] Ibid.

[212] Pariser, J., Pearce, S., Patel, S., & Bales, G., ''National Trends of Simple Prostatectomy for Benign Prostatic Hyperplasia with and Analysis of Risk Factors for Adverse Perioperative Outcomes,'' 2015, *Urology,* vol. 86(4).

applicant previously submitted applications for new technology add-on payments for FY 2017 and FY 2018 for Andexanet alfa, which were withdrawn). In the proposed rule, we discussed AndexXa™ as a reversal agent for patients treated with direct and indirect Factor Xa inhibitors when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. AndexXa™ received FDA approval on May 3, 2018, and is indicated for use in the treatment of patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. According to the FDA-approved prescribing information, AndexXa™ has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any Factor Xa inhibitors other than the direct Factor Xa inhibitors apixaban and rivaroxaban. Therefore, in this final rule, we discuss AndexXa™ in the context of the FDA-approved indication as a treatment of an anticoagulation reversal agent for rivaroxaban and apixaban only due to life-threatening or uncontrolled bleeding.

AndexXa™ is an antidote used to treat patients who are receiving treatment with the Factor Xa inhibitors rivaroxaban and apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Patients at high risk for thrombosis, including those who have been diagnosed with atrial fibrillation (AF) and venous thrombosis (VTE), typically receive treatment using long-term oral anticoagulation agents. Factor Xa inhibitors are oral anticoagulants used to prevent stroke and systemic embolism in patients who have been diagnosed with AF. These oral anticoagulants are also used to treat patients who have been diagnosed with deep-vein thrombosis (DVT) and its complications, pulmonary embolism (PE), and patients who have undergone knee, hip, or abdominal surgery. Rivarobaxan (Xarelto®), apixaban (Eliquis®), betrixaban (Bevyxxa®), and edoxaban (Savaysa®) are included in the new class of Factor Xa inhibitors, and are often referred to as ''novel oral anticoagulants'' (NOACs) or ''non-vitamin K antagonist oral anticoagulants.'' Although these anticoagulants have been commercially available since 2011, prior to May 3, 2018, there was no FDA-approved therapy used for the urgent reversal of Factor Xa inhibitors rivarobaxan and apixaban as a result of serious bleeding episodes.

As stated above, AndexXa™ received FDA approval on May 3, 2018, and is indicated for use in the treatment of patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. The applicant received approval for two unique ICD–10–PCS procedure codes that became effective October 1, 2016 (FY 2017). The approved ICD–10–PCS procedure codes are: XW03372 (Introduction of Andexanet alfa, Factor Xa inhibitor reversal agent into peripheral vein, percutaneous approach, new technology group 2); and XW04372 (Introduction of Andexanet alfa, Factor Xa inhibitor reversal agent into central vein, percutaneous approach, new technology group 2).

With regard to the ''newness'' criterion, as discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. AndexXa™ is the first and the only antidote available to treat patients receiving apixaban and rivaroxaban who suffer a major bleeding episode and require urgent reversal of anticoagulation. Other anticoagulant reversal agents, such as Kcentra™ and idarucizumab, do not reverse the effects of apixaban and rivaroxaban. Therefore, the applicant asserted that the technology is not substantially similar to any other currently approved and available treatment options for Medicare beneficiaries. We discussed the applicant's assertions in the context of the three substantial similarity criteria in the proposed rule, as also discussed below.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant indicated that AndexXa™ is the first anticoagulant reversal agent that binds to apixaban and rivaroxaban with high affinity, thereby sequestering the inhibitors and consequently rapidly reducing free plasma concentration of these Factor Xa inhibitors. The applicant asserted that this mechanism of action neutralizes the inhibitors' anticoagulant effect, which allows for the restoration of normal hemostasis. According to the applicant, AndexXa™ represents a significant therapeutic advance because it provides rapid reversal of the anticoagulation effect of apixaban and rivaroxaban in the event of a serious bleeding episode where other anticoagulant reversal agents, such as Kcentra™ and idarucizumab, do not reverse the effects of these Factor Xa inhibitors.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that AndexXa™ is the first FDA-approved anticoagulant reversal agent for patients receiving rivaroxaban and apixaban, and the first reversal agent to be FDA-approved for these Factor Xa inhibitors. The applicant further stated that other anticoagulant reversal agents, such as Kcentra™ and idarucizumab, do not reverse the effects of these Factor Xa inhibitors. Therefore, the MS–DRGs do not contain cases that represent patients who have been treated with any anticoagulant reversal agents for these Factor Xa inhibitors.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant indicated that AndexXa™ is the only anticoagulant reversal agent available for treating patients who are receiving treatment with apixaban or rivaroxaban who experience serious, uncontrolled bleeding events or who require emergency surgery. Therefore, the applicant believed that AndexXa™ would be the first type of treatment option available to this patient population. As a result, we stated in the proposed rule that we believe that it appears that AndexXa™ is not substantially similar to any existing technologies. We invited public comments on whether AndexXa™ meets the substantial similarity criteria, and whether AndexXa™ meets the newness criterion.

Comment: The applicant reiterated that AndexXa™ satisfies the newness criterion. With respect to mechanism of action, the applicant reiterated that AndexXa™ rapidly binds to apixaban and rivaroxaban with high affinity, acting as a decoy molecule that sequesters the inhibitors to rapidly reduce the free plasma concentrations and neutralize their antiacoagulant effects to allow restoration of normal hemostasis. With respect to treating the same or similar type of disease and the same or similar patient population, the applicant further indicated that, as the first and only FDA-approved antidote available for a patient population receiving treatment using apixaban or rivaroxaban who suffer a major bleeding episode and require urgent reversal of direct Factor Xa coagulation of these Factor Xa inhibitors, AndexXa™ is not substantially similar to any other currently approved and available treatment options for Medicare

beneficiaries. The applicant emphasized that, prior to the approval of AndexXa™, the management of bleeding events in patients taking the Factor Xa inhibitors apixaban and rivaroxaban had been predicated on blood transfusions (that is, whole blood, packed red blood cells (RBCs), fresh frozen plasma (FFP), and/or platelets), or the use of a number of replacement clotting factor therapies (for example, fresh frozen plasma, Prothrombin Complex Concentrates (PCC), and recombinant activated Factor VIIa)—all of which are supportive measures that do not reverse the Factor Xa activity of these inhibitors. Finally, with respect to MS–DRG assignment, because AndexXa™ is the first and only FDA-approved reversal agent of Factor Xa inhibitor for the treatment of patients receiving apixaban and rivaroxaban who experience life-threatening or uncontrolled bleeding or require emergency surgery, and the first reversal agent to be approved for these Factor Xa inhibitors, the applicant believed that the MS–DRGs do not contain any cases that represent patients treated with AndexXa™ as a reversal agent for these Factor Xa inhibitors.

Other commenters stated that AndexXa™ meets the newness criterion and is not substantially similar to any existing technologies because there is no other reversal agent available on the U.S. market for patients who are being treated with these Factor Xa inhibitors and experience severe bleeding. These commenters stated that other anticoagulant reversal agents do not reverse the effects of these Factor Xa inhibitors.

Response: We appreciate the commenters' and the applicant's input on whether AndexXa™ meets the newness criterion. After review of the information provided by the applicant and consideration of the public comments we received, we believe that AndexXa™ meets the newness criterion and consider the beginning of the technology's newness period to be May 3, 2018, when the technology received FDA approval.

With regard to the cost criterion, we stated in the proposed rule that the applicant researched the FY 2015 MedPAR claims data file for potential cases representing patients who may be eligible for treatment using AndexXa™. The applicant used three sets of ICD–9–CM codes to identify these cases: (1) Codes identifying potential cases representing patients who were treated with an anticoagulant and, therefore, who are at risk of bleeding; (2) codes identifying potential cases representing patients with a history of conditions that were treated with Factor Xa inhibitors; and (3) codes identifying potential cases representing patients who experienced bleeding episodes as the reason for the current admission. The applicant included with its application the following table displaying a complete list of ICD–9–CM codes that met its selection criteria.

ICD–9–CM codes applicable	Applicable ICD–9–CM code description
V12.50	Personal history of unspecified circulatory disease.
V12.51	Personal history of venous thrombosis and embolism.
V12.52	Personal history of thrombophlebitis.
V12.54	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits.
V12.55	Personal history of pulmonary embolism.
V12.59	Personal history of other diseases of circulatory system.
V43.64	Hip joint replacement.
V43.65	Knee joint replacement.
V58.43	Aftercare following surgery for injury and trauma.
V58.49	Other specified aftercare following surgery.
V58.73	Aftercare following surgery of the circulatory system, NEC.
V58.75	Aftercare following surgery of the teeth, oral cavity and digestive system, NEC.
V58.61	Long-term (current) use of anticoagulants.
E934.2	Anticoagulants causing adverse effects in therapeutic use.
99.00	Perioperative autologous transfusion of whole blood or blood components.
99.01	Exchange transfusion.
99.02	Transfusion of previously collected autologous blood.
99.03	Other transfusion of whole blood.
99.04	Transfusion of packed cells.
99.05	Transfusion of platelets.
99.06	Transfusion of coagulation factors.
99.07	Transfusion of other serum.

The applicant identified a total of 51,605 potential cases that mapped to 683 MS- DRGs, resulting in an average case-weighted charge per case of $72,291. The applicant also provided an analysis that was limited to cases representing 80 percent of all potential cases identified (41,255 cases) that mapped to the top 151 MS–DRGs. Under this analysis, the average case-weighted charge per case was $69,020. The applicant provided a third analysis that was limited to cases representing 25 percent of all potential cases identified (12,873 cases) that mapped to the top 9 MS–DRGs. This third analysis resulted in an average case-weighted charge per case of $46,974.

Under each of these analyses, the applicant also provided sensitivity analyses based on variables representing two areas of uncertainty: (1) Whether to remove 40 percent or 60 percent of blood and blood administration charges; and (2) whether to remove pharmacy charges based on the ceiling price of factor eight inhibitor bypass activity (FEIBA), a branded anti-inhibitor coagulant complex, or on the pharmacy indicator 5 (PI5) in the MedPAR data file, which correlates to potential cases utilizing generic coagulation factors. Overall, the applicant conducted twelve sensitivity analyses, and provided the following rationales:

- The applicant chose to remove 40 percent and 60 percent of blood and blood administration charges because potential patients who may be eligible for treatment using AndexXa™ for Factor Xa reversal may still require blood and blood products to treat other conditions. Therefore, the applicant believed that it would be inappropriate to remove all of the charges associated with blood and blood administration because all of the charges cannot be attributed to Factor Xa reversal. The

applicant maintained that the amounts of blood and blood products required for treatment vary according to the severity of the bleeding. Therefore, the applicant stated that the use of AndexXa™ may replace 60 percent of blood and blood product administration charges for potential cases with less severity of bleeding, but only 40 percent of charges for potential cases with more severe bleeding.

- The applicant maintained that FEIBA is the highest priced clotting factor used for Factor Xa inhibitor reversal, and it is unlikely that pharmacy charges for Factor Xa reversal would exceed the FEIBA ceiling price of $2,642. Therefore, the applicant capped the charges to be removed at $2,642 to exclude charges unrelated to the reversal of Factor Xa anticoagulation. The applicant also considered an alternative scenario in which charges associated with pharmacy indicator 5 (PI5) were removed from the costs of potential cases that included this indicator in the MedPAR data. On average, charges removed from the costs of potential cases utilizing generic coagulation factors were much lower than the total pharmacy charges.

The applicant noted that, in all 12 scenarios, the average case-weighted standardized charge per case for potential cases representing patients who may be eligible for treatment using AndexXa™ would exceed the average case-weighted threshold amounts in Table 10 of the FY 2018 IPPS/LTCH PPS final rule by more than $855.

The applicant's order of operations used for each analysis is as follows: (1) Removing 60 percent or 40 percent of blood and blood product administration charges and up to 100 percent of pharmacy charges for PI5 or FEIBA from the average case-weighted unstandardized charge per case; and (2) standardizing the charges per cases using the Impact File published with the FY 2015 IPPS/LTCH PPS final rule. After removing the charges for the prior technology and standardizing charges, the applicant applied an inflation factor of 1.154181, which is a combination of 9.8446 percent, the value used in the FY 2017 IPPS final rule as the 2-year outlier threshold inflation factor, and 5.074 percent, the value used in the FY 2018 IPPS final rule as the 1-year outlier threshold inflation factor, to update the charges from FY 2015 to FY 2018. The applicant did not add charges for AndexXa™ as the price had not been set at the time of conducting this analysis. Under each scenario, the applicant stated that the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount (based on the FY 2018 IPPS Table 10 thresholds). Below we provide a table for all 12 scenarios that the applicant indicated demonstrate that the technology meets the cost criterion.

Scenario	Inflated average standardized case-weighted charge per case	Average case-weighted threshold amount
100 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	$71,305	$60,209
100 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	73,108	60,209
100 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	72,172	60,209
100 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	73,740	60,209
80 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	68,400	58,817
80 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	70,184	58,817
80 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	69,279	58,817
80 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	70,826	58,817
25 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	46,127	45,272
25 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	47,730	45,272
25 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	47,089	45,272
25 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	48,403	45,272

We invited public comments on whether AndexXa™ meets the cost criterion.

Comment: The applicant reiterated that it believed AndexXa™ meets the cost criterion. The applicant noted that in all 12 scenarios submitted with the cost analysis of the application for AndexXa™ in October 2017, the average case-weighted standardized charges per case exceeded the average case-weighted threshold amounts in the FY 2018 Table 10 by an average of $8,431. The applicant further noted that, because the price of AndexXa™ had not been set at the time of conducting the analysis, it did not incorporate charges for the new technology in its application. Therefore, the applicant conducted and submitted an updated analysis that added charges for the costs of AndexXa™ as well as updated the charges related to administering AndexXa™ in response to an increase in payment rates for procedural terminology codes 96365 and 96366 for infusion administration.

The applicant indicated that the WAC for 1 gram of AndexXa™ is $28,125, and the prescribing information outlines a low-dose and a high-dose regimen. The applicant explained that, in calculating the charges for AndexXa™, the low-dose regimen was assumed for all scenarios. The applicant stated that the low-dose regimen consists of an initial IV bolus and a follow-on IV infusion. The applicant further stated that during the initial IV bolus, the patient is infused with 400 mg of AndexXa™ at the target rate of 30 mg per minute, and during the follow-on IV infusion, the patient is infused with 4 mg of AndexXa™, per minute, for 120 minutes. The applicant noted that, for purposes of simplification and consistency, the follow-on IV infusion was assumed to be the full 120 minutes for all 12 scenarios. Applying the assumptions for dosing regime and duration of follow-on IV infusion, the applicant stated that a patient receiving a low-dose regimen is administered a total of 880 mg—88 percent of 1 gram—of AndexXa™. The applicant calculated that the low-dose regime equates to a WAC of $24,750 per patient. The applicant converted the low-dose treatment cost of $24,750 to a charge using a cost to CCR of 0.5.

The applicant indicated that the addition of charges for AndexXa™ and the updated charges related to AndexXa™ administration increased the difference between the average case-weighted standardized charges per case

and the average case-weighted threshold amount in Table 10 from an average of $8,431 to an average of $57,932, or by a 587 percent increase. Below we provide a table for all 12 revised scenarios of the cost analysis conducted by the applicant to demonstrate that the technology meets the cost criterion.

Scenario	Inflated average standardized case-weighted charge per case	Average case-weighted threshold amount
100 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	$120,817	$60,209
100 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	122,619	60,209
100 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	121,683	60,209
100 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	123,252	60,209
80 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	117,911	58,817
80 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	119,696	58,817
80 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	118,790	58,817
80 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	120,338	58,817
25 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	95,638	45,272
25 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	97,242	45,272
25 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	96,600	45,272
25 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	97,914	45,272

Response: After consideration of the public comments we received, we agree that AndexXa™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that AndexXa™ represents a substantial clinical improvement for the treatment of patients who are receiving apixaban or rivaroxaban who experience serious, uncontrolled bleeding events or who require emergency surgery because the technology addresses an unmet medical need for an antidote to apixaban and rivaroxaban. According to the applicant, AndexXa™ is the only FDA-approved agent shown in prospective clinical trials to rapidly (within 2 to 5 minutes) and sustainably reverse the anticoagulation activity of these Factor Xa inhibitors; is potentially nonthrombogenic, as no serious adverse effects of thrombosis were observed in clinical trials; and could supplant currently available treatments for bleeding from anti-Factor Xa therapy, which have not been shown to be effective in the treatment of all patients.

The applicant stated that the use of any anticoagulant is associated with an increased risk of bleeding, and bleeding complications can be life-threatening. The applicant further indicated that bleeding is especially concerning for patients treated with these Factor Xa inhibitors because, prior to the FDA approval of AndexXa™, no antidotes to these Factor Xa inhibitors were available. As a result, when a patient anticoagulated with the use of apixaban or rivaroxaban presented with life-threatening bleeding, clinicians often resorted to using preparations of vitamin K dependent clotting factors, such as 4-factor prothrombin complex concentrates (PCCs), which do not reverse the effects of these Factor Xa inhibitors' anticoagulation. The applicant asserted that despite the lack of any large, prospective, randomized study examining the efficacy and safety of these agents in this patient population, administration of 4-factor PCCs as a means to ''reverse'' the anticoagulant effect of these Factor Xa inhibitors is commonplace in many hospitals due to the lack of any alternative in the setting of a serious or life-threatening bleed.

As noted above, AndexXa™ has a unique mechanism of action and represents a new biological approach to the treatment of patients receiving apixaban or rivaroxaban who have been diagnosed with acute severe bleeding who require immediate reversal of the Factor Xa inhibitor therapy. The applicant explained that although AndexXa™ is structurally very similar to native Factor Xa inhibitors, the technology has undergone several modifications that restrict its biological activity to reversing the effects of Factor Xa inhibitors by binding with and sequestering direct Factor Xa inhibitors, which allows native Factor Xa inhibitors to dictate the normal coagulation and hemostasis process. As a result, the applicant maintained that AndexXa™ represents a safe and effective therapy for the management of severe bleeding in a fragile patient population and a substantial clinical improvement over existing technologies and reversal strategies.

The applicant noted the following: (1) On average, patients with a bleeding complication were hospitalized for 6.3 to 8.5 days, and (2) the most common therapies currently used to manage severe bleeding events in patients undergoing anticoagulant treatment are blood and blood product transfusions, most frequently with packed red blood cells (RBC) or fresh frozen plasma (FFP).[213] According to the applicant, the blood products that are currently being employed as reversal agents carry significant risks. For instance, no clinical studies have evaluated the safety and efficacy of FFP transfusions to treat bleeding associated with Factor Xa inhibitors.[214] [215] Furthermore, transfusions with packed RBCs carry a risk (1 to 4 per 50,000 transfusions) of acute hemolytic reactions, in which the recipient's antibodies attack the transfused red blood cells, which is associated with clinically significant anemia, kidney failure, and death.[216] The applicant asserted that a RBC transfusion in trauma patients with major bleeding is associated with an increased risk of nonfatal vascular events and death.[217] The applicant

[213] Truven, ''2016 Truven Medicare Projected Bleeding Events'', MARKETSCAN® Medicare Supplemental Database, January 1, 2016 to December 31, 2016 Data pull, Data on File, Supplemental file.

[214] Siegal, D.M., ''Managing target-specific oral anticoagulant associated bleeding including an update on pharmacological reversal agents,'' *J Thromb Thrombolysis,* 2015 Apr, vol. 39(3), pp. 395–402.

[215] Kalus, J.S., ''Pharmacologic interventions for reversing the effects of oral anticoagulants,'' *Am J Health Syst Pharm,* 2013, vol. 70(10 Suppl 1), pp. S12–21.

[216] Sharma, S., Sharma, P., Tyler, L.N., ''Transfusion of Blood and Blood Products: Indications and Complications,'' *Am Fam Physician,* 2011, vol. 83(6), pp. 719–24.

[217] Perel, P., Clayton, T., Altman, D.G., et. al., ''Red blood cell transfusion and mortality in trauma patients: risk-stratified analysis of an observational study,'' *PLoS Med,* 2014, vol. 11(6), pp. e1001664.

noted that, although patients who are treated with AndexXa™ would receive RBC transfusions if their hemoglobin is low enough to warrant it, AndexXa™ reduces the need for RBC transfusion.

The applicant asserted that laboratory studies have failed to provide consistent evidence of ''reversal'' of the anticoagulant effect of Factor Xa inhibitors across a range of different PCC products and concentrations. Results of thrombin generation assays have varied depending on the format of the assay. Despite years of experience with low molecular weight heparins and pentasaccharide anticoagulants, neither PCCs nor factor eight inhibitor bypassing activity are recognized as safe and effective reversal agents for these Factor Xa inhibitors.[218] Unlike patients taking vitamin K antagonists, patients receiving treatment with oral Factor Xa inhibitor drugs have normal levels of clotting factors. Therefore, a strategy based on ''repleting'' factor levels is of uncertain foundation and could result in supra-normal levels of coagulation factors after rapid metabolism and clearance of the oral anticoagulant.[219]

The applicant provided results from two randomized, double-blind, placebo-controlled Phase III studies,[220] [221] the ANNEXA–A (reversal of apixaban) and ANNEXA–R (reversal of rivaroxaban) trials. The primary endpoint in both these studies was the percent change in anti-Factor Xa activity. Secondary endpoints included proportion of participants with an 80 percent or greater reduction in anti-Factor Xa activity, change in unbound Factor Xa inhibitor concentration, and change in endogenous thrombin potential (ETP). A total of 145 participants were enrolled in the studies, with 101 participants randomized to AndexXa™ and 44 participants randomized to placebo. The mean age of participants was 58 years old, and 39 percent were women. There was a mean of greater than 90 percent reduction in anti-Factor Xa activity in both parts of both studies in subjects receiving AndexXa™. The studies also demonstrated the following: (1) Rapid and sustainable reversal of anticoagulation; (2) reduced Factor Xa inhibitor free plasma levels by at least 80 percent below a calculated no-effect level; and (3) reduced anti-Factor Xa activity to the lowest level of detection within 2 to 5 minutes of infusion. The applicant noted that decreased Factor Xa inhibitor levels have been shown to correspond to decreased bleeding complications, reconstitution of activity of coagulation factors, and correction of coagulation. [222] [223] [224]

The applicant stated that the results from the two Phase III studies and previous proof-of-concept Phase II dose-finding studies showed that use of AndexXa™ can rapidly reverse anticoagulation activity of Factor Xa inhibitors and sustain that reversal. Therefore, the applicant asserted that the use of AndexXa™ has the potential to successfully treat patients who only need short-duration reversal of the Factor Xa inhibitor anticoagulant, as well as patients who require longer duration reversal, such as patients experiencing a severe intracranial hemorrhage or requiring emergency surgery. Furthermore, the applicant noted that its technology's duration of action allows for a gradual return of Factor Xa inhibitor concentrations to placebo control levels within 2 hours following the end of infusion.

With regard to AndexXa™'s nonthrombogenic nature, the applicant provided clinical trial data which revealed participants in Phase II and Phase III trials had no thrombotic events and there were no serious or severe adverse events reported. Results also showed that use of AndexXa™ has a much lower risk of thrombosis than typical procoagulants because the technology lacks the region responsible for inducing coagulation. Furthermore, the applicant asserted that the use of AndexXa™ is not associated with the known complications seen with RBC transfusions. The applicant asserted that, while the Phase II and Phase III trials and studies measured physiological hallmarks of reversal of NOACs, it is expected that the availability of a safe and reliable Factor Xa reversal will result in an overall better prognosis for patients—potentially leading to a reduction in length of hospital stay, fewer complications, and decreased mortality associated with unexpected bleeding episodes.

The applicant also stated that use of AndexXa™ can supplant currently available treatments used for reversing severe bleeding from anti-Factor Xa therapy, which have not been shown to be effective in the treatment of all patients. With regard to PCCs and FFPs, the applicant stated that there is a lack of clinical evidence available for patients taking Factor Xa inhibitors that experience severe bleeding events. The applicant noted that the case reports provide a snapshot of emergent treatment of these often medically complex anti-Factor Xa-treated patients with major bleeds. However, the applicant stated that these analyses reveal the inconsistent approach in assessing the degree of anticoagulation in the patient and the variability in treatment strategy. The applicant explained that little or no assessment of efficacy in restoring coagulation in the patients was performed, and the major outcomes measures were bleeding cessation or mortality. The applicant concluded that overall, there is very little evidence for the efficacy suggested in some guidelines, and the evidence is insufficient to draw any conclusions.

The applicant submitted interim data purporting to show substantial clinical improvement within its target patient population as part of an ongoing Phase IIIb/IV open-label ANNEXA–4 study. The ANNEXA–4 study is a multi-center, prospective, open-label, single group study that evaluated 67 patients who had acute, major bleeding within 18 hours of receipt of a Factor Xa inhibitor (32 patients receiving rivarobaxan, 31 receiving apixaban, and 4 receiving enoxaparin). The population in the study was reflective of a real-world population, with mean age of 77 years old, most patients with cardiovascular disease, and the majority of bleeds being intracranial or gastrointestinal. According to the applicant, the results of the ANNEXA–4 study demonstrate safe, reliable, and rapid reversal of Factor Xa levels in patients experiencing acute bleeding and are consistent with the results seen in the Phase II and Phase III trials, based on interim data. However, in the proposed rule, we stated we were concerned that this interim data also indicate 18 percent of patients experienced a thrombotic event and 15 percent of patients died following reversal during

[218] Sarich, T.C., Seltzer, J.H., Berkowitz, S.D., et al., ''Novel oral anticoagulants and reversal agents: Considerations for clinical development,'' *Am Heart J,* 2015, vol. 169(6), pp. 751–7.

[219] Siegal, D.M., ''Managing target-specific oral anticoagulant associated bleeding including an update on pharmacological reversal agents,'' *J Thromb Thrombolysis,* 2015 Apr, vol. 39(3), pp. 395–402.

[220] Conners, J.M., ''Antidote for Factor Xa Anticoagulants,'' *N Engl J Med,* 2015 Nov 13.

[221] Siegal, D.M., Curnutte, J.T., Connolly, S.J., et al., ''Andexanet Alfa for the Reversal of Factor Xa Inhibitor Activity,'' *N Engl J Med,* 2015 Nov 11.

[222] Lu, G., DeGuzman, F., Hollenbach, S., et al., ''Reversal of low molecular weight heparin and fondaparinux by a recombinant antidote,'' (r-Antidote, PRT064445), *Circulation,* 2010, vol. 122, pp. A12420.

[223] Rose, M., Beasley, B., ''Apixaban clinical review addendum,'' Silver Spring, MD: Center for Drug Evaluation and Research, 2012. Available at: *http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202155Orig1s000MedR.pdf.*

[224] Beasley, N., Dunnmon, P., Rose, M., ''Rivaroxaban clinical review: FDA draft briefing document for the Cardiovascular and Renal Drugs Advisory Committee,'' 2011. Available at: *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm270796.pdf.*

the 30-day follow-up period in the ANNEXA–4 study. For this reason, we stated we were concerned that there is insufficient data to determine substantial clinical improvement over existing technologies.

We invited public comments on whether AndexXa™ meets the substantial clinical improvement criterion.

Comment: The applicant reiterated that AndexXa™ satisfies the substantial clinical improvement criterion, and indicated that it is the first and only FDA-approved antidote for the direct Factor Xa inhibitors apixaban and rivaroxaban. The applicant stated that AndexXa™ has been shown to reverse the anticoagulant effect of apixaban and rivaroxaban immediately in patients needing rapid reversal of anticoagulation in emergency situations. The applicant referenced the results from 2 ANNEXA Phase III clinical trials that show that the reversal of anticoagulation activity with AndexXa™ occurred within 2 to 5 minutes in more than 90 percent of patients treated with apixaban and rivaroxaban to demonstrate its substantial clinical improvement over existing technologies.[225] The applicant also pointed out that, as shown by the clinical results, AndexXa™ rapidly reversed anti-Factor Xa activity in the ANNEXA–4 clinical trial and sustained that reversal for enrolled patients for 12 hours.[226] [227] [228] Several commenters suggested that these results showed AndexXa™ has the potential to successfully treat patients who only require short-duration reversal of the Factor Xa inhibitor anticoagulant, as well as patients who may need longer duration reversal. Furthermore, the applicant and other commenters stated that ongoing trials in which enrolled patients experienced uncontrolled bleeding while receiving apixaban and rivaroxaban have confirmed the safety and efficacy of the use of AndexXa™ in this patient population.

With respect to the 18 percent of patients that experienced a thrombotic event and 15 percent of patients that died following reversal during the 30-day follow-up period in the ongoing ANNEXA–4 trial, the applicant asserted that this is consistent with the high-risk profile of the patients who have an intrinsic risk of dying even if bleeding is reversed. Specifically, the applicant explained that the thrombotic event rate and mortality observed in the ANNEXA–4 study, to date, are a reflection of the patients taking Factor Xa inhibitors due to a prior history of venous thromboembolisms, and reversal of anticoagulation in bleeding patients by use of AndexXa™ exposes the underlying disease risk, which can result in thrombotic events. The applicant further noted that, in an expanded cohort of 227 patients, the total mortality rate was 12 percent and thrombotic events occurred within 3 days of AndexXa™ administration in only 2.6 percent of patients, and within 30 days in 11 percent of patients. The applicant also stated that other approved reversal agents have had a similar safety profile. For example, in the REVERSE–AD study for the reversal agent idarucizumab, the results indicated that use of the technology had a total mortality rate of 14 percent after reversal of anticoagulation, and the thrombotic event rates in patients not anticoagulated are roughly similar at approximately 10 to 15 percent for both REVERSE–AD and ANNEXA–4. Furthermore, the applicant stated that when comparing the results of the expanded ANNEXA–4 cohort with the results of 16 contemporary studies enrolling 30 or more patients who experienced acute major bleeding, the majority of studies indicated a thrombotic event rate of approximately 10 percent, though rates as high as 25 to 28 percent have been reported. The applicant indicated that, while several studies have lower thrombotic event rates compared with the ANNEXA–4 group, they also tended to enroll younger patients in the populations and patients with less severe bleeding events. The applicant noted that the median time to a thrombotic event ranged from as few as 1 to 2 days to as many as 8 days, with overall follow-up generally ranging from 30 to 90 days. In contrast, the applicant stated that the median time to a thrombotic event in ANNEXA–4 was 11 days.

Several commenters also supported the clinical results as demonstration of substantial clinical improvement for AndexXa™ over existing technologies. A commenter stated that the lack of a targeted antidote to Factor Xa anticoagulation is a significant unmet need and one that has been an impediment to the use of Factor Xa inhibitors such as apixaban and rivaroxaban, despite their use convenience. Other commenters believed that a serious risk inherent to Factor Xa treatment is the incidence of unanticipated bleeding, which may occur as a result of trauma or bleeding into a critical organ. Several commenters expressed concern with the high risk of death or major morbidity as a result of such bleeding, particularly in the case of an intracranial hemorrhage, which is not amenable to emergency invasive interventions to stop the bleeding; an issue these commenters believed could be resolved with the use of AndexXa™. The commenters stated that, for patients with intracranial hemorrhages that are anticoagulation-related, there are effective reversal treatments when the anticoagulation is induced by warfarin, heparin or a direct thrombin inhibitor, but none when the critical bleeding is related to a Factor Xa inhibitor such as apixaban or rivaroxaban. Therefore, the commenters believed that the approval of new technology add-on payments for AndexXa™ offers an effective treatment option for patients receiving apixaban or rivaroxaban who experience a critical bleed and require urgent reversal of the anticoagulant effect. The commenters further stated that, as the only existing Factor Xa inhibitor reversal agent for apixaban and rivaroxaban, AndexXa™ is a needed therapy in managing these critical scenarios. The commenters believed that, based on these reasons, AndexXa™ meets the substantial clinical improvement criterion.

Response: We appreciate the commenters' and the applicant's input regarding the substantial clinical improvement criterion for AndexXa™. We agree that AndexXa™ represents a substantial clinical improvement over existing technologies and provides an alternative treatment option to Medicare beneficiaries and, therefore, meets the substantial clinical improvement criterion. Specifically, AndexXa™: (1) Provides a rapid, sustained reversal of the anticoagulant effects of Factor Xa inhibitors rivaroxaban and apixaban; and (2) represents a treatment option for patients who experience severe or life-threatening bleeds, such as intracranial hemorrhages, during the administration of Factor Xa inhibitor anticoagulation. As noted above, according to the FDA-approved prescribing information, AndexXa™ has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any Factor Xa inhibitors other than apixaban and rivaroxaban.

After consideration of the public comments we received, we have determined that AndexXa™ meets all of the criteria for approval for new technology add-on payments. Therefore,

[225] Siegal DM, Curnutte JT, Connolly SJ et al. Andexanet Alfa for the Reversal of Factor Xa Inhibitor Activity. N Engl J Med. 2015; 373:2413–2424.

[226] Ibid.

[227] Connolly SJ, Milling TJ, Eikelboom JW et al. Andexanet Alfa for Acute Major Bleeding Associated with Factor Xa Inhibitors. N Engl J Med 2016;375;1131–41.

[228] Ibid.

we are approving new technology add-on payments for AndexXa™ for FY 2019. Cases involving the use of AndexXa™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW03372 and XW04372. The applicant explained that the WAC for 1 vial costs $2,750 with the use of an average of 10 vials for the low dose and 18 vials for the high dose. The applicant also noted that per the clinical trial data, 90 percent of cases were administered a low dose and 10 percent of cases the high dose. The weighted average between the low and high dose is an average of 10.22727 vials. Therefore, the cost of a standard dosage of AndexXa™ is $28,125 ($2,750 × 10.22727). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of AndexXa™ is $14,062.50 for FY 2019.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2019 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2019 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.I. of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2019 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are applying to the FY 2019 wage index appears under sections III.E.3. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2019 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the OMB labor market area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provide detailed information on the update to statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available on the OMB website at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. We noted in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354) that we did not have sufficient time to include this change in the computation of the proposed FY 2019 wage index, ratesetting, and Tables

2 and 3 associated with the FY 2019 IPPS/LTCH PPS proposed rule. We stated in the proposed rule (83 FR 20354) that this new CBSA may affect the budget neutrality factors and wage indexes, depending on whether the area is eligible for the rural floor and the impact of the overall payments of the hospital located in this new CBSA. In the proposed rule, we provided an estimate of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 wage index (described in section III.B. of the preamble of the proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 was calculated using the average hourly wage data for one provider (provider 130002).

In sections III.D. and E.2. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule, we provided the proposed FY 2019 unadjusted and occupational mix adjusted national average hourly wages. Taking the estimated average hourly wage of new CBSA 46300 and dividing by the proposed national average hourly wage resulted in the estimated wage indexes shown in the table in the proposed rule (83 FR 20354), which is also provided below.

	Estimated unadjusted wage index for new CBSA 46300	Estimated occupational mix adjusted wage index for new CBSA 46300
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

For FY 2019, we are using the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354), we stated that, in the final rule, we would incorporate this change into the final FY 2019 wage index, ratesetting, and tables. We did not receive any public comments regarding this policy area. Therefore, we have incorporated the updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01 into the final FY 2019 wage index, ratesetting, and tables for this final FY2019 rule.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html.* We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130) we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates which were effective October 1, 2017, beginning with the FY 2018 wage indexes. The updated changes were used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule.

For FY 2019, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2019, Tables 2 and 3 associated with this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect these county changes.

B. Worksheet S–3 Wage Data for the FY 2019 Wage Index

The FY 2019 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2015 (the FY 2018 wage indexes were based on data from cost reporting periods beginning during FY 2014).

1. Included Categories of Costs

The FY 2019 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2018, the wage index for FY 2019 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs

related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2019 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398).

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2019 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB Control Number 0938–0050) for cost reporting periods beginning on or after October 1, 2014, and before October 1, 2015. For wage index purposes, we refer to cost reports during this period as the ''FY 2015 cost report,'' the ''FY 2015 wage data,'' or the ''FY 2015 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. No. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2019 wage index includes FY 2015 data submitted to us as of June 20, 2018. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2019 wage index, we identified and excluded 80 providers with aberrant data that should not be included in the wage index, although we stated in the FY 2019 IPPS/LTCH PPS proposed rule that if data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2019 wage index (83 FR 20355). We also adjusted certain aberrant data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 23, 2018. In addition, as a result of the April and May appeals processes, and posting of the April 27, 2018 PUF, we have made additional revisions to the FY 2019 wage data, as described further below. The revised data are reflected in this FY 2019 IPPS/LTCH PPS final rule.

In constructing the proposed FY 2019 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2015, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believed that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed rule, we removed 8 hospitals that converted to CAH status on or after January 23, 2017, the cut-off date for CAH exclusion from the FY 2018 wage index, and through and including January 26, 2018, the cut-off date for CAH exclusion from the FY 2019 wage index. After excluding CAHs and hospitals with aberrant data, we calculated the proposed wage index using the Worksheet S–3, Parts II and III wage data of 3,260 hospitals.

Since the development of the FY 2019 proposed wage index, as a result of further review by the MACs and the April and May appeals processes, we received improved data for 28 hospitals and are including the wage data of these 28 hospitals in the final wage index. However, during our review of the wage data in preparation of the April 27, 2018 PUF, we identified and deleted the data of 2 additional hospitals whose data we determined to be aberrant (unusually low average hourly wages) relative to their CBSAs. With regard to CAHs, we have since learned of 3 additional hospitals that converted to CAH status on or after January 23, 2017, the cut-off date for CAH exclusion from the FY 2018 wage index, and through and including January 26, 2018, the cut-off date for CAH exclusion from the FY 2019 wage index. Accordingly, we have removed 11 hospitals that converted to CAH status from the FY 2019 wage index (8 CAHs for the proposed rule, and 3 more CAHs for the final rule). The final FY 2019 wage index is based on the wage index of 3,283 hospitals (3,260 + 28 − 2 − 3 = 3,283).

For the final FY 2019 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2018 wage index (82 FR 38131 through 38132); that is, using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the final FY 2019 wage index associated with this final rule (available via the internet on the CMS website), includes separate wage data for the campuses of 16 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

CCN of multicampus hospital	Full-time equivalent (FTE) percentages
050121	0.81
05B121	0.19
070022	0.99
07B022	0.01
070033	0.92
07B033	0.08
100029	0.54
10B029	0.46
100167	0.37
10B167	0.63
140010	0.82
14B010	0.18
220074	0.89
22B074	0.11
330234	0.72
33B234	0.28
360019	0.95
36B019	0.05
360020	0.99

CCN of multicampus hospital	Full-time equivalent (FTE) percentages
36B020	0.01
390006	0.95
39B006	0.05
390115	0.86
39B115	0.14
390142	0.83
39B142	0.17
460051	0.97
46B051	0.03
510022	0.95
51B022	0.05
670062	0.55
67B062	0.45

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 proposed rule, this final rule, and future rulemaking, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

D. Method for Computing the FY 2019 Unadjusted Wage Index

In the FY 2019 IPPS/LTCH PPS proposed rule, we indicated we were committed to transforming the health care delivery system, including the Medicare program, by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. One key to that transformation is ensuring that the Medicare payment rates are as accurate and appropriate as possible, consistent with the law. We invited the public to submit comments, suggestions, and recommendations for regulatory and policy changes to address wage index disparities.

CMS looks forward to continuing to work on wage index disparities, particularly for rural hospitals, to the extent permitted under current law and appreciates responses to our request for public input on this issue. By allowing the imputed floor to expire for all urban States, as described section III.G.2. of the preamble of this final rule, CMS has begun the process of making the wage index more equitable.

1. Methodology for FY 2019

The method used to compute the FY 2019 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment since FY 2012 (76 FR 51591 through 51593).

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2014, through April 15, 2016, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose any changes to the usage of the ECI for FY 2019. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2014	11/15/2014	1.02567
11/14/2014	12/15/2014	1.02413
12/14/2014	01/15/2015	1.02257
01/14/2015	02/15/2015	1.02100
02/14/2015	03/15/2015	1.01941
03/14/2015	04/15/2015	1.01784
04/14/2015	05/15/2015	1.01627
05/14/2015	06/15/2015	1.01471
06/14/2015	07/15/2015	1.01316
07/14/2015	08/15/2015	1.01161
08/14/2015	09/15/2015	1.01007
09/14/2015	10/15/2015	1.00849
10/14/2015	11/15/2015	1.00685
11/14/2015	12/15/2015	1.00516
12/14/2015	01/15/2016	1.00343
01/14/2016	02/15/2016	1.00171
02/14/2016	03/15/2016	1.00000
03/14/2016	04/15/2016	0.99824

For example, the midpoint of a cost reporting period beginning January 1, 2015, and ending December 31, 2015, is June 30, 2015. An adjustment factor of 1.01316 was applied to the wages of a hospital with such a cost reporting period.

Using the data as previously described, the FY 2019 national average hourly wage (unadjusted for occupational mix) is $42.997789358.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) (which is $42.997789358 for this FY 2019 final rule) and the national wage index, which is applied to the national labor share of the national standardized amount. Therefore, for FY 2019, there is no Puerto Rico-specific overall average hourly wage or wage index.

2. Update of Policies Related to Other Wage-Related Costs, Clarification of the Calculation of Other Wage-Related Costs, and Policies for FY 2020 and Subsequent Years

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index based on a survey of hospitals' costs that are attributable to wages and wage-related costs. In the September 1, 1994 IPPS final rule (59 FR 45356), we developed a list of ''core'' wage-related costs that hospitals may report on Worksheet S–3, Part II of the Medicare hospital cost report in order to include those costs in the wage index. Core wage-related costs include categories of retirement cost, plan administrative costs, health and insurance costs, taxes, and other specified costs such as tuition reimbursement.

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20357 through 20358), in addition to these categories of core wage-related costs, we allow hospitals to report wage-related costs other than those on the core list if the other wage-related costs meet certain criteria. The criteria for

including other wage-related costs in the wage index are discussed in the September 1, 1994 IPPS final rule (59 FR 45357) and clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38132 through 38136). In addition, the criteria for including other wage-related costs in the wage index are listed in the Provider Reimbursement Manual (PRM), Part II, Chapter 40, Sections 4005.2 through 4005.4, Line 18 on W/S S–3 Part II and Line 25 and its subscripts on W/S S–3 Part IV of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38132 through 38136), we clarified that a hospital may be able to report a wage-related cost (defined as the value of the benefit) that does not appear on the core list if it meets all of the following criteria:

- The wage-related cost is provided at a significant financial cost to the employer. To meet this test, the individual wage-related cost must be greater than 1 percent of total salaries after the direct excluded salaries are removed (the sum of Worksheet S–3, Part II, Lines 11, 12, 13, 14, Column 4, and Worksheet S–3, Part III, Line 3, Column 4).
- The wage-related cost is a fringe benefit as described by the IRS and is reported to the IRS on an employee's or contractor's W–2 or 1099 form as taxable income.
- The wage-related cost is not furnished for the convenience of the provider or otherwise excludable from income as a fringe benefit (such as a working condition fringe).

We noted that those wage-related costs reported as salaries on Line 1 (for example, loan forgiveness and sick pay accruals) should not be included as other wage-related costs on Line 18.

The above instructions for calculating the 1-percent test inadvertently omitted Line 15 for Home Office Part A Administrator on Worksheet S–3, Part II from the denominator. As we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20357), Line 15 should be included in the denominator because Home Office Part A Administrator is added to Line 1 in the wage index calculation. Therefore, in the proposed rule, we stated that we were correcting the inadvertent omission of Line 15 from the denominator, and we clarified that, for calculating the 1-percent test, each individual category of the other wage-related cost (that is, the numerator) should be divided by the sum of Worksheet S–3, Part III, Lines 3 and 4, Column 4 (that is, the denominator). Line 4 sums the following lines from Worksheet S–3, Part II: Lines 11, 12, 13, 14, 14.01, 14.02, and 15. We also directed readers to instructions for calculating the 1-percent test in the Provider Reimbursement Manual (PRM), Part II, Chapter 40, Section 4005.4, Line 25 and its subscripts on Worksheet S–3, Part IV of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050), which state: ''Calculate the 1-percent test by dividing each individual category of the other wage-related cost (that is, the numerator) by the sum of Worksheet S–3, Part III, Lines 3 and 4, Column 4, (that is, the denominator).''

In addition to our discussion about calculating the 1-percent test and other criteria for including other wage-related costs in the wage index, we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38133 through 38166) that we would consider proposing to remove other wage-related costs from the wage index entirely.

In the FY 2018 IPPS/LTCH PPS proposed and final rules (82 FR 19901 and 82 FR 38133, respectively), we stated that we originally allowed for the inclusion of wage-related costs other than those on the core list because we were concerned that individual hospitals might incur unusually large wage-related costs that are not reflected on the core list but that may represent a significant wage-related cost. However, we stated in the FY 2018 IPPS/LTCH PPS proposed and final rules (82 FR 19901 and 82 FR 38133, respectively) that we were reconsidering allowing other wage-related costs to be included in the wage index because internal reviews of the FY 2018 wage data showed that only a small minority of hospitals were reporting other wage-related costs that meet the 1-percent test described earlier.

We stated in the FY 2019 IPPS/LTCH PPS proposed rule that, as part of the wage index desk review process for FY 2019, internal reviews showed that only 8 hospitals out of the more than 3,000 IPPS hospitals in the wage index had other wage-related costs that were correctly reported for inclusion in the wage index (83 FR 20357). Given the extremely limited number of hospitals nationally using Worksheet S–3, Part IV, Line 25 and subscripts, and Worksheet S–3, Part II, Line 18, to correctly report other wage-related costs in accordance with the criteria to be included in the wage index, we continue to believe that other wage-related costs do not constitute an appropriate and significant portion of wage costs in a particular labor market area. In other words, while other wage-related costs may represent costs that may have an impact on an *individual* hospital's average hourly wage, we do not believe that costs reported by only a very small minority of hospitals (less than 0.003 percent) accurately reflect the economic conditions of the labor market area as a whole in which such an individual hospital is located. The fact that only 8 hospitals out of more than 3,000 IPPS hospitals included in the FY 2019 IPPS proposed wage index reported other wage-related costs correctly in accordance with the 1-percent test and related criteria indicates that, in fact, other wag-related costs are *not* a relative measure of the labor costs to be included in the IPPS wage index. Therefore, we stated that we believe that inclusion of other wage-related costs in the wage index in such a limited manner may distort the average hourly wage of a particular labor market area so that its wage index does not accurately represent that labor market area's current wages relative to national wages.

Furthermore, in the FY 2019 IPPS/LTCH PPS proposed rule, we also discussed that the open-ended nature of the types of other wage-related costs that may be included on Line 25 and its subscripts of Worksheet S–3 Part IV and Line 18 of Worksheet S–3 Part II, in contrast to the concrete list of core wage-related costs, may hinder consistent and proper reporting of fringe benefits. Our internal reviews indicate widely divergent types of costs that hospitals are reporting as other wage-related costs on these lines. We are concerned that inconsistent reporting of other wage-related costs further compromises the accuracy of the wage index as a representation of the relative average hourly wage for each labor market area. Our intent in creating a core list of wage-related costs in the September 1, 1994 IPPS final rule was to promote consistent reporting of fringe benefits, and we are increasingly concerned that inconsistent reporting of wage-related costs undermines this effort. Specifically, we expressed in the September 1, 1994 IPPS final rule that, since we began including fringe benefits in the wage index, we have been concerned with the inconsistent reporting of fringe benefits, whether because of a lack of provider proficiency in identifying fringe benefit costs or varying interpretations across fiscal intermediaries of the definition for fringe benefits in PRM–I, Section 2144.1 (59 FR 45356). We believe that the limited and inconsistent use of Line 25 and its subscripts of Worksheet S–3 Part IV and Line 18 of Worksheet S–3 Part II for reporting wage-related costs other than the core list indicate that including other wage-related costs in the wage

index compromises the accuracy of the wage index as a relative measure of wages in a given labor market area.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20358), for the reasons discussed earlier, for the FY 2020 wage index and subsequent years, we proposed to only include the wage-related costs on the core list in the calculation of the wage index and not to include any other wage-related costs in the calculation of the wage index. Under our proposal, we stated we would no longer consider any other wage-related costs beginning with the FY 2020 wage index. Considering the extremely limited number of hospitals reporting other wage-related costs and the inconsistency in types of other wage-related costs being reported, we indicated we believe this proposal will help ensure a more consistent and more accurate wage index representative of the relative average hourly wage for each labor market area. In addition, we stated that we believe that this proposal to no longer include other wage-related costs in the wage index calculation benefits the vast majority of hospitals because most hospitals do not report other wage-related costs. We explained that because the wage index is budget neutral, hospitals in an area without other wage-related costs included in the wage index have their wage indexes reduced when other areas' wage indexes are raised by including other wage-related costs in their wage index calculation. We also noted that this proposal to exclude other wage-related costs from the wage index, starting with the FY 2020 wage index, contributes to agency efforts to simplify hospital paperwork burden because it would eliminate the need for Line 18 on Worksheet S–3, Part II and Line 25 and its subscripts on Worksheet S–3, Part IV of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050). We noted that we would include in the FY 2019 wage index the other wage-related costs of the 8 hospitals that accurately reported those costs in accordance with the criteria in effect as of FY 2018.

In summary, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20358), we clarified that our policy for calculating the 1-percent test includes Line 15 for Home Office Part A Administrator on Worksheet S–3, Part II in the denominator. In addition, we proposed to eliminate other wage-related costs from the calculation of the wage index for the FY 2020 wage index and subsequent years, as discussed earlier.

Comment: Several commenters supported CMS' proposal to only include core wage-related costs in the wage index calculation for the FY 2020 wage index and subsequent years because only 8 hospitals out of over 3,000 IPPS hospitals in the proposed 2019 wage index calculation had costs on this line for the FY 2018 wage index. One of these commenters reiterated that the inclusion of other wage-related costs in such a limited manner distorts the average hourly wage of a given labor market area, and does not accurately reflect the labor market area's current wages relative to national wages.

A few commenters opposed this proposal. One commenter stated that the proposal would unreasonably exclude legitimate fringe benefits that can be directly linked to individual employment. Another commenter disagreed that other wage-related costs of an individual hospital do not accurately reflect the economic conditions of the labor market as a whole, stating that these costs more accurately represent the economic conditions of the labor market and that the inclusion of these costs is important for the financial sustainability of the minority of hospitals incurring other wage-related costs. The commenter urged CMS to continue allowing costs that meet current criteria for reporting other wage-related costs when hospitals undergo serious circumstantial changes and incur costs to maintain qualified staff; for example, during a nursing strike when a hospital may engage in costly contract nursing agreements that include housing costs. This commenter believed that the cost report should remain a mechanism for CMS to acknowledge unforeseen or changing other labor costs.

Response: We appreciate the commenters' support for our proposal. In response to the commenters who opposed the proposal, we continue to believe that other wage-related costs are not a relative measure of wages for the labor market area as a whole even though they may represent legitimate fringe benefits for individual hospitals. As we stated in the proposed rule, while other wage-related costs may represent costs that may have an impact on an *individual* hospital's average hourly wage, we do not believe that costs reported by only a very small minority of hospitals (less than 0.003 percent) accurately reflect the economic conditions of the labor market area as a whole in which such an individual hospital is located (83 FR 20357). Furthermore, we do not believe that our proposal to exclude these costs threatens the financial sustainability of the minority of hospitals incurring other wage-related costs because these costs are typically only a small percentage of total wages (costs need to meet the 1 percent test). Even if inclusion of these costs is indeed important for the financial sustainability of the minority of hospitals incurring other wage-related costs, we still do not agree that these costs should be included because they do not constitute a significant portion of wage costs in a particular labor market area and do not accurately represent the economic conditions of the labor market area as a whole. We also do not believe that the wage index is the appropriate mechanism to acknowledge and reimburse unforeseen other labor costs resulting from serious circumstantial changes such as nursing strikes. The wage index is intended as a relative measure of labor costs, and inclusion of other wage-related costs in the wage index arising from occasional, disruptive circumstantial changes may distort the average hourly wage of a particular labor market area so that its wage index does not accurately represent that labor market area's current wages relative to national wages.

Comment: Several commenters requested clarification whether physician malpractice costs would still be included in the calculation of the wage index if other wage-related costs are eliminated. Several commenters cited the September 1, 1994 **Federal Register** (59 FR 45358) which allows only malpractice policies that list actual names or specific titles of covered employees in the wage index as ''explicit guidance and longstanding practice'' that inclusion of malpractice costs has ''long been recognized by CMS'' when meeting certain criteria. Commenters also maintained that if CMS is proposing to exclude malpractice costs as an other wage-related cost, this would create an inconsistency when comparing hospitals across the country by treating salaried and contract physicians differently.

Furthermore, the commenters suggested that the number of hospitals reporting physician malpractice costs should be included in the number of hospitals that currently report other wage-related costs. One commenter stated that CMS' count of eight hospitals in the country reporting noncore wage-related costs is incorrect because malpractice cost is a noncore wage-related cost that is required, by cost report instruction, to be included with physician wage-related costs rather than on the noncore wage-related cost line. The commenter explained that CMS required physicians' wage-related costs to be listed separately, effective with FY 1994, because CMS anticipated

excluding Part A physicians' wage-related costs from the wage index, yet subsequently decided for FY 1999 onward to keep Part A physicians' wage-related cost in the wage index. Similarly, another commenter stated that CMS is ''vastly underestimating'' the impact of removing other wage-related costs from the wage index because malpractice insurance may currently be reported as other wage-related costs for certain categories of employees (for example, physicians, interns and residents, among others) on Lines 20 through 25, and 25.50 through 25.53 of Worksheet S–3, Part II. The commenter urged CMS to more thoroughly analyze the potential impact of the proposal, stating that it would be ''premature for CMS to eliminate other wage-related costs from the wage index without a comprehensive review'' of the magnitude of the proposal.

Response: We are clarifying that our proposal to remove other wage-related costs from the wage index includes removing all categories of other wage-related costs, even those not currently reported on Line 18 of Worksheet S–3, Part II—for example, contract labor. In addition, this removal would include other wage-related costs such as malpractice insurance associated with both employees and contract labor. The instructions for calculating the 1-percent test on Worksheet S–3, Part IV include the following note: ''The other wage related costs associated with contract labor and home office/related organization personnel are included in the numerator because these other wage related costs are allowed in the wage index (in addition to other wage related costs for direct employees), assuming the requirements for inclusion in the wage index are met.'' Therefore, by excluding other wage-related costs from the wage index, we are clarifying that other wage-related costs for contract labor would also be excluded from the wage index calculation. Therefore, we disagree with the commenter that excluding other wage-related costs creates an inconsistency when comparing hospitals across the country by treating salaried and contract physicians differently.

In response to the commenters' citation of the September 1, 1994 **Federal Register** as evidence of CMS' longstanding practice of allowing malpractice insurance in the wage index if actual names or specific titles of covered employees are listed, we emphasize that this guidance is applicable for reporting malpractice insurance as an other wage-related cost between 1994 and prior to the FY 2020 wage index, because our proposal is to prospectively eliminate other wage-related costs from the calculation of the wage index beginning with FY 2020 for reasons enumerated in the proposed rule.

Regarding the requirement for physician other wage-related costs to be listed separately, the commenters are correct that the instructions for Worksheet S–3, Part II, Line 18, currently include the following note: ''Do not include the wage-related costs for physicians Parts A and B, non-physician anesthetists Part A and B, interns and residents in approved programs, and home office personnel.'' However, we remind the commenters that *all* other wage-related costs, even those not reported on Line 18, must meet the 1-percent test for other-wage related costs, as described in the September 1, 1994 IPPS final rule (59 FR 45357) and clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38132 through 38136). Therefore, other wage-related costs associated with physicians must meet the 1-percent test. The instructions for calculating the 1-percent test on Worksheet S–3, Part IV, Line 25, read, ''Calculate the 1-percent test by dividing each individual category of the other wage related cost (that is, the numerator) by the sum of Worksheet S–3, Part III, lines 3 and 4, column 4, (that is, the denominator). The other wage related costs associated with contract labor and home office/related organization personnel are included in the numerator because these other wage related costs are allowed in the wage index (in addition to other wage related costs for direct employees), assuming the requirements for inclusion in the wage index are met. For example, if a hospital is including parking garage costs as an other wage related cost that is reported on the W–2 or 1099 form, when running the 1-percent test, include in the numerator all the parking garage other wage related cost *for direct salary employees, contracted employees, and home office employees,* and divide by the sum of Worksheet S–3, Part III, Lines 3 and 4, Column 4.

Calculate the 1-percent test only one time for a category of other wage related costs, *inclusive of other wage related costs for employees, contracted employees, and home office employees.*'' (emphasis added)

In response to the commenter who asserted that CMS is ''vastly underestimating'' the impact of removal of other wage-related costs and specifically malpractice insurance costs from the wage index, we conducted additional analysis to quantify the number of hospitals reporting malpractice insurance on lines other than Line 18 of Worksheet S–3, Part II, as an other wage-related cost meeting the 1-percent test. For the FY 2019 wage index, only 41 hospitals reported costs on Worksheet S–3, Part II, Line 22 (which includes core wage-related costs and may or may not include malpractice insurance as an other wage-related cost) that were greater than 1 percent of total salaries. Of those 41 hospitals, it is unlikely that the wage-related costs reported for Physician Part A Administrative were entirely comprised of malpractice insurance costs. Therefore, the number of hospitals reporting malpractice insurance as an other wage-related cost and which exceeds 1-percent of total salaries is likely less than 1.25 percent of the total hospitals in the wage index (that is, 41/3,283 IPPS hospitals included in the FY 2019 final wage index). In addition, we conducted further analysis and found that fewer than 30 hospitals indicated a description of malpractice on Line 25 of Worksheet S–3, Part IV, for other wage-related costs, and of those hospitals, only 3 hospitals met the 1-percent test criteria for inclusion. Consequently, we believe that we have conducted the comprehensive review requested by the commenter and thoroughly analyzed the potential impact of this proposal, and concluded that the number of hospitals reporting malpractice as an other wage-related cost is minimal. Therefore, we continue to believe that removing other wage-related costs reported on Line 18 and other lines from the wage index is appropriate because costs reported by only a very small minority of hospitals do not accurately reflect the economic conditions of the labor market area as a whole.

Comment: Commenters recommended that, if CMS eliminates other wage-related costs from the wage index, CMS revise the core wage-related costs list to include malpractice costs. The commenters noted that malpractice coverage is required by State law for a considerable number of States, and, according to one commenter, is a significant cost that consistently meets the 1-percent test. Some commenters suggested additional fringe benefits to be added to the core wage-related cost list such as employee meals, transportation and parking costs. One commenter opposed CMS removing other wage-related costs without the opportunity for public comment on expanding the categories classified as ''core'' wage-related costs. This commenter emphasized that the current list of ''core'' benefits has not been updated since FY 1995 and it is likely

that benefit cost structures and components have changed since then.

Response: We understand the commenter's assertion that expanding the categories classified as core wage-related costs may be warranted as benefit structures evolve over time. However, after conducting the additional analysis discussed earlier to evaluate the magnitude of hospitals reporting malpractice insurance costs, we disagree with the commenter's statement that malpractice insurance cost is a significant cost that consistently meets the 1-percent test, as well as the other criteria that would need to be met for malpractice insurance to be reported as an other wage-related cost. As we stated in the proposed rule (83 FR 20358), our intent in creating a core list of wage-related costs in the September 1, 1994 IPPS final rule was to promote consistent reporting of fringe benefits. The extremely limited number of hospitals correctly reporting these costs noted in the aforementioned additional analysis indicates that malpractice insurance is not a significant wage-related cost consistently reported by most hospitals. We do not believe it is warranted to add an expense to the list of core wage-related costs that is only reported by approximately less than 1.25 percent of hospitals in the wage index. Similarly, we do not believe that employee meals, transportation, and parking costs constitute a significant expense for most hospitals that should be added to the core wage-related cost list. We note that, of the 8 hospitals correctly reporting wage-related costs on Line 18 of Worksheet S–3, Part II, for the FY 2019 wage index, only 2 of those hospitals reported parking costs that met the 1-percent test, and only 2 hospitals reported cafeteria costs that met the 1-percent test.

Therefore, after consideration of the public comments we received, for the reasons discussed above and in the proposed rule, we are finalizing our proposal, without modification, to eliminate other wage-related costs from the calculation of the wage index for the FY 2020 wage index and subsequent years. We also are clarifying that all other wage-related costs, even those not reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, such as contract labor, are being removed from the calculation of the wage index, and we will update the cost report instructions accordingly.

3. Codification of Policies Regarding Multicampus Hospitals

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20358 through 20360), we have received an increasing number of inquiries regarding the treatment of multicampus hospitals as the number of multicampus hospitals has grown in recent years. While the regulations at § 412.230(d)(2)(iii) and (v) for geographic reclassification under the MGCRB include criteria for how multicampus hospitals may be reclassified, the regulations at § 412.92 for sole community hospitals (SCHs), § 412.96 for rural referral centers (RRCs), § 412.103 for rural reclassification, and § 412.108 for Medicare-dependent, small rural hospitals (MDHs) do not directly address multicampus hospitals. Thus, in the FY 2019 proposed rule, we proposed to codify in these regulations the policies for multicampus hospitals that we have developed in response to recent questions regarding CMS' treatment of multicampus hospitals for purposes other than geographic reclassification under the MGCRB.

We stated in the proposed rule (83 FR 20358) that the proposals (stated below) applied to hospitals with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meet the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, also referred to as multicampus hospitals or hospitals with remote locations. We proposed that a main campus of a hospital cannot obtain an SCH, RRC, or MDH status or rural reclassification independently or separately from its remote location(s), and vice versa. Rather, if the criteria are met in the regulations at § 412.92 for SCHs, § 412.96 for RRCs, § 412.103 for rural reclassification, or § 412.108 for MDHs (as discussed later in this section), the hospital (that is, the main campus and its remote location(s)) would be granted the special treatment or rural reclassification afforded by the aforementioned regulations.

We stated in the proposed rule that we believe this is an appropriate policy for two reasons. First, each remote location of a hospital is included on the main campus's cost report and shares the same provider number. That is, the main campus and remote location(s) would share the same status or rural reclassification because the hospital is a single entity with one provider agreement. Second, it would not be administratively feasible for CMS and the MACs to track every hospital with remote locations within the same CBSA and to assign different statuses or rural reclassifications exclusively to the main campus or to its remote location. We note that, for wage index purposes only, CMS tracks multicampus remote locations located *in different CBSAs* in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). However, for purposes of rural reclassification under § 412.103, we do not believe it would be appropriate for a main campus and remote location(s) (whether located in the same or separate CBSAs) to be reclassified independently or separately from each other because, unlike MGCRB reclassifications which are used only for wage index purposes, § 412.103 rural reclassifications have payment effects other than wage index (for example, payments to disproportionate share hospitals (DSHs), and non-Medicare payment provisions, such as the 340B Drug Pricing Program administered by HRSA).

To qualify for rural reclassification or SCH, RRC, or MDH status, we proposed that a hospital with remote locations must demonstrate that both the main campus and its remote location(s) satisfy the relevant qualifying criteria. A hospital with remote locations submits a joint cost report that includes data from its main campus and remote location(s), and its MedPAR data also combine data from the main campus and remote location(s). We believe that it would not be feasible to separate data by location, nor would it be appropriate, because we consider a main campus and remote location(s) to be one hospital. Therefore, where the regulations at § 412.92, § 412.96, § 412.103, and § 412.108 require data, such as bed count, number of discharges, or case-mix index, for example, to demonstrate that the hospital meets the qualifying criteria, we proposed to codify in our regulations that the combined data from the main campus and its remote location(s) are to be used.

For example, if a hospital with a main campus with 200 beds and a remote location with 75 beds applies for RRC status, the combined count of 275 beds would be considered the hospital's bed count, and the main campus and its remote location would be granted RRC status if the hospital applies during the last quarter of its cost reporting period and both the main campus and the remote location are located in a rural area as defined in 42 CFR part 412, subpart D. This is consistent with the regulation at § 412.96(b)(1), which states, in part, that the number of beds is determined under the provisions of § 412.105(b). For § 412.105(b), beds are counted from the main campus and remote location(s) of a hospital. We believe this is also consistent with § 412.96(b)(1)(ii), which sets forth the

criteria that the hospital is located in a rural area and the hospital has a bed count of 275 or more beds during its most recently completed cost reporting period, unless the hospital submits written documentation with its application that its bed count has changed since the close of its most recently completed cost reporting period for one or more of several reasons, *including the merger of two or more hospitals.*

Similarly, combined data would be used for demonstrating the hospital meets criteria at § 412.92 for SCH status. For example, the patient origin data, which are typically MedPAR data used to document the boundaries of the hospital's service area as required in § 412.92(b)(1)(ii) and (iii), would be used from both locations. We reiterate that we believe this is the appropriate policy because the main campus and remote location are considered one hospital and that it is the only administratively feasible policy because there is currently no way to split the MedPAR data for each location.

For § 412.103 rural reclassification, we stated in the proposed rule (83 FR 20359) that a hospital with remote location(s) seeking to qualify under § 412.103(a)(3), which requires that the hospital would qualify as an RRC or SCH if the hospital were located in a rural area, would similarly demonstrate that it meets the criteria at § 412.92 or at § 412.96, such as bed count, by using combined data from the main campus and its remote location(s) (with the exception of certain criteria discussed below related to location, mileage, travel time, and distance requirements). We refer readers to the portions of our discussion that explain how hospitals with remote locations would meet criteria for RRC or SCH status.

A hospital seeking MDH status would also use combined data for bed count and discharges to demonstrate that it meets the criteria at § 412.108(a)(1). For example, if the main campus of a hospital has 75 beds and its remote location has 30 beds, the bed count exceeds 100 beds and the hospital would not satisfy the criteria at § 412.108(a)(1)(i) (which we proposed, and are finalizing, to be redesignated as § 412.108(a)(1)(ii)).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20359), we reminded readers that, under § 412.108(b)(4) and § 412.92(b)(3)(i), an approved MDH or SCH status determination remains in effect unless there is a change in the circumstances under which the status was approved. We stated that while we believe that this proposal is consistent with the policies for multicampus hospitals that we have developed in response to recent questions, current MDHs and SCHs should make sure that this proposal does not create a change in circumstance (such as an increase in the number of beds to more than 100 for MDHs or to more than 50 for SCHs), which an MDH or SCH is required to report to the MAC within 30 days of the event, in accordance with § 412.108(b)(4)(ii) and (iii) and § 412.92(b)(3)(ii) and (iii).

In the FY 2019 proposed rule, we discussed that, with regard to other qualifying criteria set forth in the regulations at §§ 412.92, 412.96, 412.103, and 412.108 that do not involve data that can be combined, specifically qualifying criteria related to location, mileage, travel time, and distance requirements, a hospital would need to demonstrate that the main campus and its remote location(s) each independently satisfy those requirements in order for the entire hospital, including its remote location(s), to be reclassified or obtain a special status.

To qualify for SCH status, for example, it would be insufficient for only the main campus, and not the remote location, to meet distance criteria. Rather, the main campus and its remote location(s) would each need to meet at least one of the criteria at § 412.92(a). Specifically, the main campus and its remote location must each be located more than 35 miles from other like hospitals, or if in a rural area (as defined in § 412.64), be located between 25 and 35 miles from other like hospitals if meeting one of the criteria at § 412.92(a)(1) (and each meet the criterion at § 412.92(a)(1)(iii) if applicable), or between 15 and 25 miles from other like hospitals if the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years (§ 412.92(a)(2)), or travel time to the nearest like hospital is at least 45 minutes (§ 412.92(a)(3)). We believe that this is necessary to show that the hospital is indeed the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under Medicare Part A, as required by section 1886(d)(5)(D)(iii)(II) of the Act. For hospitals with remote locations that apply for SCH classification under § 412.92(a)(1)(i) and (ii), combined data are used to document the boundaries of the hospital's service area using data from across both locations, as discussed earlier, and all like hospitals within a 35-mile radius of each location are included in the analysis. To be located in a rural area to use the criteria in § 412.92(a)(1), (2), and (3), the main campus and its remote location(s) must each be either geographically located in a rural area, as defined in § 412.64, or reclassified as rural under § 412.103.

Similarly, for RRC classification under § 412.96 and MDH classification under § 412.108, the main campus and its remote location(s) must each be either geographically located in a rural area, as defined in 42 CFR part 412, subpart D, or reclassified as rural under § 412.103 to meet the rural requirement portion of the criteria at § 412.96(b)(1), § 412.96(c), or § 412.108(a)(1) (or for MDH, be located in a State with no rural area and satisfy any of the criteria under § 412.103(a)(1) or (a)(3) or under § 412.103(a)(2) as of January 1, 2018). For hospitals with remote locations that apply for RRC classification under § 412.96(b)(2)(ii) or § 412.96(c)(4), 25 miles is calculated from each location (the main campus and its remote location(s)), and combined data from both the main campus and its remote location(s) are used to calculate the percentage of Medicare patients, services furnished to Medicare beneficiaries, and discharges.

For hospitals seeking to reclassify as rural by meeting the criteria at § 412.103(a)(1), (a)(2), or (a)(6), we also proposed to codify in our regulations that it would not be sufficient for only the main campus, and not its remote location(s), to demonstrate that its location meets the aforementioned criteria. Rather, under § 412.103(a)(1) and (2) (which also are incorporated in § 412.103(a)(6)), we proposed that the main campus and its remote location(s) must each either be located (1) in a rural census tract of an MSA as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area codes (§ 412.103(a)(1)), or (2) in an area designated by any law or regulation of the State in which it is located as a rural area, or be designated as a rural hospital by State law or regulation (§ 412.103(a)(2)). For hospitals seeking to reclassify as rural by meeting the criteria in § 412.103(a)(3), which require that the hospital would qualify as an RRC or a SCH if the hospital were located in a rural area, we refer readers to our discussion presented earlier that explains how hospitals with remote locations would meet criteria for RRC or SCH status.

In the FY 2019 IPPS/LTCH PPS proposed rule, we noted that we have also received questions about how a hospital with remote locations that trains residents in approved medical residency training programs would be treated for IME adjustment purposes if

it reclassifies as rural under § 412.103. As we noted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50114), the rural reclassification provision of § 412.103 only applies to IPPS hospitals under section 1886(d) of the Act. Therefore, it applies for IME payment purposes, given that the IME adjustment under section 1886(d)(5)(B) of the Act is an additional payment under IPPS. In contrast, sections 1886(a)(4) and (d)(1)(A) of the Act exclude direct GME costs from operating costs and these costs are not included in the calculation of the IPPS payment rates for inpatient hospital services. Payment for direct GME is separately authorized under section 1886(h) of the Act and, therefore, not subject to § 412.103. Therefore, if a geographically urban teaching hospital reclassifies as rural under § 412.103, such a reclassification would only affect the teaching hospital's IME adjustment, and not its direct GME payment. Accordingly, in the FY 2019 proposed rule, we clarified that in order for the IME cap adjustment regulations at § 412.105(f)(1)(iv)(A), § 412.105(f)(1)(vii), and § 412.105(f)(1)(xv) to be applicable to a teaching hospital with a main campus and a remote location(s), the main campus and its remote location(s), respectively, must each be either geographically located in a rural area as defined in 42 CFR part 412, subpart D, or reclassified as rural under § 412.103. For direct GME purposes at § 413.79, both the main campus and its remote location(s) are required to be geographically rural because a hospital's status for any direct GME payments or adjustments is unaffected by a § 412.103 rural reclassification.

We proposed to codify these policies regarding the application of the qualifying criteria for hospitals with remote locations in the regulations at § 412.92 for SCHs, § 412.96 for RRCs, § 412.103 for rural reclassification, or § 412.108 for MDHs. Specifically, we proposed to revise these regulations as follows:

We proposed to add paragraph (a)(4) to § 412.92 to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria at § 412.92(a)(1)(i) and (ii) are met. For the mileage and rural location criteria at § 412.92(a) and the mileage, accessibility, and travel time criteria specified at § 412.92(a)(1) through (a)(3), the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements.

In § 412.96, we proposed to redesignate paragraph (d) as paragraph (e) and add a new paragraph (d) to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria at § 412.96(b)(1) and (2) and (c)(1) through (c)(5) are met. For purposes of meeting the rural location criteria in § 412.96(b)(1) and (c) and the mileage criteria in § 412.96(b)(2)(ii) and (c)(4), the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements.

We proposed to add paragraph (a)(7) to § 412.103 to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy the location criteria specified in § 412.103(a)(1) and (2) (which criteria also are incorporated in § 412.103(a)(6)). As discussed in our response to public comments below, we note that we inadvertently referenced § 412.103(a)(6) (which applies to critical access hospitals (CAHs)) in proposed paragraph § 412.103(a)(7). As explained in the proposed rule (83 FR 20358) and above, these policies apply to hospitals where services are provided and billed under the IPPS. Thus, these policies do not apply to CAHs, which are not paid under the IPPS. Accordingly, as discussed in response to comments below, we are not including a reference to § 412.103(a)(6) in § 412.103(a)(7), as finalized in this rule.

We proposed to add paragraph (a)(3) to § 412.108 to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria in § 412.108(a)(1) and (2) are met. We stated that for the location requirement specified at proposed amended paragraph (a)(1)(i) of this section, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy this requirement. (We note that we are finalizing the proposed amendments to § 412.108(a)(1)(i) as discussed in section IV.G.2.a. of the preamble of this final rule.)

Comment: Commenters expressed appreciation for CMS providing greater clarity concerning the treatment of multicampus hospitals by amending the regulations for SCHs, RRCs, rural reclassifications, and MDHs to address the situation of multicampus hospitals. One commenter specifically thanked CMS for an ''important acknowledgement of the changing nature of the hospital industry'', and stated that these proposals would give hospitals a clearer understanding of the implications of combining with other hospitals as the consolidation of the industry continues.

Several commenters requested clarification regarding the effective date of the proposals. The commenters asked what will happen to multicampus hospitals that have already reclassified as rural, and whether the proposals would affect new classification requests only and grandfather-in existing SCHs, RRCs, and MDHs, or if those hospitals with existing reclassifications or special statuses would be required to reapply according to the criteria presented in the proposed rule. One commenter specifically questioned CMS' authority to make a rule effective retroactively and asked that CMS clarify that the policy is effective for applications submitted on or after October 1, 2018. Similarly, another commenter stated that while the proposals are presented as a codification, they are a change in longstanding CMS policy because CMS has ''long been treating multicampus facilities as distinct entities for a variety of purposes.'' Some commenters requested that CMS not finalize the codification without research to demonstrate its impact because they view it as a change in policy. Commenters urged CMS to provide additional guidance and information on the policies for treatment of multicampus hospitals.

Response: We appreciate the commenters' support and agree that codification of the policies regarding the treatment of multicampus hospitals for purposes of special statuses and reclassification is appropriate and provides greater clarity. We also appreciate the commenters' feedback on

our existing policies for multicampus hospitals. However, as we stated in the proposed rule (83 FR 20358), we proposed to codify in regulations our existing policies for multicampus hospitals and did not propose to change them. Thus, the policies discussed in the proposed rule are our existing policies currently in effect, and our intent was to provide greater clarification of these policies by codifying them in the regulations. If, after further consideration of the feedback we have received, we decide to seek to change our current policies, we believe the most appropriate approach would be to propose changes to those policies through future notice-and-comment rulemaking.

In response to the commenters' questions regarding the effective date of the policies discussed in the proposed rule, we reiterate that we proposed to codify in the regulations our existing policies for multicampus hospitals, and thus these policies have been and continue to be in effect. Consequently, there is no need to ''grandfather in'' multicampus hospitals with existing special statuses or reclassifications. Similarly, we disagree that we are promulgating a rule retroactively because these policies are CMS' longstanding policies. We note that the commenter's assertion that these proposed codifications are a change in longstanding CMS policy were not accompanied by examples of CMS treating multicampus facilities as distinct entities. It is unclear what the commenter was referring to in support of this assertion. If the commenter was referring to CMS' treatment of multicampus facilities for wage index purposes, as mentioned in the proposed rule (83 FR 20358), CMS tracks multicampus remote locations located *in different CBSAs* for wage index purposes only, in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act).

Similarly, because we proposed to codify existing policy, multicampus hospitals with existing special status or rural reclassification would not be required to reapply according to the criteria codified in this rule, as the current regulations at §§ 412.92(3)(i), 412.103(f), and 412.108(b)(4) state that an approved SCH classification, rural reclassification, or MDH status determination, respectively, remains in effect without need for reapproval unless there is a change in the circumstances under which the classification or determination was approved. We are reiterating that current MDHs and SCHs should make sure that any change in circumstance (such as an increase in the number of beds to more than 100 for MDHs or to more than 50 for SCHs) as a result of the MDH or SCH opening a remote location, for example, is correctly reported to the MAC within 30 days of the event in accordance with §§ 412.108(b)(4)(ii) and (iii) and 412.92(b)(3)(ii) and (iii).

With regard to the commenters' request that CMS not finalize its proposals to codify in the regulations its existing policies, we note that not finalizing the proposals would still leave our current policies unchanged and in effect with regard to multicampus hospitals and qualification for special statuses and reclassifications, although they would not be codified in regulations. We believe not finalizing the proposals to codify these policies in regulations would create confusion surrounding the existing policies currently in effect.

In response to commenters requesting more information and guidance on our existing policies, we agree and will consider further provider education on our existing policies, where appropriate.

Comment: Several commenters opposed CMS' proposals, stating that while they understood the policy objectives being advanced by CMS and agreed that remote campuses should not be categorically ignored for purposes of these determinations, the policies associated with the codification may have the unintended consequence of harming access to rural health care. Specifically, some commenters were concerned that SCHs are at risk of losing their designation if another hospital opens a remote location near them or if the SCH opens a remote location near other hospitals, especially if the remote location is a ''microhospital'' that does not offer a full array of inpatient services.

One commenter agreed with CMS' policy in the scenario of the opening of a remote location that provides general inpatient services within 24 miles from an existing SCH. The commenter asserted that, while the remote location might cause the SCH to lose its classification as an SCH, this outcome appears ''congruent with the intent of law'' because the former SCH is no longer the sole source of inpatient services reasonably available to individuals in the geographic area. However, this commenter and other commenters disagreed with CMS' policy of including a remote location for determining SCH qualification if the remote location (either of a nearby hospital or of the SCH) does not meet the definition of a hospital or a like hospital or does not provide inpatient services reasonably available to individuals in the geographic area, such as a remote clinic with a small inpatient obstetrics and gynecology or labor and delivery unit or a few inpatient psychiatric or rehabilitation beds as a distinct part unit. One commenter stated that examining remote locations for distance requirements would be particularly concerning if the remote location does not provide 24/7 emergency care, because this would allow a small remote clinic with limited hours and providers to result in loss of access to life-saving emergency care. Another commenter similarly stated that the policy may allow a ''competitive tactic inconsistent with the intent of the rule'' if a hospital could lose SCH status as a result of a competing hospital opening a remote location that does not functionally represent a like provider.

Commenters urged CMS to carefully evaluate the impacts of the proposals on rural health care and consider a range of alternatives, including: Not finalizing the proposal to codify certain policies for multicampus hospitals with respect to SCHs; finalizing the proposal with protections for existing SCHs; excluding SCHs from the evaluation of the qualifying criteria on a combined basis; modifying the policy to apply only if the remote location is a full service inpatient facility; or apply the policy only if the remote location on its own could be licensed as a hospital under State law. One commenter specifically suggested that a remote location providing only limited inpatient services should not be considered a like provider.

Response: As stated earlier, we did not propose to change our policies; rather, we proposed to codify our current policies. We note that our current policies benefit access to rural health care for hospitals seeking RRC status and rural reclassification under § 412.103(a)(3) by allowing bed counts from the main hospital and remote locations to be combined, making RRC status and rural reclassification under § 412.103(a)(3) more easily obtainable. However, we understand the commenters' concerns that SCH status may be more difficult to obtain and maintain under our longstanding policies that consider remote locations. Therefore, we note that our current polices contain some existing safeguards for SCHs because these policies only apply to remote locations where services are provided and billed under the IPPS, and that hospitals are only compared to like hospitals for purposes of meeting SCH criteria under § 412.92(a). Specifically, according to the definition at § 412.92(c)(3), a

hospital is considered a like hospital if the hospital furnishes short-term, acute care, and the total inpatient days attributable to the units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital IPPS are more than 8 percent of the similarly calculated total inpatient days of the hospital seeking SCH designation. Furthermore, we note that, for hospitals qualifying for SCH status under the criteria at § 412.92(a)(1), SCH status may not be impacted by the opening of a remote location within 25 to 35 miles if the hospital continues to meet one of the requirements at § 412.92(a)(1)(i) through (iii). For example, a hospital that qualified for SCH classification under § 412.92(a)(1)(i) would not automatically lose SCH status if a hospital opens up within 25 to 35 miles if it continues to meet the requirements at § 412.92(a)(1)(i) by providing at least 75 percent of the inpatient care in its service area compared to like hospitals. Specifically, § 412.92(a)(1)(i) requires that no more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area.

However, we recognize that, under our current policies, for purposes of determining whether a nearby hospital consisting of a main campus and a remote location would be considered a like hospital with respect to an SCH or a hospital seeking SCH classification, the inpatient days of the remote location and the main hospital are not distinguishable for purposes of calculating the 8 percent. We also recognize that there may be scenarios in which a remote location that is within range of an SCH or a hospital seeking SCH classification and provides only very limited IPPS services is considered a like hospital by virtue of its being a remote location of a larger main hospital. We acknowledge the concerns raised by the commenters with respect to ensuring access to care in such situations, and we will take the feedback we received on this issue into consideration for potential future rulemaking.

Comment: One commenter requested that CMS eliminate the new additional burden for SCHs of ensuring that they comply with the policies by amending the regulation at § 412.92(b)(3)(ii)(A) requiring an SCH to notify the MAC within 30 days of the opening of a new hospital in its service area to exclude the opening of a new remote location of another hospital.

Response: This proposed codification of our longstanding policy with respect to SCHs did not create any new additional burden for SCHs because the requirement at § 412.92(b)(3)(ii)(A) to notify the MAC within 30 days of the opening of a new hospital in its service area always included the opening of a new remote location.

Comment: One commenter requested additional justification for the policy that both the main hospital and all remote locations must meet the same geographic criteria.

Response: With regard to the request for justification as to why both the main campus and all remote locations must meet geographic criteria, we note that we did not propose any changes to our existing policy. We continue to believe our policy to require both the main campus and remote location(s) to meet criteria involving location, mileage, travel time, and distance rather than require only the main campus to meet criteria is appropriate because both the main campus and remote location(s) benefit from the special status or rural reclassification if approved. As we stated in the proposed rule (83 FR 20358), each remote location of a hospital is included on the main campus' cost report and shares the same provider number. That is, the main campus and remote location(s) would share the same status or rural reclassification because we consider the hospital to be a single entity with one provider agreement. We also note that the main campus and remote location(s) cannot jointly meet qualifying criteria that involve location, mileage, travel time, and distance by totaling miles or minutes in the same way that data derived from the cost report or MedPAR, such as bed count, for example, can be combined. Furthermore, as we stated in the proposed rule, we believe that requiring both the main campus and remote location(s) to meet at least one of the criteria at § 412.92(a) for SCH status is necessary to show that the hospital is indeed the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under Medicare Part A, as required by section 1886(d)(5)(D)(iii)(II) of the Act. Similarly, for MDH and RRC status, we maintain that requiring both the main campus and remote location(s) to be rural is necessary for the hospital to be considered located in a rural area, as required by sections 1886(d)(5)(G)(iv)(I) and 1886(d)(5)(C)(i) of the Act. Finally, we believe that requiring both the main campus and remote location(s) to meet at least one of the criteria at § 412.103(a) for urban to rural reclassification is necessary to consider the hospital as meeting the requirements at section 1886(d)(8)(E) of the Act, which are implemented at § 412.103.

Comment: Several commenters requested clarifications of our policies. One commenter requested that CMS confirm and clarify that data from an IPPS excluded distinct part unit, such as an off-campus inpatient psychiatric unit, would not be combined with the main campus data and that the IPPS-excluded location would not be required to satisfy the SCH, RRC, MDH, or rural reclassification requirements in order for the hospital to qualify as an SCH, RRC, or MDH or to reclassify as rural. Another commenter asked for clarification regarding what standard would be applied for mileage requirements when determining distance between facilities without inpatient beds. Another commenter sought clarification to confirm that the proposals are not intended to apply to CAHs.

Response: We are confirming that the data from an IPPS-excluded unit, such as an off-campus inpatient psychiatric unit, would not be combined with the main campus data, and that a distinct part unit would not be required to satisfy the SCH, RRC, MDH, or rural reclassification requirements in order for the hospital to qualify as an SCH, RRC, or MDH or to reclassify as rural. As we stated in the proposed rule, these policies apply to hospitals with a main campus and one or more remote locations under a single provider agreement *where services are provided and billed under the IPPS* and that meet the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, also referred to as multicampus hospitals or hospitals with remote locations.

For purposes of these policies, a facility without inpatient beds would not be considered for mileage requirements. We also are clarifying that because these policies apply to hospitals where services are provided and billed under the IPPS, these policies do not apply to CAHs. We note that we inadvertently included in proposed § 412.103(a)(7) a reference to § 412.103(a)(6), which pertains to CAHs. Thus, in this final rule, we are deleting the reference to § 412.103(a)(6) in § 412.103(a)(7).

Comment: One commenter maintained that it is not feasible for providers to calculate distances between themselves and another provider's remote campus because only the main

campus address is included in Healthcare Provider Cost Reporting Information System (HCRIS) cost report data, and even where the other hospitals may report multicampus hospitals in different CBSAs on their cost report, the remote campus data do not include a street address for actual distance calculations to another hospital's remote location. The commenter, therefore, recommended that CMS not implement the proposals until such time that CMS changes the cost report Worksheet S–2 questions to include the street address of all remote locations and that information becomes available in the published HCRIS data so that hospitals can research and identify main campus and remote locations of other hospitals within the distance requirement radius.

Response: While the commenter is correct that only the address of a main campus is included in the HCRIS cost report data, we believe that the street address of another hospital's remote location is readily available public information that should be easily obtainable. We note that, for SCH applications, for which calculating distance to other like hospitals is necessary, CMS and the MACs verify all supporting documentation, which includes information regarding all other hospitals' main campuses and remote locations within distance requirements specified at § 412.92(a), or the larger of a 35-mile radius or its service area if applying under the criterion at § 412.92(a)(1)(i).

Comment: One commenter indicated that combining bed counts from a main campus and remote locations discourages MDHs from establishing remote locations because opening a remote location may cause the MDH to exceed 100 beds and lose status. The commenter urged CMS not to implement the proposals and encouraged the agency to exempt existing MDHs if these proposed codifications are finalized.

Response: We do not believe it would be appropriate to exclude beds from remote location(s) of an MDH in the hospital's bed count because we consider remote locations to be part of the hospital and section 1886(d)(5)(G)(iv)(II) of the Act describes an MDH as a hospital with not more than 100 beds. In other words, we do not believe that a hospital should maintain MDH status if the hospital has a bed count exceeding 100, which would indicate that the hospital is no longer a Medicare-dependent, small rural hospital according to the statutory criteria. Therefore, even if we were not merely codifying our existing policy, we would disagree with the commenter that CMS should modify its policy as the commenter requested.

After consideration of the public comments we received, for the reasons discussed above and in the proposed rule, we are finalizing as proposed, without modification, our codification of policies regarding multicampus hospitals in the regulations at § 412.92, § 412.96, and § 412.108. For the reason discussed in response to a comment above, we are finalizing our codification of policies regarding multicampus hospitals in the regulation at § 412.103(a)(7) with modification to remove an inadvertent reference to § 412.103(a)(6) (which pertains to CAHs). We may further consider commenters' suggestions regarding appropriate modifications to our policies in future rulemaking.

E. Occupational Mix Adjustment to the FY 2019 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019 Wage Index

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903) and final rule (82 FR 38137), a new measurement of occupational mix is required for FY 2019.

The FY 2019 occupational mix adjustment is based on a new calendar year (CY) 2016 survey. Hospitals were required to submit their completed 2016 surveys (Form CMS–10079, OMB number 0938–0907) to their MACs by July 3, 2017. The preliminary, unaudited CY 2016 survey data were posted on the CMS website on July 12, 2017. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2019 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2019

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20361), for FY 2019, we proposed to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2019 wage index. Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this final rule (which is available via the internet on the CMS website), which contains the final FY 2019 occupational mix adjusted wage index, includes separate wage data for the campuses of 16 multicampus hospitals. We refer readers to section III.C. of the preamble of this final rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2019 wage index. For the proposed FY 2019 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,260 hospitals, and we used the occupational mix surveys of 3,078 hospitals for which we also have Worksheet S–3 wage data, which represented a ''response'' rate of 94 percent (3,078/3,260). For the proposed FY 2019 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage

index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2019 occupational mix adjusted national average hourly wage was $42.948428861.

In summary, the proposed FY 2019 unadjusted national average hourly wage and the proposed FY 2019 occupational mix adjusted national average hourly wage were:

Proposed unadjusted national average hourly wage	Proposed occupational mix adjusted national average hourly wage
$42.990625267	$42.948428861

Comment: One commenter stated that all hospitals should be obligated to submit the occupational mix survey because failure to complete the survey jeopardizes the accuracy of the wage index. The commenter suggested that a penalty be instituted for nonsubmitters. This commenter also requested that, pending CMS' analysis of the Commuting Based Wage Index and given the Institute of Medicine's study on geographic variation in hospital wage costs, CMS eliminate the occupational mix survey and the significant reporting burden it creates. Another commenter believed that the substantial administrative burden imposed by the occupational mix adjustment has far exceeded whatever benefit it might have conferred.

Response: We appreciate the commenter's concern about the accuracy of the wage index. We have continually requested that all hospitals complete and submit the occupational mix surveys, although we did not establish a penalty for hospitals that did not submit the surveys. We did not establish a penalty for hospitals that did not submit the 2016 surveys. However, we are continuing to consider for future rulemaking various options for ensuring full compliance with future occupational mix surveys. Regarding the commenter's concern about the administrative burden of the occupational mix survey and the suggestion that we eliminate it, this survey is necessary to meet the provisions of section 1886(d)(3)(E) of the Act, which requires us to measure the earnings and paid hours of employment by occupational category.

After consideration of the public comments we received, for FY 2019, we are adopting as final our proposal to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index. For the final FY 2019 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,283 hospitals, and we used the occupational mix surveys of 3,114 hospitals for which we also have Worksheet S–3 wage data, which is a ''response'' rate of 95 percent (3,114/3,283). (We note that the ''response'' rate for this final rule differs from that of the proposed rule because for this final rule we have generally been able to include the occupational mix surveys of hospitals whose wage data were aberrant for the proposed rule but have since been improved and were used for this final rule. In addition, for this final rule, we have generally been able to include some occupational mix surveys that had been aberrant for the proposed rule but have since been improved and were used for this final rule.) For the final FY 2019 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the final FY 2019 occupational mix adjusted national average hourly wage is $42.955567020.

In summary, the final FY 2019 unadjusted national average hourly wage and the final FY 2019 occupational mix adjusted national average hourly wage are:

Final unadjusted national average hourly wage	Final occupational mix adjusted national average hourly wage
$42.997789358	$42.955567020

F. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2019 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2019, we are applying the occupational mix adjustment to 100 percent of the FY 2019 wage index. We calculated the occupational mix adjustment using data from the 2016 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586). Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2019 wage index results in a national average hourly wage of $42.955567020.

The FY 2019 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN	$41.66099188
National LPN and Surgical Technician	24.74107416
National Nurse Aide, Orderly, and Attendant	16.96864849
National Medical Assistant	18.13188525
National Nurse Category	35.04005228

The national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $35.04005228. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2016 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42.1 percent, and the national percentage of hospital employees in the all other occupations category is 57.9 percent. (We note that the percentage for this final rule differs from that of the proposed rule because we have recalculated this percentage based on the occupational mix data we have included for this final rule. That is, for this final rule, we have generally been able to include the occupational mix surveys of hospitals whose wage data were aberrant for the proposed rule but have since been improved and were used for this final rule. In addition, for final rule we have generally been able to include some occupational mix surveys that had been aberrant for the proposed rule but have since been improved and were used for this final rule). At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 26.6 percent in one CBSA to a high of 82.0 percent in another CBSA.

We compared the FY 2019 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the final wage index values for 233 (57.0 percent) urban areas and 23 (48.9 percent) rural areas increased. The final wage index values for 112 (27.4 percent) urban areas increased by greater than or equal to 1 percent but less than 5 percent, and the

final wage index values for 8 (2.0 percent) urban areas increased by 5 percent or more. The final wage index values for 9 (19.1 percent) rural areas increased by greater than or equal to 1 percent but less than 5 percent, and no rural area's final wage index value increased by 5 percent or more. However, the final wage index values for 176 (43.0 percent) urban areas and 24 (51.1 percent) rural areas decreased. The final wage index values for 80 (19.6 percent) urban areas decreased by greater than or equal to 1 percent but less than 5 percent, and 1 urban area's final wage index value decreased by 5 percent or more. The final wage index values of 7 (14.9 percent) rural areas decreased by greater than or equal to 1 percent and less than 5 percent, and no rural areas' final wage index values decreased by 5 percent or more. The largest final positive impacts are 6.49 percent for an urban area and 3.92 percent for a rural area. The largest final negative impacts are 5.85 percent for an urban area and 1.6 percent for a rural area. No urban area's final wage indexes and no rural area final wage indexes is unchanged by application of the occupational mix adjustment. These results indicate that a larger percentage of urban areas (57.0 percent) will benefit from the occupational mix adjustment than will rural areas (48.9 percent).

We also compared the FY 2019 wage data adjusted for occupational mix from the 2016 survey to the FY 2019 wage data adjusted for occupational mix from the 2013 survey. This analysis illustrates the effect on area wage indexes of using the 2016 survey data compared to the 2013 survey data; that is, it shows whether hospitals' wage indexes increased or decreased under the 2016 survey data as compared to the prior 2013 survey data. Of the 409 urban CBSAs and 47 rural CBSAs, our analysis shows that the FY 2019 wage index values for 228 (55.7 percent) urban areas and 23 (48.9 percent) rural areas increased using the 2016 survey data. Fifty-two (12.7 percent) urban areas increased by greater than or equal to 1 percent but less than 5 percent, and 3 (0.7 percent) urban areas increased by 5 percent or more. Seven (14.9 percent) rural areas increased by greater than or equal to 1 percent but less than 5 percent, and 0 rural areas increased by 5 percent or more. However, the wage index values for 181 (44.3 percent) urban areas and 24 (51.1 percent) rural areas decreased using the 2016 survey data. Forty nine (12.0 percent) urban areas decreased by greater than or equal to 1 percent but less than 5 percent, and 3 (0.7 percent) urban areas decreased by 5 percent or more. Two (4.3 percent) rural areas decreased by greater than or equal to 1 percent but less than 5 percent, and no rural areas decreased by 5 percent or more. The largest positive impacts using the 2016 survey data compared to the 2013 survey data are 6.31 percent for an urban area and 4.71 percent for a rural area. The largest negative impacts are 14.32 percent for an urban area and 2.34 percent for rural areas. No urban areas and no rural areas are unaffected. These results indicate that the wage indexes of more CBSAs overall (55.0 percent) increased due to application of the 2016 occupational mix survey data as compared to the 2013 occupational mix survey data to the wage index. However, a larger percentage of urban areas (55.7 percent) benefitted from the use of the 2016 occupational mix survey data as compared to the 2013 occupational mix survey data than did rural areas (48.9 percent).

G. Application of the Rural, Imputed, and Frontier Floors

1. Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2019 wage index associated with this final rule (which is available via the internet on the CMS website), we estimate that 263 hospitals will receive an increase in their FY 2019 wage index due to the application of the rural floor.

2. Expiration of Imputed Floor Policy

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the ''imputed floor'' policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy eight times, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and is set to expire on September 30, 2018. (We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FY 2014 through FY 2018 (78 FR 50589 through 50590, 79 FR 49969 through 49970, 80 FR 49497 through 49498, 81 FR 56921 through 56922, and 82 FR 38138 through 38142, respectively) and to the regulations at 42 CFR 412.64(h)(4).) Currently, there are three all-urban States—Delaware, New Jersey, and Rhode Island—with a range of wage indexes assigned to hospitals in these States, including through reclassification or redesignation. (We refer readers to discussions of geographic reclassifications and redesignations in section III.I. of the preamble of this final rule.)

In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States—New Jersey and Rhode Island—and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only 1 CBSA (Providence-New Bedford-Fall River, RI-MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor

budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the FY 2013 IPPS/LTCH PPS final rule (which is available via the internet on the CMS website) included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes. In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of wage indexes assigned to its hospitals, but the State cannot benefit under the original methodology.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590), we extended the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2014, while we continued to explore potential wage index reforms.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49970), for FY 2015, we adopted a policy to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continued to explore potential wage index reforms. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor. As discussed in section III.B. of the preamble of that FY 2015 final rule, we adopted the new OMB labor market area delineations beginning in FY 2015. Under the new OMB delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware has three CBSAs, New Jersey has seven CBSAs, and Rhode Island continues to have only one CBSA (Providence-Warwick, RI-MA). We refer readers to a detailed discussion of our adoption of the new OMB labor market area delineations in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Therefore, under the adopted new OMB delineations discussed in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule, Delaware became an all-urban State and was subject to an imputed floor as well for FY 2015.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49497 through 49498), for FY 2016, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2016. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56921 through 56922), for FY 2017, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2017. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138 through 38142), for FY 2018, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2018. In these three final rules, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the additional 1-year extensions.

The imputed floor is set to expire effective October 1, 2018, and in the FY 2019 proposed rule (83 FR 20363), we did not propose to extend the imputed floor policy. As we stated in the proposed rule (83 FR 20363), in the FY 2005 IPPS final rule (69 FR 49110), we adopted the imputed floor policy for all-urban States under the authority of section 1886(d)(3)(E) of the Act, which gives the Secretary broad authority to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates for area differences in hospital wage levels by a factor (established by the Secretary). However, we explained in the proposed rule that we have expressed reservations about the establishment of an imputed floor, considering that the imputed rural floor methodology creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor (72 FR 24786 and 72 FR 47322). As we discussed in the FY 2008 IPPS final rule (72 FR 47322), the application of the rural and imputed floors requires transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. For this reason, in the FY 2019 proposed rule, we proposed not to apply an imputed floor to wage index calculations and payments for hospitals in all-urban States for FY 2019 and subsequent years. That is, we proposed that hospitals in New Jersey, Delaware, and Rhode Island (and in any other all-urban State) would receive a wage index that is calculated without applying an imputed floor for FY 2019 and subsequent years. Therefore, only States containing both rural areas and hospitals located in such areas (including any hospital reclassified as rural under the provisions of § 412.103 of the regulations) would benefit from the rural floor, in accordance with section 4410 of Public Law 105–33. In addition, we stated that we would no longer include the imputed floor as a factor in the national budget neutrality adjustment. Therefore, the proposed wage index and impact tables associated with the FY 2019 IPPS/LTCH PPS proposed rule (which are available via the internet on the CMS website) did not reflect the imputed floor policy, and there was no proposed national budget neutrality adjustment for the imputed floor for FY 2019.

Comment: Commenters supported CMS' proposal to allow the imputed floor policy to expire. Some commenters stated they have previously commented and continue to believe that the application of the imputed floor and the budget neutrality adjustment are an unfair redistribution of IPPS payments; they fully support the expiration of the imputed floor and the removal of the related budget neutrality adjustment.

A number of commenters stated that, under the current methodology, areas with few rural hospitals, such as Massachusetts, Arizona, and California, have the ability and incentive to have major urban hospitals reclassify as rural under 42 CFR 412.103 and, by selectively doing so, such an urban to rural reclassification could significantly raise the rural floor in those States. Commenters conveyed that while the establishment of a statewide rural floor is required by statute, the method by which the floor is calculated is entirely at CMS' discretion through regulatory authority and, in fact, CMS has already used its discretion in establishing the imputed rural floor for all-urban States. The commenters indicated that any rural floor calculation should mirror the spirit and intent of the law resulting in only the ''natural'' rural providers in a State considered when calculating a rural floor. Finally, the commenters suggested that CMS consider immediately issuing a change to the existing calculation that includes only the ''natural'' rural providers in calculating the rural floor for a State.

Response: We appreciate the commenters' support for the proposal not to extend the imputed floor. While it is not clear what is meant by ''natural'' rural providers, we assume that commenters meant providers

physically located in a rural area (rather than providers with a rural reclassification). We appreciate the comments in regard to revisions to the rural floor methodology, including revising the calculation to be based only on providers that are physically located in rural areas, and not providers that are reclassified as rural. As described in the FY 2006 IPPS final rule (70 FR 47379), in our continued effort to promote consistency and equity and to simplify our rules with respect to how we construct the wage indexes of rural and urban areas, we were persuaded at that time that there was a need to modify our policy when hospital redesignations occur under section 1886(d)(8)(E) of the Act. One aspect of this discussion was the rule that the wage data of an urban hospital reclassifying into the rural area would be included in the rural area's wage index, if including the urban hospital's data increases the wage index of the rural area. Nevertheless, as we continue to evaluate ways to address wage index disparities, we will take these comments to revisit this policy into consideration.

Comment: Several commenters disagreed with the proposal to allow the imputed floor to expire, and stated that CMS should maintain the status quo, that is, continue extending the imputed floor for 1 year, until the entirety of Medicare wage index reform is complete. The commenters pointed out that CMS, in both the FY 2014 and FY 2015 IPPS final rules, extended the imputed floor for an additional year, during which time CMS stated that it would continue to explore potential wage index reform. However, the commenter stated that such reform has not occurred and, therefore, it is premature to remove the imputed floor.

Response: Section 3137(b) of the Affordable Care Act required the Secretary of Health and Human Services to submit to Congress a report to reform the Medicare Wage Index applied under the IPPS. We submitted the Report to Congress on April 11, 2012, and posted the report and other information regarding wage index reform on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*. While in past years we have stated that we continue to explore wage index reforms while extending the imputed floor in increments (for example, 78 FR 50589 through 50590 and 79 FR 49969 through 49970), we note that it has already been many years since the report was issued with no new legislation from Congress to comprehensively reform the wage index. With no such legislation from Congress, at this point, we do not find it appropriate to continue to tie the extension of the imputed floor to comprehensive wage index reform. Therefore, we disagree with the commenters that the imputed floor should be extended until such time as comprehensive wage index reform may be instituted. Furthermore, as noted by the recent request for information (RFI) in the proposed rule, we also are working to address wage index disparities. We believe that the elimination of the budget neutrality adjustment associated with the imputed floor, as also discussed below, is entirely consistent with our wage index disparities initiative.

Comment: Several commenters stated that, by eliminating the imputed floor wage index, CMS is alleviating only a fraction of the combined payment transfer from the application of the rural and imputed floors. The commenters explained that combined, hospitals in the three all-urban States (New Jersey, Rhode Island, and Delaware) accounted for less than 10 percent of the 400 hospitals nationally that received either the rural or imputed floor last year. Therefore, the commenters believed that the imputed floor budget neutrality adjustment is not resulting in the significant transfer of payments from hospitals in States with rural hospitals to hospitals in States where the imputed floor is applied.

A number of commenters believed that eliminating the imputed floor would create the same uneven playing field in all-urban States that existed prior to 2005, in response to which CMS initially established the policy. According to the commenters, the anomaly originally cited by CMS (that is, that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or ''floor,'' from declines in their wage index) would exist again if the imputed floor policy is discontinued.

In addition, the commenters stated that there are many Medicare payment programs that redirect scarce Medicare funding to a class of unique hospitals, and that not all States have hospitals that benefit from these programs. For example, according to the commenters, CMS makes payments to CAHs at a rate of 101 percent of their costs and States that do not have any CAHs do not benefit from this program. The commenters stated that while CAHs are paid outside the IPPS program, the dollars continue to come from a finite Medicare trust fund representing a transfer of payments from hospitals in States without any CAHs into States with CAHs, similar to the transfer of payments CMS cites as its rationale to discontinue the imputed floor.

The commenters also pointed out that CMS has upheld the imputed floor for over a decade as a valuable method of maintaining equitable wage index protections for all-urban States consistent with those that exist for States with rural areas. The commenters referenced previous CMS justification for creating and extending the floor in previous years, such as all-urban States are at a disadvantage due to the absence of a rural floor policy and that, in New Jersey, ''because there is no floor to protect those hospitals not located in the predominant labor market area from facing continued declines in their wage index, it becomes increasingly difficult for those hospitals to continue to compete for labor.''

Response: While, in the past, we have provided for temporary extensions of the imputed floor, we do not believe at this time it is appropriate to continue to extend the imputed floor. While the commenters raise concerns that, if the imputed floor were discontinued, hospitals in all-urban States would again be disadvantaged by the absence of rural hospitals to set a wage index floor for those States, as well as concerns about the financial impacts of discontinuing the rural floor, we have also expressed concerns about continuing the imputed floor policy. As we pointed out in the proposed rule (83 FR 20363), CMS has expressed reservations about the establishment of an imputed floor, considering that the imputed rural floor methodology creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor. As we discussed in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47322), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19905), and the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20363), the application of the rural and imputed floors requires transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. While the three all-urban States may count for a fraction of all States that received the rural and imputed floor last year, the imputed rural floor methodology still creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural or imputed floor. Therefore, we do not believe it is appropriate to continue to extend the imputed floor.

Finally, regarding the comparison made by commenters between the CAH payment methodology and the imputed floor methodology with respect to the transfer of payments, we disagree with this comparison. Because there is no national budget neutrality requirement relating to CAH payments (as there is with the imputed floor methodology), there is no transfer of payments from hospitals in States without any CAHs to hospitals in States with CAHs, similar to that which exists as a result of the application of the imputed floor. Under sections 1814(l) and 1834(g) of the Act, payments made to CAHs for inpatient and outpatient services are generally based on 101 percent of the reasonable costs of the CAH in providing such services. Reasonable cost is defined in section 1861(v)(1)(A) of the Act and determined in accordance with the regulations under 42 CFR part 413.

Comment: Several commenters opposed the continued application of the nationwide rural floor budget neutrality adjustment as described in the proposed rule. The commenters discussed section 3141 of the Affordable Care Act which established a policy of national budget neutrality for the application of the rural and imputed floors to the Medicare wage index. The commenters stated that, coupled with the orchestrated conversion of a single facility in Massachusetts—Nantucket Cottage Hospital—from a CAH to an IPPS hospital, section 3141 of the Affordable Care Act allows hospitals to unfairly manipulate the Medicare payment system and reward hospitals in Massachusetts and a few other States at the expense of other *hospitals* across the nation. The commenters stated that the adverse consequences of nationwide rural floor budget neutrality have been recognized and commented upon by HHS, CMS, and many others over the past several years. The commenters stated that, until this policy is *corrected,* the Medicare wage index system cannot possibly accomplish its objective of ensuring that payments for the wage component of labor accurately reflect actual wage costs.

The commenters also pointed out that the inequity of this provision recently was highlighted in a March 2017 Office of Inspector General (OIG) report showing how a single hospital overreported dollars and underreported hours, driving up the average hourly wage. According to the commenters, the OIG estimated that this error resulted in more than $133 million in Medicare overpayments to be paid to Massachusetts hospitals. The commenters urged CMS to use its regulatory authority to curtail the adverse effects of section 3141 of the Affordable Care Act and restore integrity to the hospital wage index system, and further encouraged CMS to publish the effects of the nationwide rural floor on Medicare outpatient services in the proposed and final hospital outpatient prospective payment system payment and policy updates for CY 2019.

Response: We thank the commenters for their comments and recommendations regarding modifications to the hospital wage index. As we stated earlier, section 4410 of the BBA requires the application of the rural floor and section 3141 of the Affordable Care Act requires a uniform, national budget neutrality adjustment for the rural floor. We do not have authority to repeal or revise these laws.

Regarding the comment encouraging CMS to publish the effects of the nationwide rural floor on Medicare outpatient services in the proposed and final hospital outpatient prospective payment system payment and policy updates for CY 2019, we will take this comment into consideration and may address them in the development of future rulemaking.

Comment: Commenters also supported the alternative methodology for calculating the imputed rural floor in Rhode Island. According to commenters, the methodology has been used since FY 2013 and has been key for the State's hospitals and maintaining access to care for residents of Rhode Island. The commenters stated that the alternative methodology for calculating the imputed floor appropriately addresses a hospital wage index reclassification system that does not reflect Rhode Island's characteristics. The commenters further stated that the alternative methodology for calculating the imputed rural floor protects its hospitals from falling to some of the lowest payment rates in the country, at the same time while competing with some of the most highly reimbursed urban hospitals. The commenters stated that the anomaly originally cited by CMS (that is, that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or ''floor,'' from declines in their wage index) would exist again if the imputed floor policy were discontinued. The commenters stressed that the elimination of imputed floor will reduce hospital Medicare payments in Rhode Island by approximately $28.6 million in FY 2019. The commenters explained that hospitals are among Rhode Island's top employers and the impact of the discontinuation of this policy would adversely impact this important sector of Rhode Island's economy. The commenters further noted that this loss of funding will put Rhode Island at a competitive disadvantage for recruiting and maintaining staff as hospitals in Rhode Island must compete with neighboring States, which are located just miles away and are benefitting from a much higher payment rate.

Response: While the commenters raised concerns that, if the imputed floor were discontinued, hospitals in all-urban States, including Rhode Island, would again be disadvantaged by the absence of rural hospitals to set a wage index floor for those States, as well as concerns about the financial impacts of discontinuing the imputed floor alternative methodology in Rhode Island, we also have expressed concerns about continuing the imputed floor policy. As we discussed in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47322), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138), and the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20363), the application of the imputed floor requires a transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the imputed floor is applied. As discussed previously, while Rhode Island and the two other all-urban States (Delaware and New Jersey) may count for a fraction of all States that received the rural and imputed floor last year, the application of the imputed rural floor methodology (both the original and alternative methodologies) still creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor. Thus, we believe it is appropriate to let the imputed floor expire as scheduled on October 1, 2018.

After consideration of public comments received, for the reasons discussed above and in the proposed rule, we believe it is appropriate to allow the imputed floor to expire on its expiration date, September 30, 2018. Therefore, we are allowing the imputed floor to expire under both the original methodology and the alternative methodology on the date it is currently set to expire, September 30, 2018. As proposed, the wage index and impact tables associated with this FY 2019 IPPS/LTCH PPS final rule (which are available on the internet via the CMS website) do not reflect the imputed floor policy and we are not applying a national budget neutrality adjustment for the imputed floor for FY 2019. There are 10 hospitals in New Jersey, 9 hospitals in Rhode Island, and 3

hospitals in Delaware that will no longer receive an increase in their FY 2019 wage index due to the expiration of the imputed floor policy.

3. State Frontier Floor for FY 2019

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In the FY 2019 IPPS/LTCH PPS proposed rule, we did not propose any changes to the frontier floor policy for FY 2019. We stated in the proposed rule that 50 hospitals would receive the frontier floor value of 1.0000 for their FY 2019 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for FY 2019. In this final rule, 50 hospitals will receive the frontier floor value of 1.0000 for their FY 2019 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

The areas affected by the final rural and frontier floor policies for the FY 2019 wage index are identified in Table 2 associated with this final rule, which is available via the internet on the CMS website.

H. FY 2019 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the internet on the CMS website. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). In addition, as discussed in section III.J. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule, we added a Table 4 associated with the proposed rule entitled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019'' (which is available via internet on the CMS website). We intend to make this information available annually via Table 4 in the IPPS/LTCH PPS proposed and final rules. We refer readers to section VI. of the Addendum to this final rule for a discussion of the final wage index tables for FY 2019.

I. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930) for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations.

2. MGCRB Reclassification and Redesignation Issues for FY 2019

a. FY 2019 Reclassification Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this final rule was constructed, the MGCRB had completed its review of FY 2019 reclassification requests. Based on such reviews, there are 303 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2019. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2019, hospitals reclassified beginning in FY 2017 or FY 2018 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 230 hospitals approved for wage index reclassifications in FY 2017 that will continue for FY 2019, and 348 hospitals approved for wage index

reclassifications in FY 2018 that will continue for FY 2019. Of all the hospitals approved for reclassification for FY 2017, FY 2018, and FY 2019, based upon the review at the time of this final rule, 881 hospitals are in a MGCRB reclassification status for FY 2019 (with 21 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2019 are incorporated into the wage index values published in this FY 2019 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

Comment: One commenter stated that CMS' policy that hospitals must request to withdraw or terminate MGCRB reclassifications within 45 days of the proposed rule is problematic because a hospital could terminate a reclassification based on information in the proposed rule and, with the publication of the final rule, discover that its original reclassified status was more desirable. The commenter stated that hospitals cannot make informed decisions concerning their reclassification status based on values in a proposed rule that are likely to change. Therefore, the commenter recommended that CMS revise its existing policy to permit hospitals to withdraw or terminate their reclassification status within 45 days after the publication of the final rule.

Response: We maintain that information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions. In addition, section 1886(d)(8)(D) of the Act requires the Secretary to adjust the standardized amounts to ensure that aggregate payments under the IPPS after implementation of the provisions of certain sections of the Act, including section 1886(d)(10) of the Act for geographic reclassifications by the MGCRB, are equal to the aggregate prospective payments that would have been made absent these provisions. If hospitals were to withdraw or terminate reclassification statuses after the publication of the final rule, as the commenter suggested CMS permit, any resulting changes in the wage index would not have been taken into account when calculating the IPPS standardized amounts in the final rule in accordance with the statutory budget neutrality requirement. Therefore, the values published in the final rule represent the final wage index values reflective of reclassification decisions.

Applications for FY 2020 reclassifications (OMB control number 0938–0573) are due to the MGCRB by September 4, 2018 (the first working day of September 2018). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal, or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2018, via the internet on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html*, or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 1508 Woodlawn Drive, Suite 100, Baltimore, MD 21207.

Under regulations in effect prior to FY 2018 (42 CFR 412.256(a)(1)), applications for reclassification were required to be mailed or delivered to the MGCRB, with a copy to CMS, and were not allowed to be submitted through the facsimile (FAX) process or by other electronic means. Because we believed this previous policy was outdated and overly restrictive and to promote ease of application for FY 2018 and subsequent years, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928), we revised this policy to require applications and supporting documentation to be submitted via the method prescribed in instructions by the MGCRB, with an electronic copy to CMS. Specifically, in the FY 2017 IPPS/LTCH PPS final rule, we revised § 412.256(a)(1) to specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS. We specified that CMS copies should be sent via email to *wageindex@cms.hhs.gov*.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928), we reiterated that MGCRB application requirements will be published separately from the rulemaking process, and paper applications will likely still be required. However, we note that, beginning with the FY 2020 reclassification application cycle, the MGCRB now requires applications, supporting documents, and subsequent correspondence to be filed electronically through the MGCRB module of the Office of Hearings Case and Document Management System (''OH CDMS''). Also, the MGCRB will issue all of its notices and decisions via email and these documents will be accessible electronically through OH CDMS. Registration instructions and the system user manual are available at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing.html*. The MGCRB makes all initial determinations for geographic reclassification requests, but CMS requests copies of all applications to assist in verifying a reclassification status during the wage index development process. We stated that we believed that requiring electronic versions would better aid CMS in this process, and would reduce the overall burden upon hospitals.

b. Revision of Reclassification Requirements for a Provider That Is the Sole Hospital in the MSA

Section 412.230 of the regulations sets forth criteria for an individual hospital to apply for geographic reclassification to a higher rural or urban wage index area. Specifically, under § 412.230(a)(1)(ii), an individual hospital may be redesignated from an urban area to another urban area, from a rural area to another rural area, or from a rural area to an urban area for the purpose of using the other area's wage

index value. Such a hospital must also meet other criteria. One of these required criteria, under § 412.230(d)(1)(iii)(C), is that the hospital must demonstrate that its own average hourly wage is, in the case of a hospital located in a rural area, at least 106 percent, and in the case of a hospital located in an urban area, at least 108 percent of the average hourly wage of all other hospitals in the area in which the hospital is located. We refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48568) for further explanation as to how the 108/106 percent average hourly wage standards were determined. In cases in which a hospital wishing to reclassify is the only hospital in its MSA, that hospital is unable to satisfy this criterion because it cannot demonstrate that its average hourly wage is higher than that of the other hospitals in the area in which the hospital is located (because there are no other hospitals in the area).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51600 through 51601), we implemented a policy change to allow for a waiver of the average hourly wage comparison criterion under § 412.230(d)(1)(iii) for a hospital in a single hospital MSA for reclassifications beginning in FY 2013 if the hospital could document that it is the single hospital in its MSA that is paid under 42 CFR part 412, subpart D (§ 412.230(d)(5)). In that final rule, we stated that we agreed that the then-current policies for geographic reclassification were disparate for hospitals located in single hospital MSAs compared to hospitals located in multiple hospital MSAs. We also acknowledged commenters' views that this disparity was sometimes a disadvantage because hospitals in single hospital MSAs had fewer options for qualifying for geographic reclassification. As we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20365), in the years since we implemented this policy change, we have encountered questions and concerns regarding its implementation. In the proposed rule, we stated that to qualify under § 412.230(d)(5) for the waiver of the average hourly wage criterion under § 412.230(d)(1)(iii)(C), a hospital must document to the MGCRB that it is the only hospital in its geographic wage index area that is paid under 42 CFR part 412, subpart D. We noted that to do so, a hospital frequently was required to contact the appropriate CMS Regional Office or MAC for a statement certifying its status as the single hospital in its MSA. We explained that hospitals have indicated that this process may be time-consuming, inconsistent in its application nationally, and poses challenges with respect to accurately reflecting situations where hospitals have recently opened or ceased operations during the application process. We stated in the proposed rule (83 FR 20365) that, in light of these questions and concerns and after reviewing the implementation of this reclassification provision, we believed that a revision of the policy was necessary to reduce unnecessary burden to affected hospitals and enhance consistency while achieving previously stated policy goals.

We explained in the proposed rule that the objective of the 108/106 percent average hourly wage criterion at § 412.230(d)(1)(iii)(C) is to require a reclassifying hospital to document that it has significantly higher average hourly wages than other hospitals in its labor market area. The stated purpose of § 412.230(d)(5) was to provide additional reclassification options for hospitals that, due to their single hospital MSA status, could not mathematically meet the requirements of § 412.230(d)(1)(iii). Therefore, in order to determine whether a hospital is the single hospital in the MSA under § 412.230(d)(5), rather than require the hospital to obtain documentation from the CMS Regional Office or the MAC to prove its single hospital MSA status, we stated that we believe it would be appropriate to use the same data used to determine whether the 108/106 percent criterion is met under § 412.230(d)(1)(iii)(C): That is, the annually published 3-year average hourly wage data as provided in § 412.230(d)(2)(ii). Specifically, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20365), we proposed that, for reclassification applications for FY 2021 and subsequent fiscal years, a hospital would provide the wage index data from the current year's IPPS final rule to demonstrate that it is the only hospital in its labor market area with wage data listed within the 3-year period considered by the MGCRB. Accordingly, we proposed to revise the regulation text at § 412.230(d)(5) to provide that the requirements of § 412.230(d)(1)(iii) would not apply if a hospital is the single hospital in its MSA with published 3-year average hourly wage data included in the current fiscal year inpatient prospective payment system final rule. In proposing this revision, we stated that we would remove the language in this regulation requiring that the hospital be the single hospital ''paid under subpart D of this part'', as we believe the proposed revisions to the regulation above more accurately identify the universe of hospitals this policy was intended to address.

As discussed in the proposed rule, the purpose of the single hospital MSA provision was to address situations where a hospital essentially had no means of comparing wages to other hospitals in its labor market area. We stated in the proposed rule that we believe this proposal would allow for a more straightforward and consistent implementation of the single hospital MSA exception and would reduce provider burden. We further stated that we believe the proposed requirements above for meeting the single hospital MSA exception could be easily verified and validated by the applicant and the MGCRB, and would continue to address the concerns expressed by commenters included in the FY 2012 IPPS/LTCH PPS final rule.

Comment: A number of commenters supported the proposal.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, for the reasons discussed above and in the proposed rule, we are finalizing our revisions to § 412.230(d)(5) as proposed without modification. Thus, for applications for reclassification for FY 2021 and subsequent fiscal years, a hospital must provide the wage index data from the current year's IPPS final rule to demonstrate that it is the only hospital in its labor market area with wage data listed within the 3-year period considered by the MGCRB. Specifically, a hospital must provide documentation from Table 2 of the Addendum to the current fiscal year IPPS/LTCH PPS final rule demonstrating it is the only CCN listed within the associated ''Geographic CBSA'' number (currently listed under column H) with a ''3-Year Average Hourly Wage (2018, 2019, 2020)'' value (currently listed under column G).

c. Clarification of Group Reclassification Policies for Multicampus Hospitals

Under current policy described in §§ 412.230(d)(2)(v), 412.232(d)(2)(iii), and 412.234(c)(2), and as discussed in the FY 2008 IPPS/LTCH final rule (72 FR 47334 through 47335), remote locations of hospitals in a distinct geographic area from the main hospital campus are eligible to seek wage index reclassification. As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20366), in Table 2 associated with that proposed rule (which is available via the internet on the CMS website), such locations are indicated with a ''B'' in the third digit of the CCN. (As

discussed in section III.C. of the preamble of that proposed rule (83 FR 20366), in past years, the ''B'' was instead placed in the fourth digit.) When CMS initially includes such a ''B'' hospital location in Table 2 for a particular fiscal year, it signifies that, for wage index purposes, the hospital indicated the presence of a remote location in a distinct geographic area on Worksheet S–2 of the cost report used to construct that current fiscal year's wage index, and hours and wages were allocated between the main campus and the remote location. For billing purposes, these ''B'' locations are assigned their own area wage index value, separate from the main hospital campus. Hospitals are eligible to seek both individual and county group reclassifications for these ''B'' locations through the MGCRB, using the wage data published for the most recent IPPS final rule for the ''B'' location. While we are not proposing any change to the multicampus hospital reclassification policy, it has come to our attention that the MGCRB has had difficulty processing certain county group reclassification applications that include multicampus locations that have not yet been assigned a ''B'' number in Table 2. Typically, this would occur when an inpatient hospital location has recently been opened or acquired, creating a new ''B'' location. Because the wage index development process utilizes cost reports that end up to 4 years prior to the upcoming IPPS fiscal year, the most recently published wage data for the hospital used to construct the wage index would not reflect the specific wage data for any new ''B'' location in a different labor market area. However, as specified in §§ 412.232(a)(2) and 412.234(a)(1) of the regulations, for county group reclassification applications, all hospitals in a county must apply for reclassification as a group. Thus, in order for hospitals in a county to obtain reclassification as a group, these new ''B'' locations are required under these regulations to be a party to any county group reclassification application, despite not having wage data published in Table 2. In a group reclassification involving a new ''B'' location, the ''B'' location would not yet have data included in the CMS hospital survey used to construct the wage index and to evaluate reclassification requests, and the most recently published wage data of the main hospital would encompass a time period well before the creation or acquisition of the new remote location. Therefore, the hospital could not submit composite average hourly wage data for the ''B'' location with the county group reclassification application. Because the county group reclassification application must list all active hospitals located in the county of the hospital group, including any ''B'' locations, if a ''B'' number is not listed in Table 2 associated with the IPPS final rule used to evaluate reclassification criteria, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20366), we requested that the county hospital group submit the application listing the remote location with a ''B'' in the third digit of the hospital's CCN to help facilitate the MGCRB's review. We stated in the proposed rule that if the county group reclassification is approved by the MGCRB, CMS will include the hospital's ''B'' location in Table 2 of the subsequent IPPS final rule, and will instruct the MAC to adjust the payment for that remote location to the appropriate reclassified area. This ''B'' location designation would be included in subsequent rules, without composite wage data, until a time when the wage data of the new location are included in the cost report used to construct the wage index in effect for IPPS purposes, and a proper allocation can be determined.

We did not receive any public comments specific to this clarification and request. Therefore, when a county group MGCRB reclassification includes a remote location of a hospital located in a different labor market area that has not yet been assigned a ''B'' number in Table 2 of the applicable IPPS final rule used to evaluate reclassification criteria, to help facilitate the MGCRB's review, the county group should submit the application to the MGCRB listing the remote location with a ''B'' in the third digit of its CCN. If the application is approved by the MGCRB, CMS will include the ''B'' location number, with applicable reclassification status and wage index values, in Table 2 of the subsequent IPPS final rule.

3. Redesignations Under Section 1886(d)(8)(B) of the Act

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the out-migration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we again clarified that such a request to waive Lugar status, received within 45 days of the publication of the proposed rule, is valid for the full 3-year period for which the hospital's out-migration adjustment is effective. We further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov.* In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov.* To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

Comment: One comment addressed an issue currently under litigation regarding counties that qualify for redesignation under section 1886(d)(8)(B) of the Act, also known as Lugar counties. The commenter, legal counsel for the hospital that is a party in the ligation, stated that, based on total commuting rates to all counties within a CBSA, under section 1886(d)(8)(B) of the Act, the hospital—which qualifies for redesignation—should be assigned to a different CBSA than it is currently assigned. The commenter also stated that the hospital considers its current assignment to be a clerical error.

Response: In the FY 2019 IPPS/LTCH PPS proposed rule, we did not propose any changes to the list of qualified counties or the commuting standards used to redesignate Lugar counties to another CBSA. As we explained in the FY 2015 IPPS/LTCH PPS final rule, the list of counties that qualified for redesignation under section 1886(d)(8)(B) of the Act and their assignments were determined based on updated OMB delineations and Census data (79 FR 49978, which states that we ''proposed to use the new OMB delineations to identify rural counties that would qualify as 'Lugar' under section 1886(d)(8)(B) of the Act and, therefore, would be redesignated to urban areas for FY 2015. . . . We did not receive any other specific comments with regard to our proposal to use the new OMB delineations to identify rural counties that would qualify as 'Lugar' under section 1886(d)(8)(B) of the Act. Therefore, we are finalizing the policy as proposed.''). The FY 2019 IPPS/LTCH PPS proposed rule used the methodology adopted in the FY 2015 IPPS/LTCH PPS final rule (and subsequent final rules) to make the Lugar determinations and designations.

The proposed Lugar assignment of the hospital at issue for FY 2019 is not a clerical error. Under OMB's standards for determining whether an outlying county should be considered part of a CBSA, OMB examines commuting to central counties of the CBSA. Our longstanding policy is that, consistent with OMB standards, we examine commuting data to central counties of CBSAs in determining whether a hospital qualifies as a Lugar hospital and in determining the urban area to which it is assigned; we do not view the two steps in isolation. The proposed Lugar assignment of the hospital at issue for FY 2019 reflects proper application of this policy.

J. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FYs 2016, 2017, and 2018 IPPS/LTCH PPS final rules (80 FR 49501, 81 FR 56930, and 82 FR 38150, respectively), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FY 2016, FY 2017, and FY 2018, and in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20367), we proposed to use them again for FY 2019. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2019. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2019, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2019, we did not propose any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

We did not receive any public comments on this proposed policy for FY 2019. Therefore, for FY 2019, we are finalizing our proposal, without modification, to continue using the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment and that were applicable for FY 2016, FY 2017, and FY 2018.

Table 2 associated with this final rule (which is available via the internet on the CMS website) includes the final out-migration adjustments for the FY 2019 wage index. In addition, as discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20367), we have added a new Table 4, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019'', associated with this final rule. For this final rule, Table 4 consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2019 identified by FIPS county code, the final FY 2019 out-migration adjustment, and the number of years the adjustment will be in effect. We believe this new table makes this information more transparent and provides the public with easier access to this information. We intend to make the information available annually via Table 4 in the IPPS/LTCH PPS proposed and final rules, and are including it among the tables associated with this FY 2019 IPPS/LTCH PPS final rule that are available via the internet on the CMS website.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act, Implemented at 42 CFR 412.103, and Change to Lock-In Date

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and

manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals.

Hospitals must meet the criteria to be reclassified from urban to rural status under § 412.103, as well as fulfill the requirements for the application process. There may be one or more reasons that a hospital applies for the urban to rural reclassification, and the timeframe that a hospital submits an application is often dependent on those reason(s). Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) that we believed there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates.

Therefore, after notice of proposed rulemaking and consideration of public comments, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by adding paragraph (6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date (the lock-in date) must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for a full discussion of this policy.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20367 through 20368), we proposed to change the lock-in date to provide for additional time in the ratesetting process and to match the lock-in date with another existing deadline. As we discussed in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25071 and 56931, respectively), the IPPS ratesetting process that CMS undergoes each proposed and final rulemaking is complex and labor-intensive, and subject to a compressed timeframe in order to issue the final rule each year within the timeframes for publication. Accordingly, CMS must ensure that it receives, in a timely fashion, the necessary data, including, but not limited to, the list of hospitals that are reclassified from urban to rural status under § 412.103, in order to calculate the wage indexes and other IPPS rates.

In order to allot more time to the ratesetting process, we proposed to revise the lock-in date such that a hospital's application for rural reclassification under § 412.103 must be approved by the CMS Regional Office no later than 60 days after the public display date of the IPPS notice of proposed rulemaking at the Office of the Federal Register in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year. We stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20368) that depending on the public display date of the proposed rule (which may be earlier in future years), this proposed revision to the lock-in date would potentially allow for additional time in the ratesetting process for CMS to incorporate rural reclassification data, which we believe would support efforts to eliminate errors and assist in ensuring a more accurate wage index.

As we stated in the proposed rule, under this revision, there would no longer be a requirement that the hospital file its rural reclassification application by a specified date (which at the time of the proposed rule was 70 days prior to the second Monday in June). While we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930 through 56932) that a hospital would need to file its reclassification application with the CMS Regional Office not later than 70 days prior to the second Monday in June, we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20368) that timeframe was a precautionary measure to ensure that CMS would receive the approval in time to include the reclassified hospitals in the wage index and budget neutrality calculations for the upcoming Federal fiscal year (60 days for the CMS Regional Office to approve an application, in accordance with § 412.103(c), and an additional 10 days to process the approval and notify CMS Central Office). We explained that while we still believe that it would be prudent for hospitals to apply approximately 70 days prior to the proposed lock-in date, we believe that requiring hospitals to apply by a set date is unnecessary because the Regional Offices may approve a hospital's request to reclassify under § 412.103 in less than 60 days, and CMS may be notified in a timeframe shorter than 10 days. Therefore, we stated that, under our proposal, any hospital with an approved rural reclassification by the lock-in date proposed above (that is, 60 days after the public display date of the IPPS notice of proposed rulemaking at the Office of the Federal Register) would be included in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, regardless of the date of filing.

In addition, we noted that CMS generally provides 60 days after the public display date of the IPPS notice of proposed rulemaking at the Office of the Federal Register for submitting public comments regarding the proposed rule for consideration in the final rule. Therefore, we believe that, in addition to providing for more time in the ratesetting process, which helps to ensure a more accurate wage index, this proposed revision would also provide clarity and simplify regulations by synchronizing the lock-in date for § 412.103 redesignations with the usual public comment deadline for the IPPS proposed rule.

Accordingly, we proposed to revise § 412.103(b)(6) to specify that in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103 no later than 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year.

We also reiterated in the proposed rule that the lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. As we discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931), this lock-in date also does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional Office receives the application, in accordance with § 412.103(d). The hospital's IPPS claims will be paid

reflecting its rural status beginning on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

Comment: One commenter stated that there is ambiguity regarding the lock-in date at § 412.103(b)(6) because the lock-in date currently references the ''filing date,'' which under the regulations at § 412.103(b)(5) is the date CMS receives the application. The commenter then maintained that the date the CMS mailroom receives the application may not necessarily be the date the CMS Regional Office recognizes as the filing date and ultimately when the provider receives rural status. The commenter requested that CMS clarify the filing date at § 412.103(b)(5) and simplify the regulations so that there is not a ''hard and fast'' deadline which can lead to an ''inaccurate'' wage index in the event of a discrepancy between the dates when the CMS mailroom and the CMS division responsible for processing rural reclassifications receive an application.

Response: We appreciate the commenter's request for CMS to simplify the regulations. Under this proposed change to the lock-in date, we are simplifying the regulations by eliminating the requirement for a hospital to file its rural reclassification application by a specified date. We are reiterating that, under our proposal, any hospital with an approved rural reclassification by the lock-in date proposed above (that is, 60 days after the public display date of the IPPS notice of proposed rulemaking at the Office of the Federal Register) would be treated as rural in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, regardless of the date of filing. Because our proposal to change the lock-in date would eliminate the reference to the ''filing date'' in § 412.103(b)(6), we believe our proposal addresses the commenter's concern regarding the use of this term in § 412.103(b)(6). We appreciate the comment and may consider the commenter's suggestion to clarify the use of this term in § 412.103(b)(5) in future rulemaking.

Comment: One commenter encouraged efforts to make sure that information is available to CMS timely for purposes of setting wage index values in the final rule, but expressed concern with CMS proposing to replace a ''provider-based deadline'' of 70 days prior to the second Monday in June with a ''CMS Regional Office deadline'' of a decision made no later than 60 days after the public display date of the proposed rule, because providers are not in control of CMS Regional Office timing. The commenter stated that providers also do not have a specific date upon which to rely for the public display of the proposed rule each year; therefore, a provider-based deadline based on that date would have to be after the display date. The commenter further pointed out that, using the FY 2019 proposed rule as an example, it appears the proposed change would not make the data available to CMS sooner because 60 days after the public display date of the proposed rule (June 25, 2018) was after the second Tuesday in June (June 12, 2018). The commenter asked that CMS set a specific provider deadline to permit the same 70 days as the current rule (60 days for CMS Regional Office processing, and 10 days for transmission) and recommended that CMS establish a single, fixed date for submission of approved applications by the CMS Regional Office to the CMS Central Office in order to adequately inform all involved parties of expectations with regard to these applications.

Response: We appreciate the commenter's encouragement of efforts to make sure that information is available to CMS timely for purposes of setting wage index values in the final rule. While we agree that providers are not in control of CMS Regional Office timing, applications for urban to rural reclassification under § 412.103 may be submitted at any time and providers are aware that, in accordance with § 412.103(c), the CMS Regional Office may take up to 60 days to approve an application. Therefore, providers seeking to be considered rural for the wage index and budget neutrality calculations can plan accordingly to submit applications for urban to rural reclassification with ample time for the application to be approved before the proposed lock-in date. Furthermore, we believe that eliminating a ''provider-based deadline'' benefits providers because a hospital that is approved for rural reclassification within 60 days of the public display date of the proposed rule would be included as rural in the final rule ratesetting even if the hospital filed less than 70 days prior to the lock-in date. We agree with the commenter that a provider-based deadline based on the date of the public display of the proposed rule, such as a requirement for a provider to file an application 70 days prior to 60 days after the display of the proposed rule, would not be practicable because providers do not have a specific date upon which to rely for the public display of the proposed rule each year. Therefore, we do not believe that CMS should set such a provider-based deadline to permit the same 70 days as the current rule. We also agree with the commenter that, using the FY 2019 proposed rule as an example, the proposed change would not have made the data available earlier than under the current policy, but we reiterate that the proposed rule may be displayed earlier in future years, which would potentially allot for more time in the ratesetting process. Therefore, we believe that it would be appropriate to revise the lock-in date as we proposed. Finally, we do not believe it is necessary to establish a single, fixed date for submission of approved applications by the CMS Regional Office to the CMS Central Office in order to adequately inform all involved parties of expectations with regard to these applications because CMS Regional Offices already have the requirement at § 412.103(c) to rule on an application within 60 days, and the CMS Central Office is copied on such approvals.

After consideration of the public comments we received, for the reasons discussed above and in the proposed rule, we are finalizing our proposal, without modification, to revise § 412.103(b)(6) to specify that in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103 no later than 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year.

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2019 wage index were made available on May 19, 2017, and the preliminary CY 2016 occupational mix data files were made available on July 12, 2017, through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page.html*.

On February 2, 2018, we posted a public use file (PUF) at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page.html* containing FY 2019 wage

index data available as of February 1, 2018. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2014 through September 30, 2015; that is, FY 2015 wage data), a tab with the occupational mix data (which includes data from the CY 2016 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the February 2, 2018 wage data PUF, and a tab containing the CY 2016 occupational mix data of the hospitals deleted from the February 2, 2018 occupational mix PUF. In a memorandum dated December 14, 2017, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the February 2, 2018 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2019 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

In a memorandum dated April 28, 2017, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files posted on May 19, 2017, and the process and timeframe for requesting revisions. The preliminary CY 2016 occupational mix survey data was posted on CMS' website on July 12, 2017.

If a hospital wished to request a change to its data as shown in the May 19, 2017 preliminary wage data files and the July 12, 2017 preliminary occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC by September 1, 2017. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. November 15, 2017 was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 4, 2017 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2018. CMS published the wage index PUFs that included hospitals' revised wage index data on February 2, 2018. Hospitals had until February 16, 2018, to submit requests to the MACs to correct errors in the February 2, 2018 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the February 2, 2018 PUF. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 23, 2018. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 5, 2018. Data that were incorrect in the preliminary or February 2, 2018 wage index data PUFs, but for which no correction request was received by the February 16, 2018 deadline, were not considered for correction at this stage. In addition, April 5, 2018 was the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the February 2, 2018 PUF and at least 14 calendar days prior to April 5, 2018 (that is, March 22, 2018), that did not arise from a hospital's request for revisions. We note that, as we did for the FY 2018 wage index, for the FY 2019 wage index, in accordance with the FY 2019 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page.html*, the April appeals had to be sent via mail and email. We refer readers to the wage index timeline for complete details.

Hospitals were given the opportunity to examine Table 2 associated with the proposed rule, which was listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Proposed-Rule-Home-Page.html*. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2015 data used to construct the proposed FY 2019 wage index. We noted in the proposed rule (83 FR 20369) that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by early February 2018.

We posted the final wage index data PUFs on April 27, 2018 via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page.html*. The April 2018 PUFs were made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 23, 2018, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2018 wage index data PUFs, changes to the wage and occupational mix data could only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 23, 2017.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 2, 2018 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2018 final wage index data PUFs, a hospital believed that its wage or occupational mix data were incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital was given

the opportunity to notify both its MAC and CMS regarding why the hospital believed an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC no later than May 30, 2018. May 30, 2018 was also the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified on or after 13 calendar days prior to April 5, 2018 (that is, March 23, 2018), and at least 14 calendar days prior to May 30, 2018 (that is, May 16, 2018), that did not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital was notified on or after 13 calendar days prior to May 30, 2018 (that is, May 17, 2018) may be appealed to the Provider Reimbursement Review Board (PRRB).) Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2019 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page.html*, the May appeals were required to be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely (that is, by May 30, 2018) by CMS and the MACs were incorporated into the final FY 2019 wage index, which is effective October 1, 2018.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2019 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision would be required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to requested changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2018, they had the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2019 wage index by August 2018, and the implementation of the FY 2019 wage index on October 1, 2018. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 30, 2018, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 30, 2018 for the FY 2019 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 30, 2018 deadline for the FY 2019 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 30, 2018 deadline for the FY 2019 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the February 2 Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.L.1. of the preamble of this final rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the February 2 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.D.2. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule, in the calculation of the proposed FY 2019 wage index, upon discovering that hospitals reported other wage-related costs on Line 18 of Worksheet S–3, despite those other wage-related costs failing to meet the requirement that other wage-related costs must exceed 1 percent of total adjusted salaries net of excluded area salaries, CMS made internal edits to remove those other wage-related costs from Line 18. Conversely, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), starting with the FY 2019 wage index, we implemented a process for hospitals to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the February 2 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) bring additional transparency to instances where CMS makes data corrections after the February 2 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2019 Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

M. Labor-Related Share for the FY 2019 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we rebased and revised the hospital market basket. We established a 2014-based IPPS hospital market basket to replace the FY 2010-based IPPS hospital market basket, effective October 1, 2017. Using the 2014-based IPPS market basket, we finalized a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. In addition, in FY 2018, we implemented this revised and rebased labor-related share in a budget neutral manner (82 FR 38522). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account

the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20371), for FY 2019, we did not propose to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, professional fees: Labor-related, administrative and facilities support services, installation, maintenance, and repair services, and all other labor-related services. Therefore, for FY 2019, we proposed to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2018.

As discussed in section IV.B. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2019, we did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

We did not receive any public comments on our proposals related to the labor-related share percentage. Therefore, we are finalizing our proposals, without modification, to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2018 for all hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.0000.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2019 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflect the national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2019, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2019, we are applying the wage index to a labor-related share of 68.3 percent of the national standardized amount.

IV. Other Decisions and Changes to the IPPS for Operating System

A. Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus 1 day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute directs us to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4

days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

2. Changes for FY 2019

As discussed in section II.F. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule, based on our analysis of FY 2017 MedPAR claims data, we proposed to make changes to a number of MS–DRGs, effective for FY 2019. Specifically, we proposed to:

- Assign CAR–T therapy procedure codes to MS–DRG 016 (proposed revised title: Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy);
- Delete MS–DRG 685 (Admit for Renal Dialysis) and reassign diagnosis codes from MS–DRG 685 to MS–DRGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively);
- Delete 10 MS–DRGs (MS–DRGs 765, 766, 767, 774, 775, 777, 778, 780, 781, and 782) and create 18 new MS–DRGs relating to Pregnancy, Childbirth and the Puerperium (MS–DRGs 783 through 788, 794, 796, 798, 805, 806, 807, 817, 818, 819, and 831 through 833);
- Assign two additional diagnosis codes to MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator);
- Reassign 12 ICD–10–PCS procedure codes from MS–DRGs 329, 330 and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 344, 345, and 346 (Minor Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively); and
- Reassign ICD–10–CM diagnosis codes R65.10 and R65.11 from MS–DRGs 870, 871, and 872 (Septicemia or Severe Sepsis with and without Mechanical Ventilation >96 Hours with and without MCC, respectively) to MS–DRG 864 (proposed revised title: Fever and Inflammatory Conditions).

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule, in light of the proposed changes to these MS–DRGs for FY 2019, according to the regulations under § 412.4(d), we evaluated these MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2017 MedPAR file. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We stated in the proposed rule that we continue to believe it is appropriate to reassess MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG. We noted that MS–DRGs 023, 329, 330, 331, 698, 699, 700, 870, 871, and 872 are currently subject to the postacute care transfer policy. We stated that as a result of our review, these MS–DRGs, as proposed to be revised, would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. We note that, as discussed in section II.F.5.b. of the preamble of this final rule, we are finalizing these proposed changes to the MS–DRGs with the exception of our proposed revisions to MS–DRGs 329, 330, 331, 344, 345, and 336, which we are not finalizing. Therefore, MS DRGs 329, 330, 331, 344, 345, and 336 are not included in the updated analysis of the postacute care transfer policy and special payment policy criteria discussed below. We note that MS–DRGs that are subject to the postacute transfer policy for FY 2018 and are not revised will continue to be subject to the policy in FY 2019.

Using the December 2017 update of the FY 2017 MedPAR file, we developed a chart for the proposed rule (83 FR 20378 through 20380) which set forth the analysis of the postacute care transfer policy criteria completed for the proposed rule with respect to each of these proposed new or revised MS–DRGs. We note that, in the proposed rule, we incorrectly stated that we used the March 2018 update for purposes of this analysis rather than the December 2017 update. We indicated that, for the FY 2019 final rule, we would update this analysis using the most recent available data at that time. The following chart reflects our updated analysis for the finalized new and revised MS–DRGs using the postacute care transfer policy criteria and the March 2018 update of the FY 2017 MedPAR file. We note that, with the additional time since the proposed rule, this analysis does take into account the change relating to discharges to hospice care, effective October 1, 2018, discussed in section IV.A.3. of the preamble of this final rule. We also note that the postacute care transfer policy status for all finalized new and revised MS–DRGs remains unchanged from the proposed rule.

LIST OF NEW OR REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2019

New or revised MS–DRG	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,432)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 8.955224%)	Postacute care transfer policy status
016	Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy (Revised).	2,095	*422	127	*6.06	No.
023	Craniotomy with Major Device Implant or Acute CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator (Revised).	9,270	5,859	1,681	18.13	Yes.
698	Other Kidney and Urinary Tract Diagnoses with MCC (Revised).	55,393	36,062	8,386	15.14	Yes.
699	Other Kidney and Urinary Tract Diagnoses with CC (Revised).	35,860	17,233	3,435	9.58	Yes.

LIST OF NEW OR REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2019—Continued

New or revised MS–DRG	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,432)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 8.955224%)	Postacute care transfer policy status
700	Other Kidney and Urinary Tract Diagnoses without CC/MCC (Revised).	4,466	1,642	187	*4.19	Yes**.
783	Cesarean Section with Sterilization with MCC (New).	193	*6	0	*0.00	No.
784	Cesarean Section with Sterilization with CC (New).	549	*19	0	*0.00	No.
785	Cesarean Section with Sterilization without CC/MCC (New).	507	*6	0	*0.00	No.
786	Cesarean Section without Sterilization with MCC (New).	755	*35	6	*0.79	No.
787	Cesarean Section without Sterilization with CC (New).	2,050	*95	3	*0.15	No.
788	Cesarean Section without Sterilization without CC/MCC (New).	1,868	*41	0	*0.00	No.
794	Vaginal Delivery with Sterilization/D&C with MCC (New).	1	*1	0	*0.00	No.
796	Vaginal Delivery with Sterilization/D&C with CC (New).	49	*2	0	*0.00	No.
798	Vaginal Delivery with Sterilization/D&C without CC/MCC (New).	160	*1	0	*0.00	No.
805	Vaginal Delivery without Sterilization/D&C with MCC New).	506	*20	0	*0.00	No.
806	Vaginal Delivery without Sterilization/D&C with CC (New).	2,143	*71	2	*0.09	No.
807	Vaginal Delivery without Sterilization/D&C without CC/MCC (New).	3,833	*71	7	*0.18	No.
817	Other Antepartum Diagnoses with O.R. Procedure with MCC (New).	75	*12	0	*0.00	No.
818	Other Antepartum Diagnoses with O.R. Procedure with CC (New).	88	*5	1	*1.14	No.
819	Other Antepartum Diagnoses with O.R. Procedure without CC/MCC (New).	53	*1	0	*0.00	No.
831	Other Antepartum Diagnoses without O.R. Procedure with MCC (New).	859	*31	1	*0.12	No.
832	Other Antepartum Diagnoses without O.R. Procedure with CC (New).	1,257	*53	13	*1.03	No.
833	Other Antepartum Diagnoses without O.R. Procedure without CC/MCC (New).	663	*11	0	*0.00	No.
864	Fever and Inflammatory Conditions (Revised).	12,206	4,064	313	*2.56	No.
870	Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours (Revised).	34,468	18,534	6,550	19.00	Yes.
871	Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC (Revised).	583,535	323,308	56,341	9.66	Yes.
872	Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours without MCC (Revised).	165,853	75,185	8,323	*5.02	Yes**.

*Indicates a current postacute care transfer policy criterion that the MS–DRG did not meet.

**As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

Based on our annual review of proposed new or revised MS–DRGs and analysis of the December 2017 update of the FY 2017 MedPAR file, we identified MS–DRGs that we proposed to include on the list of MS–DRGs subject to the special payment methodology policy. We note that, in the proposed rule, we incorrectly stated that we used the March 2018 update for purposes of this analysis rather than the December 2017 update. We noted in the proposed rule that none of the proposed revised MS–DRGs that were listed in the table included in the proposed rule as continuing to meet the criteria for postacute care transfer policy status (specifically, MS–DRGs 023, 330, 331, 698, 699, 700, 870, 871, and 872) are currently listed as being subject to the special payment methodology (as noted

above, we are not finalizing the proposed changes to MS–DRGs 330 and 331 and therefore they are not included in the updated analysis below). Based on our analysis of proposed changes to MS–DRGs included in the proposed rule, we determined that proposed revised MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) would meet the criteria for the MS–DRG special payment methodology. Therefore, we proposed that proposed revised MS–DRG 023 would be subject to the MS–DRG special payment methodology, effective FY 2019. As described in the regulations at § 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. Therefore, we proposed that MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) also would be subject to the MS–DRG special payment methodology, effective for FY 2019.

In the proposed rule, we indicated that, for the FY 2019 final rule, we would update this analysis using the most recent available data at that time. The following chart reflects our updated analysis for the finalized new and revised MS–DRGs using our criteria and the March 2018 update of the FY 2017 MedPAR file. We note that with the additional time since the proposed rule this analysis does take into account the change relating to discharges to hospice care, effective October 1, 2018, discussed in section IV.A.3. of the preamble of this final rule. We also note that status for all finalized new and revised MS–DRGs remains unchanged from the proposed rule.

LIST OF REVISED MS–DRGS SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2019

Revised MS–DRG	MS–DRG title	Geometric mean length of stay	Average charges of 1-day discharges	50 percent of average charges for all cases within MS–DRG	Special payment policy status
023	Craniotomy with Major Device Implant or Acute CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator.	7.3	$97,557	$96,623	Yes.
698	Other Kidney and Urinary Tract Diagnoses with MCC	4.9	18,290	25,199	No.
699	Other Kidney and Urinary Tract Diagnoses with CC	3.4	16,872	16,984	No.
700	Other Kidney and Urinary Tract Diagnoses without CC/MCC.	2.5	14,283	12,943	No.
870	Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours.	12.4	0	102,505	No.
871	Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC.	4.8	19,860	29,939	No.
872	Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours without MCC.	3.7	18,096	17,399	No.

We did not receive any public comments specific to our proposal that MS–DRGs 23 and 24 would be subject to the special payment methodology effective FY 2019. Therefore, we are finalizing this proposal without modification.

The special payment policy status of these MS–DRGs is reflected in Table 5 associated with this final rule, which is listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website.

3. Implementation of Changes Required by Section 53109 of the Bipartisan Budget Act of 2018

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, effective for discharges occurring on or after October 1, 2018, if a discharge is assigned to one of the MS–DRGs subject to the postacute care transfer policy and the individual is transferred to hospice care by a hospice program, the discharge would be subject to payment as a transfer case. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381 and 20382), we proposed to make conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018 as qualified discharges. We proposed that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) would be subject to the postacute care transfer policy in accordance with this statutory amendment. We stated in the proposed rule that, consistent with our policy for other qualified discharges, CMS claims processing software will be revised to identify cases in which hospice benefits were billed on the date of hospital discharge without the appropriate discharge status code. Such claims will be returned as unpayable to the hospital and may be rebilled with a corrected discharge code.

Comment: Several comments opposed the inclusion of discharges to hospice care as subject to the postacute care transfer policy. The commenters questioned the efficacy of including hospice care within the postacute care transfer policy in terms of patient choice and quality of life at end of life. The commenters believed that the proposed policy would inject payment concerns within medical decisions regarding appropriate placement and consideration of patient needs and preferences. They contended that such

payment policies would dissuade transfers to hospice care and potentially result in a perverse incentive to delay hospice care election. The commenters further contended that the initial rationale for the postacute care transfer policy does not, and should not apply to discharges to hospice. They stated that the initial impetus for the postacute care transfer policy was to discourage hospitals from admitting and then quickly discharging patients to a postacute care setting for therapeutic care. Because hospice providers would not provide curative care, the commenters believed there would be no duplicative services provided by the discharging hospital and the postacute care provider. The commenters provided academic research demonstrating the numerous patient care benefits related to fast-track discharges from hospitals to hospices. One commenter provided analysis to demonstrate that the proposed application of the postacute care transfer policy to hospice discharges could potentially negatively impact up to 25 percent of hospice admissions nationally, with some providers experiencing rates as high as 33 percent. The same commenter also suggested several ways CMS could evaluate the implementation of the postacute care transfer policy and its effects on hospice care. Several commenters requested that, at a minimum, CMS monitor and provide detailed provider-specific data on the rates of hospice transfers, including inpatient days prior to hospice election, and to track whether the policy has a material impact on timely hospice care election for patients in inpatient stays.

While several commenters recognized the statutory requirement for the proposed changes, they urged CMS to use its administrative discretion to mitigate or delay the potentially harmful effects that the policy could have on access to the hospice benefit by Medicare beneficiaries facing the end of life.

Response: We thank commenters for the analysis and feedback provided. As stated in the first year of the IPPS on the hospital-to-hospital transfer policy, we stated that ''(t)he rationale for per diem payment as part of our transfer policy is that the transferring hospital generally provides only a limited amount of treatment. Therefore, payment of the full prospective payment rate would be unwarranted'' (49 FR 244). We disagree that the postacute care transfer policy creates a perverse incentive to keep patients in the hospital longer than necessary. Our longstanding view is the policy addresses the appropriate level of payment once clinical decisions about the most appropriate care in the most appropriate setting have been made. Therefore, we do not believe it would be appropriate to treat discharges to hospice care differently than any of the other qualified postacute care settings. We believe that statute is unambiguous as to the actions CMS is required to implement for FY 2019. In addition to expanding the postacute care policy to include discharges to hospice, section 53109 of the Bipartisan Budget Act of 2018 also requires MedPAC to conduct a detailed evaluation of the implementation and impacts of this provision. Specifically, such a report must address whether the timely access to hospice care has been affected through changes to hospital policies or behaviors. Preliminary results of this report are due to Congress by March 21, 2020.

Comment: One comment requested that CMS rephrase the proposed changes to the regulation text at § 412.4(c). The commenter believed that the proposed text of ''For discharges occurring on or after October 1, 2018, to hospice care by a hospice program.'' could be interpreted to require a ''hospice program'' to initiate a qualified discharge. The commenters suggested that CMS rephrase this language to clearly indicate that a qualified discharge originates from a hospital.

Response: The terminology of ''hospice care by a hospice program'' was taken directly from section 53109 of the Bipartisan Budget Act of 2018. The terminology is similar to the language implemented in section 1861(dd) of the Act (''The term 'hospice care' means the following items and services provided to a terminally ill individual by . . . a hospice program). However, for sake of clarity, we are rephrasing the language that was originally proposed to instead read ''For discharges occurring on or after October 1, 2018, to hospice care *provided* by a hospice program.''

After consideration of the public comments we received, we are finalizing the proposed revisions to § 412.4(c) to include discharges to hospice care occurring on or after October 1, 2018 as qualified discharges, with one minor grammatical modification discussed previously. Hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) will be subject to the postacute care transfer policy in accordance with this statutory amendment, effective for discharges occurring on or after October 1, 2018.

B. Changes in the Inpatient Hospital Update for FY 2019 (§ 412.64(d))

1. FY 2019 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2019, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2018. Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to—

(a) A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act;

(b) A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act;

(c) An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and

(d) An additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act.

Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2019 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating market basket with the rebased and revised

2014-based IPPS operating market basket, effective with FY 2018.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381), we proposed to base the proposed FY 2019 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2017 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2017, which was estimated to be 2.8 percent. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2019 market basket update and the MFP adjustment in the final rule.

Based on the most recent data available for this FY 2019 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2018 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through the first quarter of 2018), we estimate that the FY 2019 market basket update used to determine the applicable percentage increase for the IPPS is 2.9 percent.

For FY 2019, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount. Based on the most recent data described above, we determined final applicable percentage increases to the standardized amount for FY 2019, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*. As discussed in the FY 2016 IPPS/LTCH PPS final rule, if IGI makes changes to the MFP methodology, we will announce them on our website rather than in the annual rulemaking.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382), for FY 2019, we proposed an MFP adjustment of 0.8 percentage point. Similar to the market basket update, for the proposed rule, we used IGI's fourth quarter 2017 forecast of the MFP adjustment to compute the proposed MFP adjustment. As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2019 market basket update and the MFP adjustment for the final rule.

Based on the most recent data available for this FY 2019 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2018 forecast of the MFP adjustment with historical data through the first quarter of 2018), for FY 2019, we have determined an MFP adjustment of 0.8 percentage point.

We did not receive any public comments on our proposals to use the most recent available data to determine the final market basket update and the MFP adjustment. Therefore, for this final rule, we are finalizing a market basket update of 2.9 percent and an MFP adjustment of 0.8 percentage point for FY 2019 based on the most recent available data.

Based on the most recent available data for this final rule, as described previously, we have determined four applicable percentage increases to the standardized amount for FY 2019, as specified in the following table:

FY 2019 Applicable Percentage Increases for the IPPS

FY 2019	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.725	−0.725
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.175	0	−2.175
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.35	−0.825	0.625	−1.55

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382), we proposed to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2019 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we proposed to revise paragraph (vii) of § 412.64(d)(1) to include the applicable percentage increase to the FY 2019 operating standardized amount as the percentage increase in the market basket

index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment and less an additional reduction of 0.75 percentage point.

We did not receive any public comments on our proposed changes to the regulations at § 412.64(d)(1) and, therefore, are finalizing these proposed changes without modification in this final rule.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. (As discussed in section IV.G. of the preamble of this FY 2019 IPPS/LTCH PPS final rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.)

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382), for FY 2019, we proposed the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 1.25 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.55 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of −0.85 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of −1.55 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As noted previously, for the FY 2019 IPPS/LTCH PPS proposed rule, we used IGI's fourth quarter 2017 forecast of the 2014-based IPPS market basket update with historical data through third quarter 2017. Similarly, we used IGI's fourth quarter 2017 forecast of the MFP adjustment. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the update in the final rule.

We did not receive any public comments with regard to our proposal. Therefore, we are finalizing the proposal to determine the update to the hospital-specific rates for SCHs and MDHs in this final rule using the most recent available data, specifically, IGI's second quarter 2018 forecast of the 2014-based IPPS market basket rate-of-increase and the MFP adjustment with historical data through the first quarter of 2018.

For this final rule, based on the most recent available data, we are finalizing the following updates to the hospital-specific rates applicable to SCHs and MDHs: An update of 1.35 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 0.625 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of –0.825 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of –1.55 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2019 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56937 through 56938), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to determine an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this final rule. Accordingly, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382), for FY 2019, we proposed an applicable percentage increase of 1.25 percent to the standardized amount for hospitals located in Puerto Rico. We note that we did not receive any public comments with regard to our proposal. Based on the most recent data available for this final rule (as discussed in section IV.B.1. of the preamble of this final rule), we are finalizing an applicable percentage increase of 1.35 percent to the standardized amount for hospitals located in Puerto Rico.

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2019.

C. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all

hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2019 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2019 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These values are based on discharges occurring during FY 2017 (October 1, 2016 through September 30, 2017), and include bills posted to CMS' records through March 2018.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20383), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2018, they must have a CMI value for FY 2017 that is at least—

- 1.66185 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region were set forth in a table in the proposed rule (83 FR 20383). We stated in the proposed rule that we intended to update the proposed CMI values in the FY 2019 final rule to reflect the updated FY 2017 MedPAR file, which would contain data from additional bills received through March 2018.

We did not receive any public comments on our proposals.

Based on the latest available data (FY 2017 bills received through March 2018), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2018, they must have a CMI value for FY 2017 that is at least:

- 1.6612 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final CMI values by region are set forth in the following table.

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.4071
2. Middle Atlantic (PA, NJ, NY)	1.4701
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5492
4. East North Central (IL, IN, MI, OH, WI)	1.5743
5. East South Central (AL, KY, MS, TN)	1.5293
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.63935
7. West South Central (AR, LA, OK, TX)	1.6859
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7366
9. Pacific (AK, CA, HI, OR, WA)	1.6613

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20384), for FY 2019, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2016 (that is, October 1, 2015 through September 30, 2016), which were the latest cost report data available at the time the proposed rule was developed. Therefore, we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for

cost reporting periods beginning on or after October 1, 2018, must have, as the number of discharges for its cost reporting period that began during FY 2016, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2019 IPPS/LTCH PPS proposed rule at 83 FR 20384.) In the proposed rule, we stated that we intended to update these numbers in the FY 2019 final rule based on the latest available cost report data.

We did not receive any public comments on our proposals.

Based on the latest discharge data available at this time, that is, for cost reporting periods that began during FY 2016, the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,431
2. Middle Atlantic (PA, NJ, NY)	9,985
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,543
4. East North Central (IL, IN, MI, OH, WI)	8,297
5. East South Central (AL, KY, MS, TN)	8,131
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,805
7. West South Central (AR, LA, OK, TX)	5,574
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,736
9. Pacific (AK, CA, HI, OR, WA)	9,017

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

D. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20384), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. (Section 50204 also extended prior changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals through FY 2018, as discussed later in this section.). Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the **Federal Register** on April 26, 2018 (83 FR 18301 through 18308). In section IV.D.2.b. of the preamble of the proposed rule and this final rule, we discuss the low-volume hospital payment adjustment policies for FY 2019.

2. Implementation of Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology Made by the Bipartisan Budget Act of 2018

a. Extension of the Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FY 2018 and Conforming Changes to Regulations

Section 50204 of the Bipartisan Budget Act of 2018 extended through FY 2018 certain changes to the low-volume hospital payment policy made by the Affordable Care Act and extended by subsequent legislation. We addressed this extension of the temporary changes to the low-volume hospital payment policy for FY 2018 in a notice that appeared in the **Federal Register** on April 26, 2018 (CMS–1677–N) (83 FR 18301 through 18308). However, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20384), we proposed to make conforming changes to the regulations text in § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2018, in accordance with section 50204 of the Bipartisan Budget Act of 2018. Specifically, we proposed to make conforming changes to paragraphs (b)(2)(ii) and (c)(2) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect for FY 2018 is the same low-volume hospital payment adjustment policy in effect for FYs 2011 through 2017 (as described in the FY 2018 IPPS notice (CMS–1677–N; 83 FR 18301 through 18308).

We did not receive any public comments on our proposal. Therefore, we are finalizing, without modification, our proposed conforming changes to paragraphs (b)(2)(ii) and (c)(2) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect for FY 2018 is the same low-volume hospital payment adjustment policy in effect for FYs 2011 through 2017.

b. Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FYs 2019 Through 2022

As discussed earlier, section 50204 of the Bipartisan Budget Act of 2018 further modified the definition of a low-

volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, section 50204 amended the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 50204 also amended section 1886(d)(12)(D) of the Act to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20385), to implement this requirement, we proposed a continuous, linear sliding scale formula to determine the low volume hospital payment adjustment for FYs 2019 through 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment originally established by the Affordable Care Act and implemented in the regulations at § 412.101(c)(2)(ii) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241). Consistent with the statute, we proposed that qualifying hospitals with 500 or fewer total discharges would receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment would be calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. That proportion is calculated by multiplying the discharges in excess of 500 by a fraction that is equal to the maximum available add-on payment (25 percent) divided by a number represented by the range of discharges for which this policy applies (3,800 minus 500, or 3,300). In other words, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, we proposed the low-volume hospital payment adjustment for FYs 2019 through 2022 would be calculated using the following formula:

Low-Volume Hospital Payment Adjustment = 0.25 − [0.25/3300] × (number of total discharges − 500) = (95/330) − (number of total discharges/13,200).

As discussed below, the formula as presented in the preamble to the proposed rule (83 FR 20385) contained a typographical error, in that an ''×'' sign was used in place of a minus (''−'') sign, as follows: (95/330) × (number of total discharges/13,200). The formula set forth in the proposed regulatory text at § 412.101(c)(3)(ii) was correct, and we have also corrected the typographical error in the formula as presented in the preamble of this final rule.

To reflect these changes for FYs 2019 through 2022, we proposed to revise § 412.101(b)(2) by adding paragraph (iii) to specify that a hospital must have fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 15 road miles from the nearest ''subsection (d)'' hospital, consistent with the amendments to section 1886(d)(12)(C)(i) of the Act as provided by section 50204(a)(2) of the Bipartisan Budget Act of 2018. We also proposed to add paragraph (3) to § 412.101(c), consistent with section 1886(d)(12)(D) of the Act as amended by section 50204(a)(3) of the Bipartisan Budget Act of 2018, to specify that:

- For low-volume hospitals with 500 or fewer total discharges during the fiscal year, the low-volume hospital payment adjustment is an additional 25 percent for each Medicare discharge.
- For low-volume hospitals with total discharges during the fiscal year of more than 500 and fewer than 3,800, the adjustment for each Medicare discharge is an additional percent calculated using the formula [(95/330) − (number of total discharges/13,200)]. (Similar to above, in the preamble to the proposed rule, we inadvertently included an ''×'' sign in place of a ''−'' sign in describing the formula that was specified in the text of proposed § 412.101(c)(3)(ii). As noted, the proposed regulatory text accurately reflected the proposed formula, and we have also corrected the typographical error in the formula as presented in the preamble of this final rule.)

In the proposed rule, we specified that the ''number of total discharges'' would be determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report.

In addition, in accordance with the provisions of section 50204(a) of the Bipartisan Budget Act of 2018, for FY 2023 and subsequent fiscal years, we proposed to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that the low-volume payment adjustment policy in effect for these years is the same low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described earlier. Lastly, we proposed to make conforming changes to paragraph (d) (which relates to eligibility of new hospitals for the adjustment), consistent with the provisions of section 50204(a) of the Bipartisan Budget Act of 2018, for FY 2019 and subsequent fiscal years, as total discharges are used under the low-volume hospital payment adjustment policy in effect for those years as described earlier.

Comment: Commenters noted a typographical error in the proposed low-volume hospital payment adjustment formula as presented in the preamble of the proposed rule. Many of these commenters also noted that the formula in proposed § 412.101(c)(3)(ii) was correct.

Response: We thank the commenters for pointing out this typographical error and, as indicated earlier, are correcting the formula as presented in the preamble of this final rule to read: Low-Volume Hospital Payment Adjustment = 0.25 − [0.25/3300] × (number of total discharges − 500) = (95/330) − (number of total discharges/13,200).

After consideration of the public comments we received, we are finalizing, without modification, our proposed changes to § 412.101(b)(2), (c), and (d) to reflect the changes in the low-volume hospital payment policy provided by section 50204 of the Bipartisan Budget Act of 2018 as discussed in this section.

3. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking (for example, the FY 2018 IPPS/LTCH PPS final rule (82 FR 38186 through 38188)), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge

criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38185 through 38188).)

As described in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20385), for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and new § 412.101(b)(2)(iii), as proposed and finalized in this final rule, a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS proposed rule, in addition to the discharge criterion, for FY 2019 and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or proposed new § 412.101(b)(2)(iii) for the fiscal year (as noted in the previous section, we have finalized the amendments to § 412.101(b)(2) and new § 412.101(b)(2)(iii) as proposed). Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2019, as noted earlier, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414). For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

As explained in the proposed rule, in accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Specifically, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20386), for FY 2019, we proposed that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Consistent with historical practice, for FY 2019, we proposed that a hospital's written request must be received by its MAC no later than September 1, 2018 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2018. If a hospital's written request for low-volume hospital status for FY 2019 is received after September 1, 2018, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2019 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Under this process, a hospital receiving the low-volume hospital payment adjustment for FY 2018 may continue to receive a low-volume hospital payment adjustment without reapplying if it continues to meet the mileage criterion (which remains unchanged for FY 2019) and it also meets the applicable discharge criterion as modified for FY 2019 (that is, 3,800 or fewer total discharges). In this case, a hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2019. (Determination of meeting the discharge criterion is discussed earlier in this section.) We noted in the proposed rule that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) in order to receive the payment adjustment in that fiscal year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275).

Comment: Commenters generally supported CMS' proposals related to the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2019. Some commenters requested clarity regarding the date used to establish the most recently submitted cost report as well as guidance regarding what information from the cost report should be used to determine the total number of discharges for purposes of the low-volume hospital payment adjustment in FY 2019 through 2022.

Response: Consistent with our process for determining whether a hospital met the discharge criterion for FYs 2005 through 2010, the most recently submitted cost report used to determine total discharges for the low-volume hospital payment policy is the most recently submitted cost report as of the date that the hospital submits its written request to the MAC, in accordance with the process discussed earlier in this section. In addition, the total discharges include only inpatient discharges as reported on Worksheet S–3, Part 1, Column 15, Line 1 in the current version of the cost report.

After consideration of the public comments we received, we are finalizing our proposals relating to the process for requesting and obtaining the low-volume hospital payment adjustment as described above, without modification.

E. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

1. IME Payment Adjustment Factor for FY 2019

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2019, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2019 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

We did not receive any comments regarding the IME adjustment factor, which, as noted earlier, is statutorily required. Accordingly, for discharges occurring during FY 2019, the IME formula multiplier is 1.35.

2. Technical Correction to Regulations at 42 CFR 412.105(f)(1)(vii)

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20386), in the regulation governing the IME payment adjustment at § 412.105(f)(1)(vii), we identified an inadvertent omission of a cross-reference relating to an adjustment to a hospital's full-time equivalent cap for a new medical residency training program. Section 412.105(f)(1)(vii) states that if a hospital establishes a new medical residency training program, as defined in § 413.79(l), the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of § 413.79(e)(1) through (e)(4). However, there is a paragraph (e)(5) under § 413.79 that we have inadvertently omitted that applies to the regulation at § 412.105(f)(1)(vii). In the proposed regulation (83 FR 20567), we proposed to correct this omission by amending § 412.105 to remove the reference to ''§§ 413.79(e)(1) through (e)(4)'' and add in its place the reference ''§ 413.79(e)'' to make clear that the provisions of § 413.79(e)(1) through (e)(5) apply. This proposed revision was intended to correct the omission and was not intended to substantially change the underlying regulation.

We did not receive any public comments on this proposed technical correction to § 412.105, and therefore are finalizing it as was proposed in the proposed regulation.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2019 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would

otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20388 and 20389), we discussed our specific policies with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals would be paid under the Maryland All-Payer Model. As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83

FR 20388), the performance period of the Maryland All-Payer Model is scheduled to end on December 31, 2018. However, since the proposed rule was issued, CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which begins on January 1, 2019. Under both the Maryland All-Payer Model and the new Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2019, and will remain ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.

• Sole community hospitals (*SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

• *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments as we do for all other IPPS hospitals. Due to the extension of the MDH program, MDHs will continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we will calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 will be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

• *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced Initiative (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

• *IPPS hospitals that are participating in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments.

• *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. At the time of issuance of the proposed rule, there were 30 hospitals participating in the demonstration program (83 FR 20389). Since issuance of the proposed rule, one hospital has withdrawn from the demonstration program. Under the payment methodology that applies during the second 5 years of the extension period under the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/*

Transmittals/2014-Transmittals-Items/R5P240.html.

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2018, and our proposed and final policies for FY 2019.

a. Calculation of Factor 1 for FY 2019

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2018, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20389), in order to determine Factor 1 in the uncompensated care payment formula for FY 2019, we proposed to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2019.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2019 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), for the proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on the Office of the Actuary's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2016 through FY 2019 are discussed in the table titled ''Factors Applied for FY 2016 through FY 2019 to Estimate Medicare DSH Expenditures Using FY 2015 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of the FY 2019 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's December 2017 Medicare DSH estimates, which were based on data from the September 2017 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2018 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2018 IPPS/LTCH PPS final rule. (We note that the proposed rule included an inadvertent reference to the HCRIS December 2017 update, which we have corrected in this final rule to reflect the September 2017 update of HCRIS, which was used by OACT in developing the December 2017 estimates. The cost report data from the December quarterly update were not available to be used in OACT's December 2017 estimates of Medicare DSH payments.) Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the December 2017 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's December 2017 Medicare DSH estimates. The 30 hospitals that were then participating in the Rural Community Hospital Demonstration Program were also excluded from these estimates because, under the payment methodology that applies during the second 5 years of the extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or interim and final uncompensated care payments.

For the proposed rule, using the data sources discussed above, the Office of the Actuary's December 2017 estimate for Medicare DSH payments for FY 2019, without regard to the application of section 1886(r)(1) of the Act, was approximately $16.295 billion. Therefore, also based on the December 2017 estimate, the estimate of empirically justified Medicare DSH payments for FY 2019, with the application of section 1886(r)(1) of the

Act, was approximately $4.074 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2019). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in the proposed rule, we proposed that Factor 1 for FY 2019 would be $12,221,027,954.62, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2019 ($16,294,703,939.49 minus $4,073,675,984.87).

Comment: Some commenters requested greater transparency in the methodology used by CMS and the OACT, particularly with respect to the calculation of estimated DSH payments for purposes of determining Factor 1, and the ''Other'' factors that are used to estimate Medicare DSH expenditures. A number of commenters urged CMS to provide a detailed explanation, including calculations, of the assumptions used to make these projections. Some commenters believed that the lack of opportunity afforded to hospitals to review the data used in rulemaking is in violation of the Administrative Procedure Act. Specifically, the commenters noted that the update factors used to derive the estimated DSH payment for FY 2019 were different from the factors used in previous years, but the changes were not addressed by CMS in the proposed rule. The commenters also noted that they have not had the opportunity to comment on the extrapolation of the 2015 DSH data and the way in which Medicaid expansion was accounted for in the DSH payment impact, or on any adjustments made to the data.

Some commenters expressed concern about whether underreporting of Medicaid coverage was factored into the calculation of Factor 1, as it was for Factor 2. The commenters noted that, in the proposed rule, CMS did not explain why OACT assumed that there is an underreporting of Medicaid coverage due to ''a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of health insurance.'' The commenters further stated that the proposed rule did not indicate that the same presumption was also applied to the calculation of Factor 1. Many commenters provided examples of other assumptions made by OACT for which CMS did not provide information in rulemaking to explain the basis for or the data used to make the assumptions. The commenters believed that, given the information available to CMS, such as enrollment and utilization information from States that have expanded Medicaid and recently released reports that concluded that the Affordable Care Act had insured fewer individuals than previously estimated (CBO September 2017 report; President's 2018 Economic Report), coverage levels were lower than estimated by CMS; and therefore, DSH payments to hospitals were suppressed. The commenters requested that CMS implement a system to reconcile uncompensated care payments once later data on Medicare DSH payments are available. One commenter thanked CMS for providing a table listing hospital-specific estimated uncompensated care payments and other DSH-related information for FY 2019. Another commenter suggested that, as CMS is permitting revisions to Factor 3, the agency consider completing reconciliation for Factor 1 and Factor 2. The commenter recognized that there are issues pertaining to completing reconciliation for all three factors, such as the determination of when to finalize all cost reports, but suggested using a methodology similar to the one used to determine the wage index by using prior years' data for settlement of a future year and developing time tables for submissions and revisions to the data.

Response: We thank the commenters for their input. For the reasons discussed below, we have been and continue to be transparent with respect to the methodology and data used to estimate Factor 1 and we disagree with commenters who assert otherwise. Regarding the commenters who reference the Administrative Procedure Act, we note that under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2019 IPPS/LTCH PPS proposed rule did include a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our estimate.

To provide context, we first note that Factor 1 is not estimated in isolation from other OACT projections. The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget.* For additional information on the specific economic assumptions used in the Midsession Review of the President's FY 2019 Budget, we refer readers to the ''Midsession Review of the President's FY 2019 Budget'' available on the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget.* We recognize that our reliance on the economic assumptions and actuarial analysis used to develop the President's Budget and the Midsession Review of the President's Budget in estimating Factor 1 has an impact on stakeholders who wish to replicate the Factor 1 calculation, such as modelling the relevant Medicare Part A portion of the budget, but we believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer the public to the Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections.

Second, as described in more detail later in this section, in the FY 2019 IPPS/LTCH PPS proposed rule, we included information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicated the historical HCRIS data update OACT used to identify Medicare DSH

payments, we explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other'' and ''Discharges'' assumptions, and also provided additional information regarding how we address the Medicaid and CHIP expansion. Thus, for example, in response to the commenters' assertion that Medicaid expansion is not adequately accounted for in the ''Other'' column, we note that the discussion in the proposed rule made clear that, based on data from the Midsession Review of the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita expenditures for a preexpansion Medicaid beneficiary due to the better health of these beneficiaries. Taken as a whole, this description of our proposed methodology for estimating Factor 1 and the data sources used in making this estimate was entirely consistent with the requirements of the Administrative Procedure Act, and gave stakeholders adequate notice of and a meaningful opportunity to comment on the proposed estimate of Factor 1.

Regarding the commenters' assertion that, similar to the adjustment for Medicaid underreporting on survey data in the estimation of Factor 2, we should also account for this underreporting in our estimate of Factor 1, we note that the Factor 1 calculation uses Medicaid enrollment data and estimates and does not require the adjustment because it does not use survey data.

Lastly, regarding the commenters' suggestion that CMS consider reconciling the estimates of Factors 1, 2, and 3, we continue to believe that applying our best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; and 82 FR 38195). We believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenters' suggestion that we should establish a process for reconciling our estimates of the three factors, which would be contrary to the notion of prospectivity. We also address comments specifically requesting that we establish procedures for reconciling Factor 3 later in this section, as part of the discussion of the comments received on the proposed methodology for Facto 3.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2019. We discuss the resulting Factor 1 amount for FY 2019 below.

For this final rule, the OACT used the most recently submitted Medicare cost report data from the March 2018 update of HCIRS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2018 IPPS/LTCH PPS final rule and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The June 2018 OACT estimate for Medicare DSH payments for FY 2019, without regard to the application of section 1886(r)(1) of the Act, was approximately $16.339 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on the June 2018 estimate, the estimate of empirically justified Medicare DSH payments for FY 2019, with the application of section 1886(r)(1) of the Act, was approximately $4.085 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2019). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the OACT. Therefore, in this final rule, Factor 1 for FY 2019 is $12,254,291,878.57, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2019 ($16,339,055,838.09 minus $4,084,763,959.52).

The Office of the Actuary's final estimates for FY 2019 began with a baseline of $13.230 billion in Medicare DSH expenditures for FY 2015. The following table shows the factors applied to update this baseline through the current estimate for FY 2019:

FACTORS APPLIED FOR FY 2016 THROUGH FY 2019 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2015 BASELINE

FY	Update	Discharges	Case-mix	Other	Total	Estimated DSH payment (in billions) *
2016	1.009	0.9864	1.031	1.0443	1.071589	14.177
2017	1.0015	0.9931	1.004	1.0662	1.064673	15.094
2018	1.018088	0.9892	1.02	1.0277	1.055689	15.935
2019	1.0185	1.0014	1.005	1.00035	1.025384	16.339

* Rounded.

In this table, the discharges column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2016 and FY 2017 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2018 is based on preliminary data for 2018. The discharge figure for FY 2019 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FY 2016 and FY 2017 are based on actual data adjusted by a completion factor. The FY 2018 increase is based on preliminary data. The FY 2019 increase is an estimate based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors

include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on this information, it is assumed that 50 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2016 resided in States that had elected to expand Medicaid eligibility and, for 2017 and thereafter, that 55 percent of such individuals would reside in expansion States. In the future, these assumptions may change based on actual participation by States. For a discussion of general issues regarding Medicaid projections, we refer readers to the 2016~~7~~ Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2016.pdf*. We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on data from the Mid-Session Review of the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

The table below shows the factors that are included in the ''Update'' column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2016	2.4	−0.2	−0.5	−0.8	0.9
2017	2.7	−0.75	−0.3	−1.5	0.15
2018	2.7	−0.75	−0.6	0.4588	1.8088
2019	2.9	−0.75	−0.8	0.5	1.85

Note: All numbers are based on the Midsession Review of FY 2019 President's Budget projections.

b. Calculation of Factor 2 for FY 2019

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides that, for each of FYs 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (1) who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (2) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point for each of FYs 2015, 2016, and 2017.

Section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65. Specifically, the statute states that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019.

(2) Methodology for Calculation of Factor 2 for FY 2019

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (a) The extent to which the source accounted for the full U.S. population; (b) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (c) the extent to which the source utilized data from the Census Bureau; (d) the timeliness of the estimates; (e) the continuity of the estimates over time; (f) the accuracy of the estimates; and (g) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the FY 2018 IPPS/LTCH PPS final rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20391), we proposed to use the same methodology as was used in FY 2018 to determine Factor 2 for FY 2019.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the source that, on balance, best meets all of these considerations is the uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has

been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured because this mix is integral to the well-established NHEA methodology. Below we describe some aspects of the methodology used to develop the NHEA that were particularly relevant in estimating the percent change in the rate of uninsurance for FY 2018 and that we believe continue to be relevant in developing the estimate for FY 2019. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/DSM-15.pdf*.

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the United States, plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. In past years, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the United States across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2016, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2016. The NHEA data are publicly available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at: *http://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2014, the OACT extrapolates from the 2009 CPS data using data from the National Health Interview Survey (NHIS). For both 2015 and 2016, OACT's estimates of the rate of uninsurance are derived by applying the NHIS data on the proportion of uninsured individuals to the total U.S. population as described above. The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The U.S. Census Bureau is the data collection agent for the NHIS. The NHIS results have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at: *https://www.cdc.gov/nchs/nhis/index.htm*.

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both calendar years 2018 and 2019. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections (currently for years 2017 through 2026) use the latest NHEA historical data, which presently run through 2016. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

As discussed in the FY 2018 IPPS/LTCH PPS final rule, the use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the

upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

Using these data sources and the methodologies described above, the OACT estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2018 and 2019 is 9.1 percent and 9.6 percent, respectively.[229] As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates.

As with the CBO estimates on which we based Factor 2 in prior fiscal years, the NHEA estimates are for a calendar year. In the rulemaking for FY 2014, many commenters noted that the uncompensated care payments are made for the fiscal year and not on a calendar year basis and requested that CMS normalize the CBO estimate to reflect a fiscal year basis. Specifically, commenters requested that CMS calculate a weighted average of the CBO estimate for October through December 2013 and the CBO estimate for January through September 2014 when determining Factor 2 for FY 2014. We agreed with the commenters that normalizing the estimate to cover FY 2014 rather than CY 2014 would more accurately reflect the rate of uninsurance that hospitals would experience during the FY 2014 payment year. Accordingly, we estimated the rate of uninsurance for FY 2014 by calculating a weighted average of the CBO estimates for CY 2013 and CY 2014 (78 FR 50633). We have continued this weighted average approach in each fiscal year since FY 2014.

We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year more accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20393), we proposed to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2019. The OACT has certified this estimate of the fiscal year rate of uninsurance to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act.

The calculation of the proposed Factor 2 for FY 2019 using a weighted average of the OACT's projections for CY 2018 and CY 2019 was as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2018: 9.1 percent.
- Percent of individuals without insurance for CY 2019: 9.6 percent.
- Percent of individuals without insurance for FY 2019 $(0.25 \times 0.091) + (0.75 \times 0.096)$: 9.48 percent.

$1 - |((0.0948 - 0.14)/0.14)| = 1 - 0.3229 = 0.6771$ (67.71 percent)

0.6771 (67.71 percent) − .002 (0.2 percentage points for FY 2019 under section 1886(r)(2)(B)(ii) of the Act) = 0.6751 or 67.51 percent

0.6751 = Factor 2

Therefore, we proposed that Factor 2 for FY 2019 would be 67.51 percent.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20393), we stated that the proposed FY 2019 uncompensated care amount was: $\$12,221,027,954.62 \times 0.6751 = \$8,250,415,972.16$.

We invited public comments on our proposed methodology for calculation of Factor 2 for FY 2019.

Comment: A number of commenters expressed appreciation for CMS' recognition that the aggregate amount available to be distributed to hospitals for uncompensated care costs will increase by approximately $1.5 billion based on the most recently available projections of Medicare DSH payments for FY 2019 by CMS' Office of the Actuary. Other commenters stated the increase in the estimated amount available to make uncompensated care payments in FY 2019 was not enough to address the underpayments to hospitals that occurred as a result of using CBO data since FY 2014 to estimate the change in the rate of uninsurance. Several commenters supported CMS' continued use of the uninsured estimates produced by the OACT as part of the development of the National Health Expenditure Accounts in estimating the percent change in the rate of uninsured for FY 2019. Some of these commenters stated that, in their view, the estimates produced by the OACT are more complete and more accurately capture the change in the rate at which uninsured individuals have obtained health insurance. A few commenters noted that the data source added greater transparency to the process as the NHEA estimates are publicly available, while other commenters urged CMS to ensure that all data are provided with complete transparency with respect to the type of data and data collection methods that are used.

Response: We appreciate the support for our proposal to continue using the uninsured estimates produced by OACT in the computation of Factor 2 for FY 2019. Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. We believe that the NHEA data, on balance, best meet all of our considerations to ensure that the data source meets the statutory requirement that the estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle.

In response to commenters who stated the increase in the estimated amount available to make uncompensated care payments in FY 2019 was not enough to address the underpayments to hospitals that occurred as a result of using CBO data in the past to estimate the change in the rate of uninsurance, we do not agree that addressing any difference between the prospectively determined estimates using the CBO data and later retrospective estimates would be appropriate for reasons we have articulated in past rulemaking and earlier in this section. We continue to believe that applying our best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; and 82 FR 38195). We believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenters' suggestion that we should establish a process for reconciling our estimate of Factor 2 for any given year using later estimates.

After consideration of the public comments we received, we are finalizing the calculation of Factor 2 for FY 2019 as proposed. The estimates of the percent of uninsured individuals have been certified by the Chief Actuary of CMS, as discussed in the proposed rule. The calculation of the final Factor 2 for FY 2019 using a weighted average of OACT's projections for CY 2018 and CY 2019 is as follows:

[229] Certification of Rates of Uninsured. March 22, 2018. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2019-CMS-1694-P-OACT.pdf.*

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2018: 9.1 percent.
- Percent of individuals without insurance for CY 2019: 9.6 percent.
- Percent of individuals without insurance for FY 2019 (0.25 times 0.091) + (0.75 times 0.096): 9.48 percent.

1 − |((0.0948 − 0.14)/0.14)| = 1 − 0.3229 = 0.6771 (67.71 percent)

0.6771 (67.71 percent) − .002 (0.2 percentage points for FY 2019 under section 1886(r)(2)(B)(ii) of the Act) = 0.6751 or 67.51 percent

0.6751 = Factor 2

Therefore, the final Factor 2 for FY 2019 is 67.51 percent.

The final FY 2019 uncompensated care amount is: $12,254,291,878.57 × 0.6751 = $8,272,872,447.22.

Final FY 2019 Uncompensated Care Amount	$8,272,872,447.22

c. Calculation of Factor 3 for FY 2019

(1) Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year this provision was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we believed that the utilization of insured low-income patients, as measured by patient days, would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision making was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that concerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believed it was also appropriate to use proxy data to calculate Factor 3 for these years. We indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. Analyses performed by MedPAC had already shown that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011 Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the

data on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). In addition, a 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA) had suggested that Medicaid days and low-income Medicare days are not an accurate proxy for uncompensated care costs (80 FR 49525).

Subsequent analyses from Dobson/DaVanzo, originally commissioned by CMS for the FY 2014 rulemaking and updated in later years, compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. The most recent update of this analysis, which used IRS Form 990 data for tax years 2011, 2012, and 2013 (the latest available years) as a benchmark, found that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data continue to be highly correlated and that this correlation continues to increase over time, from 0.80 in 2011 to 0.85 in 2013.

This empirical evidence led us to believe that we had reached a tipping point in FY 2018 with respect to the use of the Worksheet S–10 data. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses.

We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals following the publication of the FY 2017 IPPS/LTCH PPS final rule. In the FY 2017 IPPS/LTCH PPS final rule, as part of our ongoing quality control and data improvement measures for the Worksheet S–10, we referred readers to Change Request 9648, Transmittal 1681, titled ''The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCHs),'' issued on July 15, 2016 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1681OTN.pdf*). In this transmittal, as part of the process for ensuring complete submission of Worksheet S–10 by all eligible DSH hospitals, we instructed MACs to accept amended Worksheets S–10 for FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that, for revisions to be considered, hospitals were required to submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016. For the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19949 through 19950), we examined hospitals' FY 2014 cost reports to see if the Worksheet S–10 data on those cost reports had changed as a result of the opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014. Specifically, we compared hospitals' FY 2014 Worksheet S–10 data as they existed in the first quarter of CY 2016 with data from the fourth quarter of CY 2016. We found that the FY 2014 Worksheet S–10 data had changed over that time period for approximately one quarter of hospitals that receive uncompensated care payments. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following a review of the cost report data they originally submitted and that the revised Worksheet S–10 information is available to be used in determining uncompensated care costs contributed to our belief that we could no longer conclude that alternative data are available that are a better proxy than the Worksheet S–10 data for the costs of subsection (d) hospitals for treating individuals who are uninsured.

We also recognized commenters' concerns that, in using Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014, the 2011, 2012, and 2013 Medicaid days used to calculate uncompensated care payments in FYs 2015, 2016, and 2017 are the latest available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we had used only low-income insured days to estimate uncompensated care in FY 2018, we would have needed to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. As a result, we would have been using older data that may provide a less accurate proxy for the level of uncompensated care being furnished by hospitals, contributing to our growing concerns regarding the continued use of low-income insured days as a proxy for uncompensated care costs in FY 2018.

In summary, as we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38203), when weighing the new information regarding the growing correlation between the Worksheet S–10 data and IRS 990 data that became available to us after the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we analyzed as part of our consideration of this issue in prior rulemaking, we determined that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We also stated that we believe that continued use of Worksheet S–10 will improve the accuracy and consistency of the reported data, especially in light of CMS' concerted efforts to allow hospitals to review and resubmit their Worksheet S–10 data for past years and the use of select audit protocols to trim aberrant data and replace them with more reasonable amounts. We also committed to continue to work with stakeholders to address their concerns regarding the accuracy of the reporting of uncompensated care costs through provider education and refinement of the instructions to Worksheet S–10.

(2) Methodology Used To Calculate Factor 3 in Prior Fiscal Years

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the

Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2017 IPPS/LTCH PPS final rule, in order to mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods, we finalized a policy of calculating a hospital's share of uncompensated care based on an average of data derived from three cost reporting periods instead of one cost reporting period. As explained in the preamble to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959), instead of determining Factor 3 using data from a single cost reporting period as we did in FY 2014, FY 2015, and FY 2016, we used data from three cost reporting periods (Medicaid data for FYs 2011, 2012, and 2013 and SSI days from the three most recent available years of SSI utilization data (FYs 2012, 2013, and 2014)) to compute Factor 3 for FY 2017. Furthermore, instead of determining a single Factor 3 as we had done since the first year of the uncompensated care payment in FY 2014, we calculated an individual Factor 3 for each of the three cost reporting periods, which we then averaged by the number of cost reporting years with data to compute the final Factor 3 for a hospital. Under this policy, if a hospital had merged, we would combine data from both hospitals for the cost reporting periods in which the merger was not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital. Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we combined data from the multiple cost reports so that a hospital could have a Factor 3 calculated using more than one cost report within a cost reporting period. We codified these changes for FY 2017 by amending the regulations at § 412.106(g)(1)(iii)(C).

For FY 2018, consistent with the methodology used to calculate Factor 3 for FY 2017, we advanced the time period of the data used in the calculation of Factor 3 forward by one year and used data from FY 2012, FY 2013, and FY 2014 cost reports. We believed it would not be appropriate to use Worksheet S–10 data for periods prior to FY 2014, as hospitals did not have notice that the Worksheet S–10 data from these years might be used for purposes of computing uncompensated care payments and, as a result, may not have fully appreciated the importance of reporting their uncompensated care costs as completely and accurately as possible. Rather, for cost reporting periods prior to FY 2014, we believed it would be appropriate to continue to use low-income insured days. Accordingly, for the time period consisting of three cost reporting years, including FY 2014, FY 2013, and FY 2012, we used Worksheet S–10 data for the FY 2014 cost reporting period and the low-income insured days proxy data for the two earlier cost reporting periods. In order to perform this calculation, we drew three sets of data (2 years of Medicaid utilization data and 1 year of Worksheet S–10 data) from the most recent available HCRIS extract. Accordingly, for FY 2018, in addition to the Worksheet S–10 data for FY 2014, we used Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We also continued to use FY 2012 cost report data submitted to CMS by IHS and Tribal hospitals to determine FY 2012 Medicaid days for those hospitals. (Cost report data from IHS and Tribal hospitals are included in HCRIS beginning in FY 2013 and are no longer submitted separately.) We continued the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers as well as the policies finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957).

To limit the effect of aberrant reporting of Worksheet S–10 data, we identified those hospitals that had high levels of reported uncompensated care relative to the total operating costs reported on the cost report. Specifically, for those hospitals where the ratio of uncompensated care costs relative to total operating costs for the hospital's 2014 cost report exceeded 50 percent, we determined the ratio of uncompensated care costs relative to total operating costs from the hospital's 2015 cost report and applied that ratio to the hospital's total operating costs from the 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. We then substituted this amount for the FY 2014 Worksheet S–10 data when determining Factor 3 for FY 2018. We believed that this approach, which affected the data for three hospitals in FY 2018, balanced our desire to exclude potentially aberrant data from a small number of hospitals in the determination of Factor 3 with our concern regarding inappropriately reducing FY 2018 uncompensated care payments to a hospital that may have a legitimately high ratio. We stated our intent to consider in future rulemaking whether continued use of this adjustment or an alternative adjustment is necessary for subsequent years.

Due to concerns that the uncompensated care data reported by Puerto Rico hospitals and Indian Health Service and Tribal hospitals need to be examined further, we concluded that the Worksheet S–10 data for these hospitals should not be used to determine Factor 3 for FY 2018 (82 FR 38209). We also determined that Worksheet S–10 data should not be used to determine Factor 3 for all-inclusive rate providers, whose CCRs were deemed to be potentially erroneous and in need of further examination (82 FR 38212). For the reasons described earlier related to the impact of the Medicaid expansion beginning in FY 2014, we did not believe it was appropriate to calculate a Factor 3 for these hospitals using FY 2014 low-income insured days. Because we did not believe it was appropriate to use the FY 2014 uncompensated care data for these hospitals and we also did not believe it was appropriate to use the FY 2014 low-income insured days, we concluded that the best proxy for the costs of Puerto Rico, Indian Health Service and Tribal hospitals, and all-inclusive rate providers for treating the uninsured was the low-income insured days data for FY 2012 and FY 2013. Accordingly, in order to determine the Factor 3 for FY 2018 for these hospitals, we calculated an average of three individual Factor 3s using the Factor 3 calculated using FY 2013 cost report data twice and the Factor 3 calculated using FY 2012 cost report data once. We believed it was appropriate to double-weight the Factor 3 calculated using FY 2013 data as it reflects the most recent available information regarding the hospital's low-income insured days before any expansion of Medicaid. We stated that we would reexamine the use of the Worksheet S–10 data for Puerto Rico, Indian Health Service and Tribal

hospitals, and all-inclusive rate providers as part of the FY 2019 rulemaking. In addition, for Puerto Rico hospitals, we continued to use a proxy for SSI days consisting of 14 percent of a hospital's Medicaid days, as was first applied in FY 2017 (82 FR 38209).

Therefore, for FY 2018, we computed a Factor 3 for each hospital by—

- Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio;
- Step 2: Calculating Factor 3 using the insured low-income days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio;
- Step 3: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data (or using the Factor 3 calculated in Step 2 for Puerto Rico, IHS/Tribal hospitals, and all-inclusive rate providers); and
- Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

We stated our belief that if we were to propose to continue this methodology for FY 2019 and FY 2020, this approach would have the effect of transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3 because an additional year of Worksheet S–10 data would be incorporated into the calculation of Factor 3 in FY 2019, and the use of low-income insured days would be phased out by FY 2020.

(3) Methodology for Calculating Factor 3 for FY 2019

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20396), since the publication of the FY 2018 IPPS/LTCH PPS final rule, we have continued to monitor the reporting of Worksheet S–10 data in anticipation of using Worksheet S–10 data from hospitals' FY 2014 and FY 2015 cost reports in the calculation of Factor 3. We acknowledge the concerns that have been raised regarding the instructions for Worksheet S–10. In particular, commenters have expressed concerns that the lack of clear and concise line level instructions prevents accurate and consistent data from being reported on Worksheet S–10. We note that, in November 2016, CMS issued Transmittal 10, which clarified and revised the instructions for the Worksheet S–10, including the instructions regarding the reporting of charity care charges. Transmittal 10 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R10P240.pdf*. In Transmittal 10, we clarified that hospitals may include discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period. This clarification applied to cost reporting periods beginning prior to October 1, 2016, as well as cost reporting periods beginning on or after October 1, 2016. As a result, nothing prohibits a hospital from considering a patient's insurance status as a criterion in its charity care policy. A hospital determines its own financial criteria as part of its charity care policy. The instructions for the Worksheet S–10 set forth that hospitals may include discounts given to uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider, who meet the hospital's charity care criteria in effect for that cost reporting period. In addition, we revised the instructions for the Worksheet S–10 for cost reporting periods beginning on or after October 1, 2016, to provide that charity care charges must be determined in accordance with the hospital's charity care criteria/policy and written off in the cost reporting period, regardless of the date of service.

During the FY 2018 rulemaking, commenters pointed out that, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56963), CMS agreed to institute certain additional quality control and data improvement measures prior to moving forward with incorporating Worksheet S–10 data into the calculation of Factor 3. However, the commenters indicated that, aside from a brief window in 2016 for hospitals to submit corrected data on their FY 2014 Worksheet S–10 by September 30, 2016, and the issuance of revised instructions (Transmittal 10) in November 2016 that are applicable to cost reports beginning on or after October 1, 2016, CMS had not implemented any additional quality control and data improvement measures. We stated in the FY 2018 IPPS/LTCH PPS final rule that we would continue to work with stakeholders to address their concerns regarding the reporting of uncompensated care through provider education and refinement of the instructions to the Worksheet S–10 (82 FR 38206).

On September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care, as well as modified the calculations relative to uncompensated care costs and added edits to ensure the integrity of the data reported on Worksheet S–10. Transmittal 11 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf*. We further clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy (hereinafter referred to as Financial Assistance Policy or FAP) may be included on Line 20, Column 1 of Worksheet S–10. These clarifications apply to cost reporting periods beginning on or after October 1, 2013. We also modified the application of the CCR. We specified that the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. The CCR will be applied to the charges for uninsured patients approved for charity care or an uninsured discount, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs.

We also provided another opportunity for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports. We refer readers to Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S 10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1981OTN.pdf*). In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal states that hospitals must submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than January 2, 2018. We note that this transmittal supersedes the previous deadline in Change Request 10026, which was issued on June 30, 2017, with respect to the dates by which hospitals must submit their revised or newly submitted Worksheet S–10 in

order to be considered for purposes of this rulemaking, as well as the dates by which MACs must accept these data and upload a revised cost report to HCRIS. Under the deadlines established in Change Request 10378, in order for revisions to be guaranteed consideration for the FY 2019 proposed rule, hospitals had to submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than December 1, 2017. We also indicated that, all revised data received by December 1, 2017, would be considered for purposes of the FY 2019 IPPS/LTCH PPS proposed rule, and all revised data received by the January 2, 2018 deadline would be available to be considered for purposes of the FY 2019 IPPS/LTCH PPS final rule.

However, for the FY 2019 IPPS/LTCH PPS proposed rule, we were able to include data updated in HCRIS through February 15, 2018. Specifically, in light of the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate) and the extension of the deadline for resubmitting Worksheets S–10 for FY 2014 and FY 2015 through January 2, 2018, we believed it was appropriate to use data updated through February 15, 2018, rather than the December 2017 HCRIS update, which we typically use for the annual proposed rule. We believe that providing the additional time to allow cost reports that may have been delayed due to these unique circumstances to be included in our calculations for purposes of the FY 2019 proposed rule, enabled us to use more accurate uncompensated care cost data in calculating the proposed Factor 3 values.

We examined hospitals' FY 2014 and FY 2015 cost reports to determine if the Worksheet S–10 data on those cost reports had changed as a result of the additional opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014 and FY 2015. Specifically, we compared hospitals' FY 2014 and FY 2015 Worksheet S–10 data as reported in the fourth quarter of CY 2016 update of HCRIS to the February 15, 2018 update of HCRIS. We examined hospitals' cost report data to determine if the Worksheet S 10 data had changed for any of the following lines: Total bad debt from Line 26, charity care for uninsured patients from Line 20, Column 1, or charity care for insured patients from Line 20, Column 2. Based on our review, we found that Worksheet S–10 data for both FY 2014 and FY 2015 had changed over that time period for approximately one-half of the hospitals that were eligible to receive Medicare DSH payments in FY 2018. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following the opportunity to review their previously submitted cost report data and submit a revised Worksheet S–10, and that this revised Worksheet S–10 information is available to be used in determining uncompensated care costs, contributes to our determination that it is appropriate to continue to incorporate Worksheet S–10 data into the calculation of Factor 3 values for hospitals that are eligible to receive Medicare DSH payments.

As we stated in the FY 2019 IPPS/LTCH PPS proposed rule, with the additional steps we have taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continue to believe that we can no longer conclude that alternative data to the Worksheet S–10 are currently available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, the actions that we have taken to improve the accuracy and consistency of the Worksheet S–10 data, including the opportunity for hospitals to resubmit Worksheet S–10 data for FY 2015, lead us to conclude that there are no alternative data to the Worksheet S–10 data currently available for FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating uninsured individuals. As such, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20400), we proposed to advance the time period of the data used in the calculation of Factor 3 forward by 1 year and to use data from FY 2013, FY 2014, and FY 2015 cost reports to determine Factor 3 for FY 2019. For the reasons we described earlier, we stated that we continue to believe it is inappropriate to use Worksheet S–10 data for periods prior to FY 2014. Rather, for cost reporting periods prior to FY 2014, we believe it is appropriate to continue to use low-income insured days. Accordingly, with a time period that includes 3 cost reporting years consisting of FY 2015, FY 2014, and FY 2013, we proposed to use Worksheet S–10 data for the FY 2014 and FY 2015 cost reporting periods and the low-income insured days proxy data for the earliest cost reporting period. As in previous years, in order to perform this calculation, we drew three sets of data (1 year of Medicaid utilization data and 2 years of Worksheet S–10 data) from the most recent available HCRIS extract, which, for purposes of the FY 2019 proposed rule, was the HCRIS data updated through February 15, 2018. In the FY 2019 IPPS/LTCH PPS proposed rule, we stated that we expected to use the March 2018 update of HCRIS for the final rule. However, due to unique circumstances regarding the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate) and the extension of the deadline to resubmit Worksheet S–10 data through January 2, 2018, and the subsequent impact on the MAC review timeline, we indicated that we might consider using data updated through May 31, 2018, in the final rule, if necessary.

Accordingly, for FY 2019, in addition to the Worksheet S–10 data for FY 2014 and FY 2015, we proposed to use Medicaid days from FY 2013 cost reports and FY 2016 SSI ratios. We noted that cost report data from Indian Health Service and Tribal hospitals are included in HCRIS beginning in FY 2013 and no longer need to be incorporated from a separate data source. We also proposed to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers. In addition, we proposed to continue the policies that were finalized in the FY 2018 IPPS/LTCH PPS final rule to address technical considerations related to the calculation of Factor 3 and the incorporation of Worksheet S–10 data (82 FR 38213 through 38220). In that final rule, we adopted a policy, for purposes of calculating Factor 3, under which we annualize Medicaid days data and uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data. As in FY 2018, for FY 2019, we did not propose to annualize SSI days because we do not obtain these data from hospital cost reports in HCRIS. Rather, we obtain these data from the latest available SSI ratios posted on the Medicare DSH homepage (*https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/AcuteInpatientPPS/dsh.html*), which are aggregated at the hospital level and do not include the information needed to determine if the data should be annualized. To address the effects of averaging Factor 3s calculated for 3 separate fiscal years, we proposed to continue to apply a scaling factor to the Factor 3 values of all DSH eligible hospitals such that total uncompensated care payments are consistent with the estimated amount available to make uncompensated care payments for the

applicable fiscal year. With respect to the incorporation of Worksheet S–10, we indicated that we believe that the definition of uncompensated care adopted in FY 2018 is still appropriate because it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, including charity care costs and non-Medicare bad debt costs, and correlates to Line 30 of Worksheet S–10. Therefore, we again proposed that, for purposes of calculating Factor 3 and uncompensated care costs in FY 2019, ''uncompensated care'' would be defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

We noted that we were proposing to discontinue the policy finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957). Under this policy, we would first combine the data across the multiple cost reports before determining the difference between the start date and the end date to determine if annualization is needed. The policy was developed in response to commenters' concerns regarding the unique circumstances of hospitals that filed cost reports that are shorter or longer than 12 months. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959) and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19953), we believed that, for hospitals that file multiple cost reports beginning in the same year, combining the data from these cost reports had the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. As we stated in the FY 2019 IPPS/LTCH PPS proposed rule, we now believe that concerns about the equitability of the data used as the basis of hospital uncompensated care payments are more thoroughly addressed by the policy finalized in the FY 2018 IPPS/LTCH PPS final rule, under which CMS annualizes the Medicaid days and uncompensated care cost data of hospital cost reports that do not equal 12 months of data. Based on our experience, we stated that we believe that in many cases where a hospital files two cost reports beginning in the same fiscal year, combining the data across multiple cost reports before annualizing would yield a similar result to choosing the longer of the two cost reports and then annualizing the data if the cost report is shorter or longer than 12 months. Furthermore, even in cases where a hospital files more than one cost report beginning in the same fiscal year, it is not uncommon for one of those cost reports to span exactly 12 months. In this case, if Factor 3 is determined using only the full 12-month cost report, annualization would be unnecessary as there would already be 12 months of data. Therefore, for FY 2019, we stated that we believed it was appropriate to propose to eliminate the additional step of combining data across multiple cost reports if a hospital filed more than one cost report beginning in the same fiscal year. Instead, for purposes of calculating Factor 3, we would use data from the cost report that is equivalent to 12 months or, if no such cost report exists, the cost report that is closest to 12 months and annualize the data. Furthermore, we acknowledged that, in rare cases, a hospital may have more than one cost report beginning in one fiscal year, where one report also spans the entirety of the following fiscal year, such that the hospital has no cost report beginning in that fiscal year. For instance, a hospital's cost reporting period may have started towards the end of FY 2012 but cover the duration of FY 2013. In these rare situations, we proposed to use data from the cost report that spans both fiscal years in the Factor 3 calculation for the latter fiscal year as the hospital would already have data from the preceding cost report that could be used to determine Factor 3 for the previous fiscal year.

We also proposed to continue to apply statistical trims to anomalous hospital CCRs using the methodology adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38219), where we stated our belief that, just as we apply trims to hospitals' CCRs to eliminate anomalies when calculating outlier payments for extraordinarily high cost cases (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs on Worksheet S–10, Line 1, that are considered anomalies. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling''). This mean is recalculated annually by CMS and published in the proposed and final IPPS rules each year.

Similar to the process used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38218) for trimming CCRs, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20398), we proposed the following steps for FY 2019:

Step 1: Remove Maryland hospitals. In addition, we would remove All Inclusive Rate Providers because they have charge structures that differ from other IPPS hospitals. For providers that did not report a CCR on Worksheet S–10, Line 1, we would assign them the statewide average CCR in step 5 below.

Step 2: For each fiscal year (FY 2014 and FY 2015), calculate a CCR ''ceiling'' with the following data: For each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we would use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same FY is no longer necessary in this step, as the longer cost report would be selected). The ceiling would be calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. (For this final rule, this trim would remove 5 hospitals that have a CCR above the calculated ceiling of 1.031 for FY 2014 and 9 hospitals that have a CCR above the calculated ceiling of 0.93 for FY 2015.)

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2014 and for FY 2015 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total inpatient discharges and outpatient visits from Worksheet S–3, Part I, Line 14, Column 14.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals with a CCR for the applicable fiscal year greater than 3 standard deviations above the corresponding national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For this final rule, the statewide average CCR would therefore be applied to 14 hospitals, of which 2 hospitals in FY 2014 have Worksheet S–10 data and 5 hospitals in FY 2015 have Worksheet S–10 data.

After applying the applicable trims to a hospital's CCR as appropriate, we proposed that we would calculate a hospital's uncompensated care costs for the applicable fiscal year as being equal

to Line 30, which is the sum of Line 23, Column 3 and Line 29, as follows:

Hospital Uncompensated Care Costs = Line 30 (Line 23, Column 3 + Line 29), which is equal to—

[(Line 1 CCR (as adjusted, if applicable) × Uninsured patient charity care Line 20, Column 1) − (Payments received from uninsured patient charity care Line 22, Column 1)] + [(Insured patient charity care Line 20, Column 2) − Insured patient charges from days beyond length of stay limit * (1 − (Line 1 CCR (as adjusted, if applicable))) − (Payments received from insured patient charity care Line 22, Column 2)] + [(Line 1 CCR (as adjusted, if applicable) × Non-Medicare bad debt Line 28) + (Medicare allowable bad debts Line 27.01 − Medicare reimbursable bad debt Line 27)].

Similar in concept to the policy that we adopted for FY 2018, for FY 2019, we stated in the proposed rule that we continue to believe that uncompensated care costs that represent an extremely high ratio of a hospital's total operating expenses (such as the ratio of 50 percent used in the FY 2018 IPPS/LTCH PPS final rule) may be potentially aberrant, and that using the ratio of uncompensated care costs to total operating costs to identify potentially aberrant data when determining Factor 3 amounts has merit. That is, we stated that we continue to believe that, in the rare situations where a hospital has a ratio of uncompensated care costs to total operating expenditures that is extremely high, the issue is most likely with the hospital's uncompensated care costs and not its total operating costs. We noted that we had instructed the MACs to review situations where a hospital has an extremely high ratio of uncompensated care costs to total operating costs with the hospital, but indicated that we did not intend to make the MACs' review protocols public. As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964), for program integrity reasons, CMS desk review and audit protocols are confidential and are for CMS and MAC use only. If the hospital cannot justify its reported uncompensated care amount, we stated that we believed it would be appropriate to utilize data from another fiscal year to address the potentially aberrant Worksheet S–10 data for FY 2014 or FY 2015. As we have previously indicated, we do not believe it would be appropriate to use Worksheet S–10 data from years prior to FY 2014 in the determination of Factor 3. Therefore, the most widely available Worksheet S–10 data available to us if a hospital has an extremely high ratio of uncompensated care costs to total operating expenses based on its FY 2014 or FY 2015 Worksheet S–10 data are the FY 2015 and FY 2016 Worksheet S–10 data. Accordingly, similar in concept to the approach we used in FY 2018, in cases where a hospital's uncompensated care costs for FY 2014 are an extremely high ratio of its total operating costs and the hospital cannot justify the amount it reported, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20399), we proposed to determine the ratio of FY 2015 uncompensated care costs to FY 2015 total operating expenses from the hospital's FY 2015 cost report and apply that ratio to the FY 2014 total operating expenses from the hospital's FY 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. We proposed that we would then use this adjusted amount to determine Factor 3 for FY 2019. Similarly, if a hospital has uncompensated care costs for FY 2015 that are an extremely high ratio of its total operating costs for that year and the hospital cannot justify its reported amount, we proposed to follow the same methodology using data from the hospital's FY 2016 cost report to determine an adjusted amount of uncompensated care costs for FY 2015. That is, we would determine the ratio of FY 2016 uncompensated care costs to FY 2016 total operating expenses from a hospital's FY 2016 cost report and apply that ratio to the FY 2015 total operating expenses from the hospital's FY 2015 cost report to determine an adjusted amount of uncompensated care costs for FY 2015. We proposed that we would then use this adjusted amount when determining Factor 3 for FY 2019. We tentatively included the data for hospitals that had a high ratio of uncompensated care costs to total operating expenses when calculating Factor 3 for the proposed rule. However, we noted in the proposed rule that our calculation of Factor 3 for this final rule would be contingent on the results of the ongoing MAC reviews of these hospitals. In the event those reviews necessitate supplemental data edits, we stated that we would incorporate such edits in the final rule for the purpose of correcting aberrant data.

We also stated in the proposed rule that, for FY 2019, we believe that situations where there were extremely large dollar increases or decreases in a hospital's uncompensated care costs when it resubmitted its FY 2014 Worksheet S–10 or FY 2015 Worksheet S–10 data, or when the data it had previously submitted were reprocessed by the MAC, may reflect potentially aberrant data and warrant further review. For example, although we do not make our actual review protocols public, we indicated that we might conclude that it would be appropriate to review hospitals with increases or decreases in uncompensated care costs in the top 1 percent of such changes. We noted that we had instructed our MACs to review these situations with each hospital. If it is determined after this review that an increase or decrease in uncompensated care costs cannot be justified by the hospital, we proposed to follow the same approach that we proposed to use to address situations when a hospital's ratio of its uncompensated care costs to its operating expenses is extremely high and the hospital cannot justify its reported amount. Specifically, if after review, the increase or decrease in uncompensated care costs for FY 2014 or FY 2015 cannot be justified by the hospital, we proposed that we would determine the ratio of the uncompensated care costs to total operating expenses from the hospital's cost report for the subsequent fiscal year and apply that ratio to the total operating expenses from the hospital's resubmitted cost report with the large increase or decrease in uncompensated care payments to determine an adjusted amount of uncompensated care costs for the applicable fiscal year. We indicated that we had tentatively included the data for hospitals where there was an extremely large increase or decrease in uncompensated care payments when calculating Factor 3 for the proposed rule. However, we noted in the proposed rule that our calculation of Factor 3 for the final rule was contingent on the results of the ongoing MAC reviews of these hospitals. In the event those reviews necessitate supplemental data edits, we stated that we would incorporate such edits in the final rule for the purpose of correcting aberrant data.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20400), for Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers, we proposed to continue the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), the use of data from Worksheet S–10 to calculate the uncompensated care amount for Indian Health Service and Tribal hospitals may jeopardize these hospitals' uncompensated care payments due to their unique funding structure. With

respect to Puerto Rico hospitals, we continue to agree with concerns raised by commenters that the uncompensated care data reported by these hospitals need to be further examined before the data are used to determine Factor 3 (82 FR 38209). Finally, the CCRs for all-inclusive rate providers are potentially erroneous and still in need of further examination before they can be used in the determination of uncompensated care amounts for purposes of Factor 3 (82 FR 38212). For the reasons described earlier, related to the impact of the Medicaid expansion beginning in FY 2014, we stated in the proposed rule that we also continue to believe that it is inappropriate to calculate a Factor 3 using FY 2014 and FY 2015 low-income insured days. Because we do not believe it is appropriate to use the FY 2014 or FY 2015 uncompensated care data for these hospitals and we also do not believe it is appropriate to use the FY 2014 or FY 2015 low-income insured days, the best proxy for the costs of Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers for treating the uninsured continues to be the low-income insured days data for FY 2013. Accordingly, for these hospitals, we proposed to determine Factor 3 only on the basis of low-income insured days for FY 2013. We stated that we believe this approach is appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In the proposed rule, we did not make any proposals with respect to the calculation of Factor 3 for FY 2020 and indicated that we will reexamine the use of the Worksheet S–10 data for Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and all-inclusive rate providers as part of the FY 2020 rulemaking. In addition, because we proposed to continue to use 1 year of insured low-income patient days as a proxy for uncompensated care and residents of Puerto Rico are not eligible for SSI benefits, we proposed to continue to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Therefore, for FY 2019, we proposed to compute Factor 3 for each hospital by—

Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days);

Step 2: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;

Step 3: Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and

Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3 (or for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers using the Factor 3 value from Step 1).

We also proposed to amend the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (5) to reflect this proposed methodology for computing Factor 3 for FY 2019.

In the proposed rule, we noted that if a hospital does not have both Medicaid days for FY 2013 and SSI days for FY 2016 available for use in the calculation of Factor 3 in Step 1, we consider the hospital not to have data available for the fiscal year, and will remove that fiscal year from the calculation and divide by the number of years with data. A hospital will be considered to have both Medicaid days and SSI days data available if it reports zero days for either component of the Factor 3 calculation in Step 1. However, if a hospital is missing data due to not filing a cost report in one of the applicable fiscal years, we will divide by the remaining number of fiscal years.

Although we did not make any proposals with respect to the development of Factor 3 for FY 2020 and subsequent fiscal years, in the proposed rule, we noted that the above methodology would have the effect of fully transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3 if used in FY 2020. Starting with 1 year of Worksheet S–10 data in FY 2018, an additional year of Worksheet S–10 data will be incorporated into the calculation of Factor 3 in FY 2019 under the policies included in this final rule, and the use of low-income insured days would be phased out by FY 2020 if the same methodology is proposed and finalized for that year. We also indicated that it is possible that when we examine the FY 2016 Worksheet S–10 data, we may determine that the use of multiple years of Worksheet S–10 data is no longer necessary in calculating Factor 3 for FY 2020. For example, given the efforts hospitals have already undertaken with respect to reporting their Worksheet S–10 data and the subsequent reviews by the MACs that had already been conducted prior to the development of this final rule, along with additional review work that may take place following the issuance of this final rule, we may consider using 1 year of Worksheet S–10 data as the basis for calculating Factor 3 for FY 2020.

For new hospitals that do not have data for any of the three cost reporting periods used in the Factor 3 calculation, we proposed to continue to apply the new hospital policy finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643). That is, the hospital would not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. However, if the hospital is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2019 cost report, the hospital would also receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2019 cost report, and the denominator is the sum of uncompensated care costs reported on Worksheet S–10 of all DSH eligible hospitals' FY 2015 cost reports. Due to the uncertainty regarding the completeness and accuracy of the FY 2019 uncompensated care cost data at the time this calculation would need to be performed, we stated that we believe it would be more appropriate to use the sum of the uncompensated care costs reported on Worksheet S–10 of all DSH eligible hospitals' cost reports from FY 2015, the most recent year of the 3-year time period used in the development of Factor 3, to determine the denominator of Factor 3 for new hospitals. We noted that, given the time period of the data used to calculate Factor 3, any hospitals with a CCN established after October 1, 2015 would be considered new and subject to this policy.

As we have done for every proposed and final rule beginning in FY 2014, we stated that, in conjunction with both the FY 2019 IPPS/LTCH PPS proposed rule and this final rule, we would publish on the CMS website a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2019 (that is, those hospitals that would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. We noted that, at the time of the

development of the proposed rule, the FY 2016 SSI ratios were available. Accordingly, for modeling purposes, we computed the proposed Factor 3 for each hospital using the most recent available data regarding SSI days from the FY 2016 SSI ratios.

In conjunction with the proposed rule, we also published a supplemental data file containing a list of the mergers that we were aware of and the computed uncompensated care payment for each merged hospital. Hospitals had 60 days from the date of public display of the FY 2019 IPPS/LTCH PPS proposed rule to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of any inaccuracies. Comments could be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We stated that we would address these comments as appropriate in the table and the supplemental data file that we will publish on the CMS website in conjunction with the publication of this FY 2019 IPPS/LTCH PPS final rule. After the publication of this FY 2019 IPPS/LTCH PPS final rule, hospitals will have until August 31, 2018, to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with this final rule. Comments may be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2018, and any changes to Factor 3 will be posted on the CMS website prior to October 1, 2018.

Comment: A number of commenters supported CMS' proposal to continue using data from Worksheet S–10 in the calculation of Factor 3 for FY 2019. These commenters stated that using Worksheet S–10 data, in conjunction with select auditing of cost reports, will lead to better estimates of uncompensated care costs than the continued use of the current proxy of Medicaid and SSI days. Other commenters noted that the metrics from Worksheet S–10 appear to provide a better assessment of a hospital's uncompensated care costs than the current proxy data, which assess only low-income insured days and distribute the bulk of Medicare DSH payments based on the amount of inpatient care a hospital delivers to Medicaid patients and recipients of SSI payments. Thus, the commenters stated, using data from Worksheet S–10 will address the inequity across Medicaid expansion/nonexpansion States in distributing disproportionate share hospital dollars. One commenter stated that the use of Worksheet S–10 data in calculating the distribution of uncompensated care payments will continue CMS on a path to improve transparency and accuracy with regard to hospitals' share of uncompensated care costs. Other commenters noted that any negative effects from the transition to using the Worksheet S–10 will be eased due to the $1.5 billion increase in the amount available to make uncompensated care payments relative to FY 2018. In addition, several commenters pointed to the evaluation performed by the consulting firm Dobson DaVanzo, which found a high degree of correlation between data reported on Worksheet S–10 and audited uncompensated care data, as evidence that the information currently reported on Worksheet S–10 is satisfactory for purposes of allocating uncompensated care payments.

Other commenters opposed the use of Worksheet S–10 to compute Factor 3 and allocate uncompensated care costs in FY 2019. Many of these commenters maintained their position from previous years that, while Worksheet S–10 has the potential to serve as a more exact measure of hospital uncompensated care costs, the data reported are not presently a reliable and accurate reflection of these uncompensated care costs. The commenters also noted that the administrative burden for hospitals to complete Worksheet S–10 is high. These commenters asserted that CMS should suspend its use, or not advance its implementation, until the agency can demonstrate that the data being reported are accurate and consistent, or at least until FY 2021. Some commenters pointed to the evaluation performed by Dobson DaVanzo and asserted that, while the analysis demonstrated correlation between Worksheet S–10 and IRS Form 990, it did not address potentially significant differences in the reporting requirements for the forms.

Response: We appreciate the support for our proposal to continue incorporating Worksheet S–10 data into the computation of Factor 3 for FY 2019. We also appreciate the input from those commenters who are opposed to the use of data from Worksheet S–10 in the calculation of Factor 3. We understand the commenters' concerns about the limitations of the IRS 990 correlation analysis and the shortcomings of using the findings from this study to support assertions about the validity of the Worksheet S–10 data. Notwithstanding these limitations, a number of commenters supported the findings of the study and our proposal to use of Worksheet S–10 in FY 2019. Furthermore, as explained in the FY 2019 IPPS/LTCH PPS proposed rule, we did not make the decision to continue Worksheet S–10 implementation in FY 2019 based on the correlation analysis alone. Historical analyses performed by MedPAC also show a high level of correlation between audited uncompensated care data and uncompensated care costs reported on Worksheet S–10 and a lower correlation between the audited uncompensated care data and Medicaid and SSI days. Furthermore, hospitals have expended considerable effort to resubmit their FY 2014 and FY 2015 data and the MACs have dedicated significant resources to conducting the subsequent reviews in the time available for the FY 2019 rulemaking, and we believe that, overall, those efforts have improved the data.

In the FY 2019 IPPS/LTCH PPS proposed rule, we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 and FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Our reviews of selected FY 2014 and FY 2015 data and the potential data aberrancies pointed out by commenters have not altered that conclusion. We continue to acknowledge that the Worksheet S–10 data are not perfect, but there are no perfect data sources available to us. We also acknowledge that the approximately $1.5 billion increase in the overall amount available to make uncompensated care payments will help to mitigate the impact of any redistribution of uncompensated care payments due to the continued incorporation of Worksheet S–10 data on hospitals that serve a large number of Medicaid and SSI patients, yet report proportionately lower uncompensated care amounts.

Comment: Most commenters, whether supportive of or opposed to the use of data from Worksheet S–10 to compute Factor 3, believed that it was premature to use Worksheet S–10 data in the calculation of Factor 3 for FY 2019, and expressed concerns about the lack of accurate and consistent data being reported on Worksheet S–10, primarily due to what they perceive as a lack of clear and concise line-level instructions for reporting on the Worksheet S–10. Some commenters acknowledged and appreciated the changes CMS had implemented through the issuance of revised instructions (Transmittal 11) in September 2017, and the opportunity for hospitals to revise their uncompensated care data previously reported on Worksheet S–10 for FY 2014 and FY 2015. These commenters also appreciated CMS' instructions to the MACs to contact hospitals with aberrant data. These commenters noted

that, given all of the steps that CMS has taken to improve the data from Worksheet S–10, it would be reasonable to see large increases or decreases in hospital uncompensated care costs. Other commenters expressed continued concerns with the clarity of the instructions and indicated that even with the revisions implemented under Transmittal 11, a great deal of ambiguity remains in the Worksheet S–10 instructions, leading to inconsistent reporting among hospitals and questionable accuracy of the updated data.

Many commenters recognized the efforts undertaken by CMS in contacting select hospitals to verify reported data, and some commenters noted data improvements since the release of Transmittal 11 and CMS' subsequent contact with individual hospitals. However, a number of commenters provided specific examples of potentially aberrant data that they asserted are a result of the ambiguity of the Worksheet S–10 instructions. These examples of potentially aberrant data related in large part to the reporting of charity care charges and uninsured discounts on Worksheet S–10, Line 20, Columns 1 and 2. For example, commenters noted that some hospitals reported charity care coinsurance and deductibles of more than 25 percent of their total charity care charges; some hospitals reported charity care charges that were, on average, 80 percent of total hospital charges; and some hospitals reported negative charity care charges. Several commenters also noted potentially aberrant data related to bad debt, including, for example, cases in which a hospital reported Medicare allowable bad debt elsewhere on the cost report, but those amounts were not reflected in its Worksheet S–10; hospitals that reported having more Medicare bad debt than total hospital bad debts; and hospitals with significant differences in bad debt charges over time. With respect to uncompensated care costs, commenters noted that, for example, some hospitals reported uncompensated care costs that were 30 to 70 percent of total hospital costs; and some hospitals reported uncompensated care costs that ranged from 0.14 percent to 250 percent of total hospital revenue. Commenters remarked that these results are implausible and indicate that CMS must continue working to improve the reliability of Worksheet S–10. Several commenters observed that the current Worksheet S–10 methodology may provide an incentive to hospitals to overstate charity care, compromising the fidelity of the information collected. Another commenter was concerned that the revisions to the Worksheet S–10 instructions through Transmittal 11 and subsequent opportunity for hospitals to resubmit their cost reports for prior years created an incentive for hospitals to inflate charges for charity care. Finally, some commenters requested that CMS continue to offer hospitals the opportunity to amend, or require them to amend, cost reports for FY 2014, FY 2015, and later years.

Response: We believe that continued use of Worksheet S–10 will improve the accuracy and consistency of the reported data. In addition, we intend to continue with and further refine our efforts to review the Worksheet S–10 data submitted by hospitals based on what we have learned from the review process we conducted for the FY 2019 rulemaking. We also intend to consider the various issues raised by the commenters specifically related to the reporting of charity care and bad debt costs on Worksheet S–10 as we continue to review the Worksheet S–10 data and instructions. In addition, we will continue to work with stakeholders to address their concerns regarding the accuracy and consistency of reporting of uncompensated care costs through provider education and further refinement of the instructions to the Worksheet S–10 as appropriate.

As noted in the FY 2019 IPPS/LTCH PPS proposed rule, (83 FR 20396 and 20397), on September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for reporting uncompensated care, non-Medicare bad debt, nonreimbursed Medicare bad debt, and charity care, as well as modified the calculations relative to uncompensated care costs and added edits to improve the integrity of the data reported on Worksheet S–10. We also provided another opportunity for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports. We refer readers to Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S–10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1981OTN.pdf*). In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none have been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that hospitals must submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than January 2, 2018. Under the deadlines established in Change Request 10378, in order for revisions to be guaranteed consideration for the FY 2019 proposed rule, hospitals had to submit their amended FY 2014 and FY 2015 cost reports containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than December 1, 2017. We also indicated that all revised data received by December 1, 2017, would be considered for purposes of the FY 2019 IPPS/LTCH PPS proposed rule, and all revised data received by the January 2, 2018 deadline would be available to be considered for purposes of the FY 2019 IPPS/LTCH PPS final rule. However, for the FY 2019 IPPS/LTCH PPS proposed rule, we were able to include data updated in HCRIS through February 15, 2018, and for this FY 2019 IPPS/LTCH PPS final rule, we have been able to include data updated in HCRIS through June 30, 2018. Specifically, in light of the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate), the extension of the deadline for resubmitting Worksheets S–10 for FY 2014 and FY 2015 through January 2, 2018, and our targeted provider outreach, we determined that it would be appropriate to use data updated through June 30, 2018, rather than the March 2018 HCRIS update, which we would typically use for the annual final rule. We believe that providing this additional time to allow data from resubmitted cost reports that may have been delayed due to the unique circumstances during 2017 and 2018 to be included in our calculations for purposes of this FY 2019 final rule, enabled us to use more accurate uncompensated care cost data in calculating the final Factor 3 values.

We believe that the new Worksheet S–10 instructions implemented in Transmittal 11 were sufficiently clear to allow hospitals to accurately complete Worksheet S–10, and that hospitals were provided ample time following the issuance of Transmittal 11 to revise and amend Worksheet S–10 for FY 2014 and FY 2015. Because we recognize that there were delays in processing Worksheet S–10 to reflect the revisions in Transmittal 11 and consistent with our historical practice of using the best data available, we are using the June 30,

2018 HCRIS update to calculate Factor 3 for this FY 2019 IPPS/LTCH PPS final rule. We continue to believe that Worksheet S–10 data are the best data available to use in calculating uncompensated care costs for purposes of determining Factor 3 of the uncompensated care payment methodology. As stated in the FY 2018 IPPS/LTCH PPS final rule, (82 FR 38203), the agency can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, we believe that the Worksheet S–10 data for FY 2014 are the best available data on the costs of subsection (d) hospitals for treating the uninsured during that fiscal year.

In response to the request by some commenters that CMS continue to offer hospitals the opportunity to amend, or require them to amend, cost reports for FY 2014, FY 2015 and later years, we are using data from a June 30, 2018 HCRIS update to determine Factor 3 for this FY 2019 IPPS/LTCH PPS final rule. We believe this gave hospitals ample time to review the revised instructions in Transmittal 11, and to resubmit Worksheet S–10 for these years. Furthermore, as discussed earlier with respect to our estimates of Factors 1 and 2, we continue to believe that applying our best estimates to determine uncompensated care payment amounts prospectively would be most conducive to administrative efficiency, finality, and predictability in payments. We believe that, in affording the Secretary the discretion to estimate the amount of the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree that we should continue to offer hospitals the opportunity to amend, or require them to amend their FY 2014 and FY 2015 cost reports for purposes of determining uncompensated care payments for FY 2019, as this would be contrary to the notion of prospectivity. To the extent these commenters were requesting a further opportunity to revise their Worksheet S–10 data for use in future rulemaking for FY 2020 or later years, we are not addressing the issue of future resubmissions in this final rule. Therefore, the normal timelines and procedures apply for a hospital to request to amend a cost report.

Comment: A number of stakeholders commented on Transmittal 10 (issued on November 17, 2016) in which we clarified that hospitals may include discounts given to the uninsured who meet the hospital's charity care criteria in effect for that cost reporting period and Transmittal 11 (issued on September 29, 2017) in which we clarified definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care; modified the calculations relative to uncompensated care costs; and added edits to ensure the integrity of Worksheet S–10 data. In general, the commenters appreciated the release of these transmittals, particularly the revisions issued in Transmittal 11. Several commenters believed that the release of Transmittal 11 was a step forward to improve the Worksheet S–10 instructions, reporting consistency, and data accuracy and quality, in addition to offering an opportunity for hospitals to revise their FY 2014 and FY 2015 Worksheet S–10 reports and instructing the MACs flag potentially aberrant data.

However, numerous commenters also expressed concerns with the release of the transmittals, noting that between Transmittal 10 and 11, there were significant changes in the instructions and clarifications that resulted in significant modifications to hospitals' reporting. One commenter also pointed out that CMS' requests for data resubmissions in both Transmittal 10 and Transmittal 11 were only 1 year apart, adding to hospitals' administrative burden. One commenter stated that, by the time Transmittal 11 was issued, hospitals had already filed their initial FY 2014 and FY 2015 cost reports, with some hospitals having already updated Worksheet S–10 data through amended cost reports. Several commenters believed that Transmittal 11 added significant strain on and caused confusion for hospitals.

Aside from these concerns about the timing of and differences between Transmittals 10 and 11, numerous commenters pointed out specific reasons as to why the guidelines were confusing and difficult to be carried out, especially with regard to the changes made in Transmittal 11. For example, one commenter pointed out that providers that have already complied with CMS' updated instructions would not have to change submitted data. However, it was not clear from Transmittal 11 how hospitals were supposed to proceed in such a situation or if they simply had to calculate Worksheet S–10 data again and then resubmit.

Among the chief concerns raised by commenters regarding the release of Transmittal 11 was that hospitals did not have enough time or sufficient resources to revise their Worksheet S–10 data. According to commenters, the timeframe afforded by CMS was not long enough, given the administrative burden of complying with all of the changes in Transmittal 11. In addition, a few commenters pointed out that the Electronic Health Record audit by the Office of the Inspector General was earlier than the release of Transmittal 11, contributing to an even shorter timeline for hospitals to respond to changes in cost reporting for Worksheet S–10.

Many commenters also stated that among the factors contributing to restrict hospitals' ability to make timely revisions to their Worksheet S–10 data in response to Transmittal 11 were the limited personnel and financial resources available to make the changes in cost reporting outlined in Transmittal 11. The commenters also indicated that hospitals with inadequate internal financial management tracking systems were at an extreme disadvantage in meeting CMS' timeline.

On a related issue, many commenters stated that the software updates, which were required to accommodate the changes reflected in Transmittal 11, reduced the timeframe hospitals had to amend their cost reports by the deadline for inclusion in the proposed rule. At times, according to one commenter, the changes mandated by Transmittal 11 could not be executed by hospitals' information systems until a software update was possible, which likely did not coincide with the submission timeframe for the revisions.

Some commenters pointed out that the MACs' review of data following the issuance of Transmittal 11 largely focused on FY 2015 data, and perhaps paid much less attention to equally troubling FY 2014 data. Other commenters stated that only limited education efforts accompanied the issuance of Transmittal 11.

Response: We appreciate all of the comments raising concerns regarding Transmittals 10 and 11. However, we believe that hospitals were provided sufficient time to address the changes outlined in Transmittal 11 and to submit an amended Worksheet S–10 in time for it to be considered for the FY 2019 rulemaking, especially given our extension of the deadline to file resubmissions to January 2, 2018, as evidenced by the many hospitals that were able to resubmit their information by this deadline. Specifically, we issued Transmittal 11 on September 29, 2017,

and indicated that all revised data received by December 1, 2017, would be considered for purposes of the FY 2019 IPPS/LTCH PPS proposed rule. In light of the 2017 hurricanes (Harvey, Irma, Maria, Nate), we provided a further opportunity for hospitals to revise their Worksheet S–10 data for both FY 2014 and FY 2015 through Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S–10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017. This change request stated that hospitals needed to submit revised data by January 2, 2018. In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to HCRIS in a timely manner. Based on the significant number of resubmissions, we believe that hospitals were given ample time to revise and amend their Worksheets S–10 for FY 2014 and FY 2015 to reflect the instructions in Transmittal 11.

Regarding the confusion Transmittal 11 may have caused among stakeholders, we note Transmittal 11 was designed to be responsive to previous stakeholder concerns regarding Worksheet S–10, such as reporting of uninsured patient discounts and the modification of certain calculations to account for nonreimbursable Medicare bad debt. We also note that some commenters indicated that Worksheet S–10 instructions, consistency, and data accuracy have improved as a result Transmittal 11. However, we recognize that there are continuing opportunities to further improve guidance and education, and we will continue to work with our stakeholders to address their concerns through provider education and further refinement of the instructions.

Comment: Several commenters provided specific merger information and requested that CMS include these mergers in determining Factor 3 for FY 2019 payments. Several commenters noted other inaccuracies in the FY 2019 Proposed Rule Supplemental Data File, such as incorrect merger information errors in claims average calculations.

Response: We thank the commenters for their input. We have updated our list of mergers based on information received by the MACs as of June 2018. In addition, we have reviewed the commenters' submissions regarding mergers not previously identified in the proposed rule and have updated our list accordingly. We note that, under the policy finalized in FY 2015 IPPS/LTCH PPS final rule, a merger is defined as an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider (79 FR 50020). We have also corrected the other inaccuracies identified by commenters, and will continue to pay diligent attention to data inaccuracies and work internally and with our contractors to resolve these issues in a timely manner.

Comment: Numerous commenters expressed concerns that HCRIS data do not reflect hospital submissions in response to Transmittal 11. For example, one commenter pointed out that the March HCRIS data update still reflects data reported under the Transmittal 10 instructions rather than the Transmittal 11 instructions for a large number of hospitals. Commenters also expressed that, given problems with some amended cost reports not automatically being reprocessed with the Transmittal 11 calculation modification, the May 31, 2018 HCRIS file will provide the best data in determining Factor 3.

Several commenters specifically requested that their cost data in the proposed FY 2019 DSH Supplemental Data File be updated in a timely manner to reflect the latest HCRIS information in order ensure that their Factor 3 for FY 2019 accurately reflects their uncompensated care costs. A few commenters also expressed concerns that many hospitals were still having challenges in resubmitting their corrections to Worksheet S–10 data and having them accepted by the MACs. One commenter urged CMS to validate the information in HCRIS before pulling data for the proposed and final rules. Another commenter suggested that CMS implement an alternative means for hospitals to submit cost report data to alleviate burden on hospitals and improve accuracy.

Response: We appreciate the commenters' diligence in checking that their own reports were properly reprocessed under Transmittal 11. We also understand their concerns regarding the timeliness of updates to the HCRIS data. We recognize that hospitals' data in the March HCRIS update may not have reflected all corrections made to Worksheet S–10 data in response to Transmittal 11. Although we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to HCRIS in a timely manner, we recognize that there were unusual delays in processing the amended Worksheets S–10 to reflect the revisions in response to Transmission 11. Consistent with our historical practice of using the best data available, and due to the unique circumstances that affected hospitals' ability to resubmit Worksheet S–10, as discussed in the proposed rule, and the delays in processing by the MACs, we used a June 30, 2018 HCRIS update to calculate Factor 3 for this FY 2019 IPPS/LTH PPS final rule.

We have not previously been able to use such a recent update of HCRIS for purposes of the annual rulemaking, and it was operationally challenging to take the steps necessary to be able to use a June 30, 2018 update to calculate Factor 3 for FY 2019. The time required to complete the public use file process, which involves interactions with the MACs to ensure all reports have been appropriately included, would have exceeded the time we had available. In order to have the data with a bare minimum of time to use it in performing our calculations for the final rule, we needed to use a new expedited ad hoc process outside of the established process normally used to develop the public use file. We were not sure it even would be feasible to develop such an expedited ad hoc process. Ultimately, in order to develop the expedited process that was used, we had to bypass some of the safeguards built into the ordinary process and forgo our opportunity to further review the data. Given the unique circumstances that affected hospitals' ability to resubmit their Worksheet S–10 for FY 2014 and/or FY 2015, and the delays in processing by the MACs, we concluded that the potential to include additional, revised data for the final rule outweighed the risk that we might not include a report that would have been properly included had we been able to follow the usual process for preparing a public use file. Therefore, under ordinary circumstances, we would not even have contemplated this approach because the additional review time afforded by the use of the March extract under the established public use file process is important from an enhanced quality assurance standpoint and the benefits of this enhanced quality assurance were only outweighed by the extenuating circumstances affecting the timeline for both the resubmission of Worksheet S–10 data and the review of these data by the MACs in time to allow the data to be considered in this final rule.

Following the publication of this final rule, hospitals will have until August 31, 2018, to review and submit comments on the accuracy of the table

and supplemental data file published in conjunction with this final rule relative to information they submitted to their MAC by the deadlines prescribed in Transmittal 11 and Change Request 10378.

Comment: Some commenters expressed specific concerns related to possible violations of the Administrative Procedure Act by CMS. These commenters suggested that any final rule issued by CMS that disregards information in the rulemaking record, including copies of revised Worksheets S–10, that are submitted as attachments to comments, would violate the Administrative Procedure Act because it would not be supported by substantial evidence. The commenters urged CMS to calculate Factor 3 with the best possible data. One commenter also asserted that CMS is not upholding its statutory obligation unless it continues to accept updated Worksheets S–10 for the duration of time that the rulemaking period is open. The commenter cited the decision in *Baystate Medical Center* v. *Leavitt,* in which CMS was instructed to use the best data available to determine Medicare DSH payments under section 1886(d)(5)(F) of the Act. Another commenter also noted that, in the FY 2019 IPPS/LTCH PPS proposed rule, CMS proposed to use a May 31, 2018 HCRIS update for Factor 3 calculations in the final rule. The commenter stated that this proposal could lead to a situation where hospitals see their final uncompensated care payment amounts only in the final rule, and thus the hospitals would not have the ability to comment on these amounts, which the commenter suggests is in violation of both the Administrative Procedure Act and the Medicare statute.

One commenter also suggested that CMS allow for administrative or judicial review of its Medicare DSH payment calculations, which would provide an important check if the agency makes errors in the calculations. One commenter also asked CMS to reconsider its decision not to reconcile final payments for uncompensated care with actual data for cost reporting periods during FY 2019. One commenter included a request to reopen its cost reports for FY 2014 and FY 2015 to make corrections.

Response: We appreciate commenters' concerns regarding Factor 3 calculations and the importance of using the best available data. In response to these concerns, and in light of the considerations we have previously discussed, we used a June 30, 2018 HCRIS update to perform the Factor 3 calculations for this FY 2019 IPPS/LTCH PPS final rule, which was the best data available for purposes of this final rule.

Unless the relevant information was also reflected in the June 30, 2018 HCRIS update, we have not considered information from any revised Worksheets S–10 that were submitted as attachments to comments. We do not believe it would be appropriate to allow a hospital to use the rulemaking process to circumvent the requirement that cost report data need to be submitted to the MAC or the requirement that requests to reopen cost reports need to be submitted to the MAC. Otherwise we would have multiple potentially conflicting sources of information about a hospital's uncompensated care data or, more broadly, any cost report data that might be submitted during the rulemaking process. In addition, there are validity checks and other safeguards incorporated into the cost report submission process that would not be automatically applied to cost reports only submitted through rulemaking.

Furthermore, as noted earlier, under the deadlines established in Change Request 10378, we stated that all amended FY 2014 and FY 2015 cost reports containing a revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) received by January 2, 2018 would be available to be considered for purposes of the FY 2019 IPPS/LTCH PPS final rule. This date was important to allow sufficient time for reviews by MACs for potentially aberrant reports prior to the FY 2019 PPS/LTCH PPS final rule.

Also, as discussed earlier, we continue to believe that using the best data available to prospectively estimate Factor 3 is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; and 82 FR 38195). Further, we believe that, in affording the Secretary the discretion to estimate the amount of the three factors used to determine these uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. In light of this preclusion, we do not have the ability to allow for administrative or judicial review of our estimates.

Regarding the concerns related to the Administrative Procedure Act, we note that, under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2019 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed methodology for calculating Factor 3 and the data that would be used. We made public the best data available at the time of the proposed rule, in order to allow hospitals to understand the anticipated impact of the proposed methodology. Moreover, following the publication of the proposed rule, we continued our efforts to ensure that information hospitals properly submitted to their MAC in the prescribed timeframes would be available to be used in this final rule in the event we finalized our proposed methodology. We believe the fact that we provided data with the proposed rule while concurrently continuing to review that data with individual hospitals is entirely consistent with the Administrative Procedure Act. There is no requirement under either the Administrative Procedure Act or the Medicare statute that CMS make the actual data that will be used in a final rule available as part of the notice of proposed rulemaking. Rather, it is sufficient that we provide stakeholders with notice of our proposed methodology and the data sources that will be used, so that they may have a meaningful opportunity to submit their views on the proposed methodology and the adequacy of the data for the intended purpose. This requirement for notice and comment does not, however, extend to a requirement that we make all data that will be used to compute payments available to the public, so that they may have an opportunity to comment on accuracy of the data reported for individual hospitals. Similarly, there is no requirement that we provide an opportunity for comment on the actual payment amounts determined for each hospital.

Comment: Many commenters recommended that CMS delay the use of data from Worksheet S–10 for at least 1 year, and up to 3 years until FY 2021, as CMS had originally stated in its FY 2017 IPPS/LTCH PPS final rule, or until CMS has put processes in place to ensure accurate and consistent submissions by all hospitals as discussed in the FY 2018 IPPS/LTCH PPS final rule. Many commenters believed that this delay would allow hospitals the time to absorb the changes they have to make in order to better report their uncompensated care costs on the Worksheet S–10, as well as to prepare for potential losses due to policy changes. The commenters also believed that this delay will allow CMS the time to analyze how hospitals have

responded to the changes to the Worksheet S–10 that have already been implemented, identify problems that still remain, and develop an action plan moving forward. Specifically, a significant number of commenters requested that CMS further educate hospitals on how to accurately and consistently complete the Worksheet S–10 ''before advancing the transition to a greater use of Worksheet S–10 data.'' Although many commenters discussed how the CMS' current educational efforts—release of Transmittal 11, a Medicare Learning Network Matters article, along with Frequently Asked Questions document—were welcome and served as much needed guidance for the field, they provided recommendations for CMS to continue to partner with stakeholders in addressing these and other outstanding issues. Several commenters expressed their willingness and readiness to continue work with the agency in this particular area.

Response: We acknowledge the concerns raised by commenters regarding our proposal to use data from Worksheet S–10 in the calculation of Factor 3 for FY 2019. However, as we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20394), when weighing the new information that has become available to us since the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data against the low-income days proxy that we have analyzed as part of our consideration of this issue in prior rulemaking, we can no longer conclude that alternative data to the Worksheet S–10 are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. We also note that, as part of our ongoing quality control and data improvement measures to continue to improve the Worksheet S–10 data over time, we have revised the cost report instructions (Transmittal 11) and are currently developing an audit process. Continuing our education efforts of past years, we will continue to work with stakeholders to address their concerns regarding the Worksheet S–10 data through further provider education.

Comment: Many commenters urged CMS to implement a full desk auditing process to ensure the accuracy and consistency of the Worksheet S–10 data. A large proportion of the commenters requested an audit process that would be as rigorous, detailed, and thorough as the process used for the hospital wage index, as opposed to the less rigorous HITECH audits. In addition to auditing negative, missing, or suspicious values, many commenters also requested that CMS audit the revised data resubmitted by hospitals as a result of the release of Transmittal 11. One commenter believed that the Worksheet S–10 data needs real auditing, thorough auditing, professional auditing, and not the mere desk auditing that CMS previously indicated will be introduced in 2020. Another commenter recommended an alternative audit approach of ''probe and educate'' as it has been used to review data submitted for Medicaid DSH, where hospitals are allowed a grace period before the results of audits lead to financial consequences. Regardless of the approach, many commenters stated that they cannot overemphasize the importance of auditing the Worksheet S–10 data, given the inaccurate, inconsistent, and anomalous reporting of these data, as well as the data's crucial role in the distribution of Medicare DSH uncompensated care payments, which these commenters viewed as finite and an example of a ''classic zero-sum game.'' A few commenters explained that this is because for every additional dollar gained by a hospital, which could be a result of inaccurate and inconsistent reporting, another hospital must lose a dollar. Several commenters also asked CMS to implement edits within the cost report to ensure internal consistency between the amounts for data elements that must reported on several different worksheets and that the reported amounts equal calculated amounts.

Many commenters disagreed with CMS' stance on not sharing desk review and audit protocols with hospitals. These commenters pointed out that CMS has indicated that such protocols are confidential, but they believe this opacity could lead to inconsistencies in the reporting of Worksheet S–10 data and different interpretations of the Provider Reimbursement Manual among hospitals and even MACs. The commenters encouraged CMS to release the audit criteria for non-Medicare bad debt and charity care claimed on Worksheet S–10.

One commenter believed that CMS and the MACs hide behind the ''bar to judicial review'' that exists under the provisions of the statute governing the determination of uncompensated care payments, and this allows the MACs to commit outright errors that go unchecked if a hospital is otherwise unable to convince the MAC of the error. A few commenters expressed disappointment with what they characterized as the inconsistent and arbitrary decisions made by MACs in their reviews of Worksheet S–10 data and expressed the need for CMS to provide guidance to MACs to clarify which uninsured discounts CMS expects MACs to accept when reported on amended and/or corrected cost reports. Commenters pointed out that MACs may lack sufficient guidance, instruction, and training with respect to the inclusion of all discounts under the hospital's financial assistance policy in Line 20 of Worksheet S–10. For example, one commenter mentioned that some hospitals have experienced MAC audit disallowances of certain charity care and uninsured costs reported on Worksheet S–10 and stated that such disallowances can be egregious and cause significant reductions in the hospitals' uncompensated care payments. Commenters also suggested that these disallowances highlight the need for more upfront guidance and clearly defined terms as well as consistency by the MACs in the application of that guidance in their reviews.

Several commenters also were concerned or believed that MACs had created their own audit protocols for the Worksheet S–10 for purposes of auditing Electronic Health Record incentive payments under the HITECH Act without any guidance from CMS, and that any disparate interpretations could create disparities in the accuracy of the data across MACs. This, according to one commenter, allows MACs' audits to be subject to open interpretation. Another commenter expressed concern that the MACs are overstepping their authority to determine what the requirements for hospitals' financial assistance policies should be, when in fact hospitals are free to determine these requirements. The commenter also stated that the IRS already reviews and ensures that hospitals follow their financial assistance policy, and therefore there is no need for CMS and the MACs to duplicate its efforts.

Response: With respect to the audit process, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964), we stated that we intended to provide standardized instructions to the MACs to guide them in determining when and how often a hospital's Worksheet S–10 should be reviewed. To the extent the commenters are referring to concerns with EHR incentive payment audits, CMS strives to take lessons learned from these audits to improve the audits of Worksheet S–10 for purposes of Medicare DSH uncompensated care payments. We indicated that we would not make the MACs' review protocol public, as all CMS desk review and audit protocols are confidential and are for CMS and MAC use only. The instructions for the

MACs are still under development and will be provided to the MACs as soon as possible and in advance of any audit. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for a complete discussion concerning the issues that we are considering in developing the instructions that will be provided to the MACs. Due to the overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we expect audits to begin in the Fall of 2018. We also will continue to work with stakeholders to address their concerns regarding the accuracy and consistency of data reported on the Worksheet S–10 through provider education and further refinement of the instructions for the Worksheet S–10 as appropriate.

Comment: Many commenters supported CMS' proposal to use a 3-year average to calculate Factor 3 for FY 2019. Other commenters opposed the use of Worksheet S–10 data to determine Factor 3 for FY 2019 and also provided suggestions for modified or alternative methodologies to calculate Factor 3 in FY 2019 and beyond. Many of the commenters recommended a delay of at least 1 year to allow for further refinement of the Worksheet S–10 instructions and the development of audit protocols to identify and remove aberrant uncompensated care costs. One commenter asked that CMS consider a permanent 50–50 percent blend of the low-income insured days proxy data and Worksheet S–10 data. Other commenters suggested that CMS freeze the methodology used in calculating Factor 3 for FY 2018, under which we used 2 years of low-income insured days data and 1 year of Worksheet S–10 data, for the foreseeable future. Some commenters who suggested this freeze also recommended using Worksheet S–10 data from FY 2015 for the FY 2019 rulemaking, rather than FY 2014 data, reasoning that FY 2015 data are more likely to be consistently reported than FY 2014 data. One commenter suggested that CMS consider a proxy that would use SSI days to adjust the uncompensated care costs used in calculating Factor 3 starting in FY 2020.

Many commenters approved of the proposal to phase-in the use of data from the Worksheet S–10. However, other commenters had other varying opinions regarding the length of the phase-in period. Some commenters agreed with the proposal to continue the 3-year phase-in. However, other commenters requested that CMS consider a longer phase-in period or delay the transition to the use of Worksheet S 10 data. These commenters recommended a minimum 5-year transition period to gradually phase-in the use of Worksheet S–10 data, once the data have been audited. According to the commenters, this longer phase-in would mitigate the effect on hospitals of the redistribution in uncompensated care payments resulting from the inclusion of data from the Worksheet S–10.

Some commenters stated that the proposed methodology of using 1 year of low-income insured days and 2 years of uncompensated care data from Worksheet S–10 to compute uncompensated care payments for FY 2019 would be highly redistributive, and some commenters asked that CMS implement a stop-loss policy to protect hospitals that lose 5 to 10 percent in DSH payments in any given year as a result of transitioning to the use of Worksheet S–10 data. These commenters suggested that this stop-loss policy should extend beyond the 3-year phase-in to help hospitals with decreasing uncompensated care payments that are disproportionately affected by the transition to Worksheet S–10 data adjust to their new payment levels. However, another commenter noted that a stop-loss policy would not be warranted, given that a 3-year phase-in is an appropriate way to temporarily reduce the impact of new provisions.

Response: We appreciate the commenters' support for our proposal to use a 3-year average in the calculation of Factor 3 for FY 2019. We also appreciate the comments regarding alternative ways to blend prior years' data for purposes of incorporating Worksheet S–10 data into the calculation of Factor 3 and the suggestions for alternative methods for computing proxies for uncompensated care costs. However, our primary reason for using a 3-year average is to provide assurance that hospitals' uncompensated care payments will remain reasonably stable and predictable, and less subject to unpredictable swings and anomalies in a hospital's low-income insured days or reported uncompensated care costs between cost reporting periods. While the 3-year average effectively functions as a transition from the use of the low-income insured days proxy to the use of Worksheet S–10 data, that is not its purpose. Furthermore, as we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20394), we can no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 and FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Therefore, we disagree with commenters who suggested the use of a longer phase-in or alternative blends to determine Factor 3 for FY 2019 in order to provide for an extended transition to the use of the Worksheet S–10. We note that the proposals in the FY 2019 IPPS/LTCH PPS proposed rule were limited to FY 2019, and that we did not make any proposals with respect to the data that would be used to calculate Factor 3 for subsequent years. As a result, it would be premature for CMS to establish policies regarding the data that will be used to determine Factor 3 for future years in this final rule. We will consider the commenters' suggestions for further incorporating Worksheet S–10 into the calculation of Factor 3, or computing proxies for uncompensated care costs using a blend of Worksheet S–10 data, low-income insured days, or other data sources, as we develop our proposed policies for determining uncompensated care payments for FY 2020 and subsequent years.

Regarding the commenters' recommendation that we adopt a stop-loss policy, we believe that the use of 3 years of data to determine Factor 3 for FY 2019 already provides assurance that hospitals' uncompensated care payments will remain reasonably stable and predictable, and would not be subject to unpredictable swings and anomalies in a hospital's low-income insured days or reported uncompensated care costs. As a result, because there is already a mechanism that has the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data in place, we do not believe a stop-loss policy is necessary.

Comment: A few commenters stated that the current CCR trimming methodology is not adequate to address the data anomalies in the Worksheet S–10 data reported by certain hospitals. Other commenters supported the current methodology. A few commenters also stated that hospitals that have been identified as potential outliers should have the opportunity to explain their data and correct errors before the trim methodology is applied, which would facilitate data validity. Other commenters requested that the trimming methodology not be finalized until an audit of the data has been conducted, and that hospitals with extremely high CCRs be audited and an appropriate CCR determined instead of applying an arbitrary trim to a statewide average. Several commenters expressed concern over the proposed trim methodology because hospitals that are considered ''all-inclusive rate providers'' are not required to complete

Worksheet C, Part I, which is used for reporting the CCR on Line 1 of the Worksheet S–10. Commenters noted that, as a result, the proposed trim methodology inappropriately modifies their uncompensated care costs, and that a high CCR could be accurate if the hospital's charges are close to costs, as is usually the case for all-inclusive rate hospitals. One commenter noted that CMS is proposing to continue to use the low-income patient day proxy to distribute Medicare DSH uncompensated care payments to all-inclusive rate providers. The commenter encouraged CMS to engage with hospitals in determining the best way to use Worksheet S–10 data to distribute uncompensated care payments to all-inclusive rate providers in the future and also recommended that CMS assess how the current CCR trim methodology would affect all-inclusive rate providers.

Response: We appreciate the additional information provided by the commenters related to applying trims to the CCRs. We intend to further explore which trims are most appropriate to apply to the CCRs on Line 1 of Worksheet S–10, including whether it would be appropriate to apply a unique trim for certain subsets of hospitals, such as all-inclusive rate providers. We note that all-inclusive rate providers have the ability to compute and enter their appropriate information (for example, departmental cost statistics) on Worksheet S–10, Line 1, by answering ''Yes'' to the question on Worksheet S–2, Part I, Line 115, rather than having it computed using information from Worksheet C, Part I. We intend to give additional consideration to the utilization of statewide averages in place of outlier CCRs, and will also consider other approaches that could ensure the validity of the trim methodology, while not penalizing hospitals that use alternative methods of cost apportionment. We may consider incorporating these alternative approaches through rulemaking for future years. However, as we have previously discussed, because all-inclusive rate providers have charge structures that differ from other IPPS hospitals, we did not propose to use data from the Worksheet S–10 to determine Factor 3 for these hospitals for FY 2019. Instead, we have determined Factor 3 for these hospitals using low-income insured days for FY 2013.

Regarding the commenters' view that CCR trims should not take place before we conduct audits and give providers further opportunities to explain or amend their data, we agree that, in an ideal circumstance, CCR trims without audits would not be needed. However, providers have had sufficient time to amend their data and/or contact CMS to explain that the FY 2019 DSH Supplemental Data File posted in conjunction with FY 2019 IPPS/LTCH PPS proposed rule had incorrect data. As a result, we consider CCRs greater than 3 standard deviations above the national geometric mean CCR for the applicable fiscal year to be aberrant CCRs. We are finalizing the trim methodology as proposed.

Comment: Many commenters requested that the cost of graduate medical education (GME) be included within the CCR calculation to account for the costs associated with the training of interns and residents. The commenters stated that not only does GME represent a significant portion of the overhead costs of teaching hospitals, but these trained interns and residents treat patients from all financial backgrounds, including the uninsured. Therefore, the commenters believed that including GME costs in the CCR calculation and then using this adjusted CCR for Worksheet S–10 would more accurately represent the true uncompensated care costs for teaching hospitals. Some commenters observed that GME is included in the denominator but not the numerator of the Worksheet S–10 CCR and that this discrepancy should be rectified. One commenter noted that this inconsistency occurs because Line 1 uses data from Worksheet C, Column 3 (''costs,'' which do not include GME) and Worksheet C, Column 8 (''charges,'' which do include GME). Commenters recommended using the ''costs'' definition from Worksheet B, Part I, Column 24, Line 118 to reconcile the discrepancy. Other commenters requested that the Reasonable Compensation Equivalency (RCE) be removed from the calculation of the CCR. One commenter stated that the current Worksheet S–10 ignores substantial costs hospitals incur in training medical residents, supporting physician and professional services, and paying provider taxes associated with Medicaid revenue. Therefore, this commenter recommended that CMS use the total of Worksheet A, Column 3, Lines 1 through 117, reduced by the amount on Worksheet A–8, Line 10, as the cost component of the CCR; and use Worksheet C, Column 8, Line 200, as the charge component. The commenter noted that this result would more accurately reflect the true cost of hospital services compared with the CCR currently used in Worksheet S–10.

Response: As we have stated previously in response to this issue, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR on Line 1 of Worksheet S–10 is pulled from Worksheet C, Part I, and is also used in other IPPS ratesetting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude GME because GME is paid separately from the IPPS, we hesitate to adjust the CCRs in the narrower context of calculating uncompensated care costs. Therefore, we continue to believe that it is not appropriate to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include GME costs in the numerator.

With regard to the comment that the CCRs on Worksheet S–10 are reported with the RCE limits applied, we believe the commenter is mistaken. Line 1 of Worksheet S–10 instructs hospitals to compute the CCR by dividing the costs from Worksheet C, Part I, Line 202, Column 3, by the charges on Worksheet C, Part I, Line 202, Column 8. The RCE limits are applied in Column 4, not in Column 3; thus, the RCE limits do not affect the CCR on line 1 of Worksheet S–10.

Comment: Several commenters supported the proposed definition of uncompensated care as charity care plus non-Medicare bad debt. However, some commenters suggested that uncompensated care should include shortfalls from Medicaid, CHIP, and State and local indigent care programs. The most common concern expressed was the exclusion of Medicaid shortfalls from the definition of uncompensated care as captured by Worksheet S–10. Commenters stated that excluding Medicaid shortfalls from the definition of uncompensated care severely penalizes hospitals that care for large numbers of Medicaid patients because many States do not fully cover the costs associated with newly insured Medicaid recipients. One commenter noted that just because patients are covered by Medicaid does not mean that they have no remaining uncompensated care costs, and that, as the policy stands now, Medicare will significantly subsidize those States with Medicaid payment rates that cover the cost of care relative to those with lower Medicaid payment rates that do not cover the cost of care. However, some commenters noted that Worksheet S–10 provides an incomplete picture of Medicaid shortfalls and should be revised to instruct hospitals to deduct intergovernemental transfers,

certified public expenditures, and provider taxes from their Medicaid revenue. One commenter questioned why CHIP and indigent care data are collected on Worksheet S–10 if there is no plan to utilize this information in the calculation of Factor 3.

Several commenters urged CMS to use Worksheet S–10, Line 31 to identify a hospital's share of uncompensated care costs rather than Line 30. These commenters did not believe that Line 30 adequately captures a hospital's uncompensated care because it excludes unreimbursed costs for State and local indigent care programs. Commenters also believed that CMS' use of Line 30 results in a mismatch between payment and costs for care furnished to the uninsured and underinsured due to lack of clear reporting guidelines. The commenters believed that this is because many States support uncompensated care through supplemental Medicaid programs funded through their Federal Medicaid DSH allotment or a Medicaid waiver program. The commenters stated that these supplemental payments are likely reported on Worksheet S–10 as Medicaid revenue while some of the hospital's uncompensated care costs are reported as charity care, as such reporting was at a hospital's discretion at the time of cost report filing.

In addition to comments about the Medicaid shortfalls, commenters observed that States differ in how they define uncompensated care costs, and that not all costs incurred by hospitals in treating the uninsured are categorized as charity care and bad debt, such as in the case of discounts to the uninsured who are unable to pay or unwilling to provide means-tested information. One commenter supported CMS' definition of uncompensated care costs as the cost of all charity care and non-Medicare bad debt but expressed concerns with the proposed expansion under Transmittal 10 to include discounts to the uninsured. The commenter stated that its health system has a long history of providing discounts to the uninsured through a voluntary agreement with the Attorney General's Office. The commenter also argued that higher adoption of high-deductible health plans should be considered.

Response: In general, we will attempt to address commenters' concerns through future cost report clarifications to further improve and refine the information that is reported on Worksheet S–10 in order to support collection of the information necessary to implement section 1886(r)(2) of the Act. With regard to the comments regarding Medicaid shortfalls, we recognize commenters' concerns but continue to believe there are compelling arguments for excluding Medicaid shortfalls from the definition of uncompensated care, including the fact that several key stakeholders, such as MedPAC, do not consider Medicaid shortfalls in their definition of uncompensated care, and that it is most consistent with section 1886(r)(2) of the Act for Medicare uncompensated care payments to target hospitals that incur a disproportionate share of uncompensated care for patients with no insurance coverage.

Conceptual issues aside, we note that even if we were to adjust the definition of uncompensated care to include Medicaid shortfalls, this would not be a feasible option at this time due to computational limitations. Specifically, computing such shortfalls is operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid ''shortfalls.'' Therefore, it is not clear how CMS would determine how much of the ''shortfall'' is left after the Medicaid DSH payment is made. In addition, in some States, hospitals return a portion of their Medicaid revenues to the State via provider taxes, making the computation of ''shortfalls'' even more complex.

With regard to the comments that States differ in how they define uncompensated care costs, and that hospitals' costs of treating the uninsured are not always categorized as charity care and bad debt, such as in the case of discounts to the uninsured who are unable to pay or unwilling to provide income information, we believe the commenters are referring to the Worksheet S–10 instructions for Line 20, revised in Transmittal 10, which state, in part, ''Enter in column 1, the full charges for uninsured patients and patients with coverage from an entity that does not have a contractual relationship with the provider who meet the hospital's charity care policy or FAP.'' We believe that hospitals have the discretion to design their charity care policies as appropriate and may include discounts offered to uninsured patients as ''charity care.'' Accordingly, for the reasons discussed in the proposed rule and previously in this final rule, we are finalizing our proposal to define uncompensated care costs as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

Comment: Many commenters had several specific concerns regarding the instructions for reporting charity care and Medicare bad debt on the Worksheet S–10. Commenters acknowledged that while Transmittal 11 helped provide clarification, certain aspects of the instructions remain vague and ambiguous. For example, one commenter asked whether non-Medicare bad debt expenses must meet requirements equivalent to the statutory requirements applicable to Medicare bad-debt as described in CMS Pub. 15–1 Chapter 3. In addition, some commenters questioned whether guidance related to the recognition of bad debt expense for purposes of Medicare bad debts is also applicable for non-Medicare bad debt. A few commenters also suggested that CMS allow bad debt related to unpaid coinsurance and deductibles to be included on the Worksheet S–10 without multiplying these amounts by the CCR, similar to the modification made for charity care.

A few commenters also expressed concerns about the Financial Accounting Standards Board (FASB) update 2014–09 Topic 606. These commenters noted that the FASB guidelines indicate that bad debt is to be reported based on historical experience and that recoveries may not correlate to reported bad debt expense on the general ledger. Specifically, commenters asked that CMS address whether bad debt should still be reported net of recoveries on the Worksheet S–10.

Several commenters also expressed concerns that instructions pertaining to Worksheet S–10, Line 20 are not clear. The commenters stated, for example, that many hospitals incorrectly report ''insured'' charity care on Worksheet S–10, Line 20, Column 2 (which is not reduced by CCR), citing, as an example, noncovered Medicaid charges, which need to be reported as ''uninsured'' on Worksheet S–10 and reduced by CCR, as stated in the Worksheet S–10 instructions. The commenters pointed out that this inconsistency with respect to the reporting of charity care costs is commonly due to misinterpretation of instructions because of lack of clarity, and may be contributing to the overstatement of charity care costs.

Several commenters also pointed out that some hospitals may interpret the instructions literally, while other hospitals do not. The commenters asked CMS to correct this uncertainty and ambiguity to avoid inconsistent interpretations. In relation to this, one commenter asserted that contradictory and confusing language in the instructions leaves key terms undefined,

such as determination of uninsured status. The commenter believed that the focus in determining whether a patient is ''uninsured'' should be on whether the patient has coverage for the specific services provided, in the same manner that CMS defines ''uninsured'' and ''no health insurance'' for purposes of Medicaid DSH.

Some commenters questioned whether guidance on determining indigence of a Medicare beneficiary should be applicable to non-Medicare patients to determine whether charity care was furnished. Several commenters also suggested improvements that could be made to the instructions of Worksheet S–10, such as adding a requirement to report utilization data to add context to the monetary amounts reported for uncompensated care.

Response: We thank commenters for sharing their concerns and making suggestions regarding potential revisions to the instructions for Worksheet S–10. Some of these questions and concerns have been raised in previous rulemaking. (For example, we refer readers to the related discussion in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38219 and 38220).) We also note that a number of these questions and concerns are addressed by the updated instructions for Worksheet S–10 that were issued in November 2016 through Transmittal 10, as well as those issued on September 2017 through Transmittal 11, where we clarified definitions and the instructions for reporting uncompensated care, non-Medicare bad debt, nonreimbursed Medicare bad debt, charity care, and modified the calculations relative to uncompensated care costs. Additional reference materials include the MLN article titled ''Updates to Medicare's Cost Report Worksheet S–10 to Capture Uncompensated Care Data'', available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17031.pdf* as well as the Worksheet S–10 Q&As on the CMS DSH website in the download section, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/Worksheet-S-10-UCC-QandAs.pdf*. To the extent that commenters have raised new questions and concerns, we will continue to work with stakeholders to address their questions and concerns through further refinement of the instructions to the Worksheet S–10 as appropriate.

Comment: Several commenters supported the proposal to use one cost report beginning in each fiscal year to derive the uncompensated care costs for that year, and to annualize Medicaid days and uncompensated care data for hospitals with less than 12 months of data. However, one commenter noted that this proposal may lead to double counting of the uncompensated care costs of acquired hospitals with short cost reporting periods and recommended that CMS modify its methodology to ensure that the data for acquired hospitals is not annualized twice. In addition, for acquired hospitals with more than one cost report beginning in the same Federal fiscal year, the commenter recommended that CMS not automatically select the one with the longer cost reporting period, in order to avoid double-counting. The commenter also recommended that CMS include the report record number in the DSH Supplemental File.

Response: We appreciate the support for our proposal to annualize cost reports that do not equal 12 months of data. We may consider adopting the commenters' recommendations regarding alternatives to the use of the longer cost report in specific situations through future rulemaking if objective and administratively feasible criteria can be developed. However, at present, we continue to believe that our current approach of annualizing the cost report data from the longest cost reporting period during the applicable fiscal year is generally the most accurate and consistent across hospitals. We do not believe it is necessary to include report record numbers in the DSH Supplemental File, as the quarterly HCRIS Public Use Files can be used to reference cost report records for this additional detail. Accordingly, for the reasons discussed in the proposed rule, and previously in this final rule, we are finalizing the proposal to use the longest cost report beginning in the applicable fiscal year and to annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data.

Comment: A number of commenters supported the proposal to adjust a hospital's uncompensated care costs when those costs are extremely high in relation to its total operating costs for the same year. The commenters noted that this adjustment would help to control for data anomalies. However, one commenter noted that the trim currently uses a 50-percent threshold for the ratio of uncompensated care costs to total operating costs, yet the national average is 6 percent. Another commenter recommended that CMS investigate in cases where a hospital's uncompensated care value is an unrealistically high proportion of total revenue and ask for additional documentation before either allowing the value or requiring a modification. This commenter suggested that CMS could focus on providers at or near trim points initially, then expand to other providers with unlikely values.

Response: We appreciate the support for our proposal to adjust uncompensated care costs that are an extremely high ratio of a hospital's total operating costs for the same year. We believe that the proposed approach balances our desire to exclude potentially aberrant data, with our concern regarding inappropriately reducing FY 2018 uncompensated care payments to a hospital that may have a legitimately high ratio. We are finalizing this adjustment. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20399), we noted that our calculation of Factor 3 for the final rule would be contingent on the results of the ongoing MAC reviews of hospitals' Worksheet S–10 data, and in the event those reviews necessitate supplemental data edits, we would incorporate such edits in the final rule for the purpose of correcting aberrant data. After the completion of the MAC reviews, we are not incorporating any additional edits to the Worksheet S–10 data that we did not propose in the proposed rule. While, as stated earlier, we acknowledge that the Worksheet S–10 data are not perfect, we need to balance the possibility of potentially improving the accuracy of the Worksheet S–10 data for some hospitals through the creation of additional data edits against the possibility of inadvertently reducing the uncompensated care payments for other hospitals that might fail the edit, but whose data might in fact be accurate. For FY 2019, we have concluded that it is best to err on the side of not inadvertently reducing the uncompensated care payments for hospitals whose data might in fact be accurate.

Comment: Two commenters requested that CMS consider using a proxy for Puerto Rico hospitals' SSI days in computing the empirically justified DSH payment amount, or 25 percent of the amount that would have been paid for Medicare DSH prior to implementation of section 3133 of the Affordable Care Act.

Response: In the FY 2019 IPPS/LTCH PPS proposed rule, we did not propose any changes to the methodology used to calculate empirically justified Medicare DSH payments. Therefore, we consider this comment to be outside the scope of the proposed rule. However, we note that, while section 1886(r)(2)(C)(i) of the Act allows for the use of alternative data as a proxy to determine the costs of

subsection (d) hospitals for treating the uninsured for purposes of determining uncompensated care payments, section 1886(r)(1) of the Act requires the Secretary to pay an empirically justified DSH payment that is equal to 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(d)(5)(F)(vi) of the Act, which prescribes the disproportionate patient percentage used to determine empirically justified Medicare DSH payments, specifically calls for the use of SSI days in the Medicare fraction and does not allow the use of alternative data, we do not believe there is any legal basis for CMS to use a proxy for Puerto Rico hospitals' SSI days in the calculation of the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act.

Comment: Several commenters supported the proposal to continue to use 14 percent of Medicaid days as a proxy for Medicare SSI days when determining Factor 3 of the uncompensated care payment methodology for Puerto Rico Hospitals. The commenters stated that they appreciated the attention and effort by CMS to develop a fair and appropriate method to estimate SSI days for Puerto Rico, as the SSI program is statutorily unavailable to U.S. citizens residing in the Territories.

One commenter recommended that CMS identify and seek comment on alternate sources of proxy data for Puerto Rico Hospitals for use in future years, such as using data for Medicare beneficiaries with Medicaid eligibility (dual eligible beneficiaries).

Response: We appreciate the support for our proposal to use 14 percent of a Puerto Rico hospital's Medicaid days as a proxy for SSI days. Because we are continuing to use insured low-income patient days as a proxy for uncompensated care in determining Factor 3 for FY 2019, and residents of Puerto Rico are not eligible for SSI benefits, we believe it is important to create a proxy for SSI days for Puerto Rico hospitals in the Factor 3 calculation. Regarding the recommendation that we consider using inpatient days for Medicare beneficiaries receiving Medicaid as a proxy for uncompensated care in the future, we have examined this concept and have been unable to identify a systematic source for these data for Puerto Rico hospitals. Specifically, we note that inpatient utilization for Medicare beneficiaries who are also entitled to Medicaid is not reported by hospitals on the Medicare cost report, either within or outside Puerto Rico. We expect to further address issues related to estimating the amount of uncompensated care for hospitals in Puerto Rico in future rulemaking.

After consideration of the public comments we received, and for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposal to use 2 years of Worksheet S–10 data from FY 2014 and FY 2015 cost reports in conjunction with data on low-income insured days that reflects Medicaid days from FY 2013 and SSI days from FY 2016, to calculate Factor 3 for FY 2019.

Therefore, for FY 2019, we are finalizing a policy to compute Factor 3 for each hospital by—

Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days);

Step 2: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;

Step 3: Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and

Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3 (or for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers using the Factor 3 value from Step 1).

We also are finalizing the following proposals: (1) For providers with multiple cost reports beginning in the same fiscal year, to use the longest cost report and annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) to discontinue the policy of combining cost reports for providers with multiple cost reports beginning during the same fiscal year; (3) where a provider has multiple cost reports beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year such that the hospital has no cost report for that fiscal year, to use the cost report that spans both fiscal years for the latter fiscal year; and (4) to apply statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs.

For this FY 20019 IPPS/LTCH PPS final rule, we are finalizing a HCRIS cutoff of June 30. This cutoff also applies to revised reports from providers who were contacted by their MAC regarding potentially aberrant uncompensated care costs.

We are also finalizing our proposal to amend the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (*5*) to reflect the methodology for computing Factor 3 for FY 2019. We note that are making a technical correction to the uncompensated care definition in proposed paragraph (*5*) to include nonreimbursable Medicare bad debt to conform with our proposal in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20398) to define uncompensated care costs as the amount on Worksheet S–10 line 30, which includes charity care and non-Medicare and non-reimbursable Medicare bad debt), and which we are also finalizing in this final rule.

G. Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospitals (MDHs) (§§ 412.90, 412.92, and 412.108)

1. Background on SCHs and MDHs

Sections 1886(d)(5)(D) and (d)(5)(G) of the Act provide special payment protections under the IPPS to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs), respectively. Section 1886(d)(5)(D)(iii) of the Act defines an SCH in part as a hospital that the Secretary determines is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 43897).

Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, or is located in an all-urban State but meets one of the specified statutory criteria for rural reclassification (as added by section 50205 of the Bipartisan Budget Act of 2018, Pub. L. 115–123), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be

classified as an MDH. For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).

2. Implementation of Legislation Relating to the MDH Program

a. Legislative Extension of the MDH Program

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been extended by subsequent legislation. Most recently, section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for FYs 2018 through 2022 (that is, for discharges occurring before October 1, 2022). (Additional information on the extensions of the MDH program after FY 2012 and through FY 2017 can be found in the FY 2016 interim final rule with comment period (80 FR 49596).)

Section 50205 of the Bipartisan Budget Act of 2018 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program for discharges occurring on or after October 1, 2017, through FY 2022 (that is, for discharges occurring on or before September 30, 2022).

We noted in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20401) that, consistent with the previous extensions of the MDH program, generally, a provider that was classified as an MDH as of September 30, 2017, was reinstated as an MDH effective October 1, 2017, with no need to reapply for MDH classification. However, if the MDH had classified as an SCH or cancelled its rural classification under § 412.103(g) effective on or after October 1, 2017, the effective date of MDH status may not be retroactive to October 1, 2017. We refer readers to the FY 2018 IPPS notice that appeared in the **Federal Register** on April 26, 2018 (CMS–1677–N; 83 FR 18303) for more information on the MDH extension in FY 2018.

b. MDH Classification for Hospitals in All-Urban States

In addition to extending the MDH program, section 50205 amended section 1886(d)(5)(G)(iv) of the Act to include in the definition of an MDH a hospital that is located in a State with no rural area (as defined in paragraph (2)(D)) and satisfies any of the criteria in section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act, in addition to the other qualifying criteria.

Section 50205 of the Bipartisan Budget Act of 2018 also amended section 1886(d)(5)(G)(iv) of the Act by adding a provision following section 1886(d)(5)(G)(iv)(IV), which specifies that new section 1886(d)(5)(G)(iv)(I)(bb) of the Act applies for purposes of the MDH payment under sections 1886(d)(5)(G)(ii) of the Act (that is, 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years) only for discharges of a hospital occurring on or after the effective date of a determination of MDH status made with respect to the hospital after the date of the enactment of this provision. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20401), we noted that, under existing regulations, the effective date for a determination of MDH status is 30 days after the date the MAC provides written notification of MDH status. We also noted that we were proposing in section IV.G.3. of the preamble of the proposed rule to change the effective date for a determination of MDH status. We stated that if the proposal is finalized, the policy would not be effective until FY 2019 (October 1, 2018) and therefore would not apply to hospitals applying for MDH classification before October 1, 2018. Furthermore, this new provision also specifies that, for purposes of new section 1886(d)(5)(G)(iv)(I)(bb) of the Act, section 1886(d)(8)(E)(ii)(II) of the Act shall be applied by inserting ''as of January 1, 2018,'' after ''such State'' each place it appears. Section 50205 of the Bipartisan Budget Act also made conforming amendments to sections 1886(b)(3)(D) (in the language proceeding clause (i)) and 1886(b)(3)(D)(iv) of the Act.

Section 1886(d)(8)(E) of the Act provides for an IPPS hospital that is located in an urban area to be reclassified as a rural hospital if it submits an application in accordance with CMS' established process and meets certain criteria at section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (these statutory criteria are implemented in the regulations at § 412.103(a)(1) through (3)). A subsection (d) hospital that is located in an urban area and meets one of the three criteria under § 412.103(a) can reclassify as rural and is treated as being located in the rural area of the State in which it is located. However, a hospital that is located in an all-urban State is ineligible to reclassify as rural in accordance with the provisions of § 412.103 because the State in which it is located does not have a rural area into which it can reclassify. Prior to the amendments made by the Bipartisan Budget Act, a hospital could only qualify for MDH status if it was either geographically located in a rural area or if it reclassified as rural under the regulations at § 412.103. This precluded hospitals in all-urban States from being classified as MDHs. The newly added provision in the Bipartisan Budget Act of 2018 allows a hospital in an all-urban State to be eligible for MDH classification if, in addition to meeting the other criteria for MDH eligibility, it satisfies one of the criteria for rural reclassification under section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (as of January 1, 2018, where applicable), notwithstanding its location in an all-urban State.

As noted earlier, prior to the enactment of the Bipartisan Budget Act of 2018, a hospital in an all-urban State was ineligible for MDH classification because it could not reclassify as rural. With the new provision added by section 50205 of the Bipartisan Budget Act of 2018, a hospital in an all-urban State can apply and be approved for MDH classification if it can demonstrate that: (1) It meets the criteria at § 412.103(a)(1) or (3) or the criteria at § 412.103(a)(2) as of January 1, 2018, for the sole purposes of qualifying for MDH classification; and (2) it meets the MDH classification criteria at § 412.108(a)(1)(i) through (iii), which, as amended, would be redesignated as § 412.108(a)(1)(i) through (iv). We noted in the proposed rule that for a hospital in an all-urban State to demonstrate that it would have qualified for rural reclassification notwithstanding its location in an all-urban State (as of January 1, 2018, where applicable), it must follow the applicable procedures for rural reclassification and MDH classification at § 412.103(b) and § 412.108(b), respectively. We also noted that we were not proposing any changes to the reclassification criteria under § 412.103 and that a hospital in an all-urban State that qualifies as an MDH under the newly added statutory provision will not be considered as having reclassified as rural but only as having satisfied one of the criteria at section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (as of January 1, 2018, as applicable) for purposes of MDH classification, in accordance with amended section 1886(d)(5)(G)(iv) of the Act.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20402), we proposed to make conforming changes to the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the extension of the MDH program for FY 2018 through FY 2022 and the additional MDH classification provision made for hospitals located in all-urban States by section 50205 of the Bipartisan Budget

Act of 2018. We proposed a similar conforming change to § 412.90(j) to reflect the extension of the MDH program through FY 2022.

Comment: Commenters supported our proposals to make conforming changes to the regulations to reflect the legislation extending the MDH provision.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting as final the proposed conforming changes to the regulations text at §§ 412.90 and 412.108 to reflect the extension of the MDH program through FY 2022 and the additional MDH classification provision made for hospitals located in all-urban States in accordance with section 50205 of the Bipartisan Budget Act of 2018. We are finalizing the proposed changes in paragraphs (a)(1) and (c)(2)(iii) of § 412.108 and paragraph (j) of § 412.90 without modification.

3. Change to SCH and MDH Classification Status Effective Dates

The regulations at 42 CFR 412.92(b)(2)(i) set forth an effective date for SCH classification of 30 days after the date of CMS' written notification of approval. Similarly, § 412.92(b)(2)(iv) specifies that a hospital classified as an SCH receives a payment adjustment effective with discharges occurring on or after 30 days after the date of CMS' approval of the classification.

Section 401 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113, Appendix F) amended section 1886(d)(8) of the Act to add paragraph (E) which authorizes reclassification of certain urban hospitals as rural if the hospital applies for such status and meets certain criteria. The effective date for rural reclassification status under section 1886(d)(8)(E) of the Act is set forth at 42 CFR 412.103(d)(1) as the filing date, which is the date CMS receives the reclassification application (§ 412.103(b)(5)). One way that an urban hospital can reclassify as rural under § 412.103 (specifically, § 412.103(a)(3)) is if the hospital would qualify as a rural referral center (RRC) as set forth in § 412.96, or as an SCH as set forth in § 412.92, if the hospital were located in a rural area. A geographically urban hospital may simultaneously apply for reclassification as rural under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and apply to obtain SCH status under § 412.92 based on that acquired rural reclassification. However, the rural reclassification is effective as of the filing date, while the SCH status is effective 30 days after approval. In addition, while § 412.103(c) states that the CMS Regional Office will review the application and notify the hospital of its approval or disapproval of the request within 60 days of the filing date, the regulations do not set a timeframe by which CMS must decide on an SCH request. Therefore, geographically urban hospitals that obtain rural reclassification under § 412.103 for the purposes of obtaining SCH status may face a payment disadvantage because they are paid as rural until the SCH application is approved and the SCH classification and payment adjustment become effective 30 days after approval.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20402 and 20403), to minimize the lag between the effective date of rural reclassification under § 412.103 and the effective date for SCH status, we proposed to revise § 412.92(b)(2)(i) and (b)(2)(iv) so that the effective date for SCH classification and for the payment adjustment would be the date that CMS receives the complete SCH application, effective for SCH applications received on or after October 1, 2018. However, as discussed in response to comments below, because the MAC receives SCH applications and not CMS, we are clarifying in this final rule that under our policy, as finalized below, the effective date is the date that the MAC receives the complete application. We have revised our finalized regulatory text and this preamble throughout to reflect that the MAC, and not CMS, receives the SCH application. A complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for SCH status as of the date of application, which includes documentation of rural reclassification in the case of a geographically urban hospital. We stated in the proposed rule that for an application to be complete, all criteria must be met as of the date CMS receives the SCH application, but, similar to above, we are clarifying in this final rule and revising this preamble discussion to reflect that all criteria must be met as of the date the MAC receives the SCH application, because the MAC, and not CMS, receives SCH applications. For example, a hospital applying for SCH status on the basis of a § 412.103 rural reclassification must submit its § 412.103 application no later than its SCH application in order to be considered rural as of the date the MAC receives the SCH application.

Similar to rural reclassification obtained under § 412.103, we proposed that the effective date for SCH status would be the date that CMS receives the complete application. We also proposed conforming changes to the effective date at § 412.92(b)(2)(ii) for instances when a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses a CMS denial of SCH status and no further appeal is made. In the interest of a clear and consistent policy, we proposed that this change in the SCH effective date would also apply for hospitals not reclassifying as rural under § 412.103, such as geographically rural hospitals obtaining SCH status. We stated that we believe these proposals to update the regulations at § 412.92 to provide an effective date for SCH status that is consistent with the effective date for rural reclassification under § 412.103 would benefit hospitals by minimizing any payment disadvantage caused by the lag between the effective date of rural reclassification and the effective date of SCH status. We also stated that we believe this proposal to align the SCH effective date with the § 412.103 effective date supports agency efforts to reduce regulatory burden because it would provide for a more uniform policy.

In addition, we proposed to make parallel changes to the effective date for an MDH status determination under § 412.108(b)(4). As discussed earlier, section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program through FY 2022 by amending section 1886(d)(5)(G) of the Act. Similar to the proposed change in effective date for SCH status approvals, we proposed that a determination of MDH status would be effective as of the date that CMS receives the complete application, for applications received on or after October 1, 2018, rather than the current effective date at § 412.108(b)(4) of 30 days after the date the MAC provides written notification to the hospital. However, as discussed in response to comments below, because the MAC receives MDH applications and not CMS, we are clarifying in this final rule that under our policy, as finalized below, the effective date is the date that the MAC receives the complete application. We have revised our finalized regulatory text and this preamble throughout to reflect that the MAC, and not CMS, receives the MDH application. Similar to applications for SCH status, a complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for MDH status as of the date of application. We stated in the proposed rule that for an application to be complete, all criteria must be met as of the date CMS receives

the MDH application, but, similar to above, we are clarifying in this final rule and revising our preamble discussion to reflect that all criteria must be met as of the date the MAC receives the SCH application, because the MAC, and not CMS, receives MDH applications. For example, a cost report must be settled at the time of application for a hospital to use that cost report as one of the cost reports required in § 412.108(a)(1)(iii)(C) (redesignated as § 412.108(a)(1)(iv)(C) pursuant to our finalized changes to this regulation, as discussed in the prior section), and a hospital applying for MDH status on the basis of a § 412.103 rural reclassification must submit its § 412.103 application no later than its MDH application in order to be considered rural as of the date the MAC receives the MDH application. (We noted that a hospital in an all-urban State that applies for MDH status under the expanded definition at section 50205 of the Bipartisan Budget Act of 2018 would need to submit its application for a determination that it meets the criteria at § 412.103(a)(1) or (3) or the criteria at § 412.103(a)(2) as of January 1, 2018 (as discussed in the previous section) no later than its MDH application in order for the application to be considered complete.)

We stated that we believe that concurrently changing the SCH and MDH status effective dates from 30 days after the date of approval to the date the complete application is received would allow for consistency in the regulations governing effective dates of special rural hospital status. In addition, we stated that this proposal would benefit urban hospitals that are requesting § 412.103 rural reclassification at the same time as MDH status because it would synchronize effective dates to eliminate any payment consequences caused by a lag between effective dates for rural reclassification and MDH status.

Comment: Commenters supported this proposal and agreed with CMS that this policy to change the effective dates of SCH and MDH classifications will streamline the process, reduce burden, and align the SCH and MDH status timeline with the rural reclassification process in some cases. The commenters further agreed with CMS that this policy change would benefit hospitals by minimizing the disadvantages associated with a lag between reclassification and SCH or MDH status, and encouraged CMS to finalize this policy as proposed. Other commenters supported the proposal as a positive change expediting the effective date of these classifications but noted that the SCH and MDH regulations at § 412.92(b)(l)(i) and § 412.108(b)(2) require those applications to go to the MAC, rather than to CMS. The commenters therefore requested clarification regarding the proposed effective date of ''the date CMS receives the complete application''.

Response: We appreciate the commenters' support for our proposal as a positive change that would benefit hospitals by reducing burden and minimizing potential payment disadvantages. The commenters' observation that the regulations require that SCH and MDH applications be submitted to the MAC, rather than to CMS, is correct and we are making the appropriate changes in the regulation and clarifying our policy in the preamble to this final rule. Specifically, we are finalizing that the effective date of SCH and MDH classification status is the date that the MAC (rather than CMS) receives the complete application.

After consideration of the public comments we received, we are finalizing our proposed changes to § 412.92(b)(2)(i) and (b)(2)(iv), with modification, so that for applications received on or after October 1, 2018, the effective date for SCH classification and for the payment adjustment is the date that the MAC, rather than CMS, receives the complete SCH application. We also are finalizing with modification conforming changes to the effective date at § 412.92(b)(2)(ii) for instances when a court order or a determination by the PRRB reverses a CMS denial of SCH status and no further appeal is made, so that if the hospital's application for SCH status was received on or after October 1, 2018, the effective date is the date the MAC receives the complete application.

Similarly, we are finalizing our proposed changes to § 412.108(b)(4), with modification, to specify that for applications received on or after October 1, 2018, a determination of MDH status made by the MAC is effective as of the date the MAC receives the complete application.

4. Conforming Technical Changes to Regulations

We note that, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20403), we also proposed to make technical conforming changes to the regulations in § 412.92 and § 412.108 to reflect the change CMS made some time ago to identify fiscal intermediaries as Medicare administrative contractors (MACs).

We did not receive any public comments on the proposed conforming changes to the regulations text at §§ 412.92 and 412.108 to reflect the change CMS made some time ago to identify fiscal intermediaries as MACs. Therefore, in this final rule, we are adopting as final the proposed revisions to § 412.92 and § 412.108 without modification.

H. Hospital Readmissions Reduction Program: Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, amended by section 10309 of the Affordable Care Act, and further amended by section 15002 of the 21st Century Cures Act, established the Hospital Readmissions Reduction Program. Under the Program, Medicare payments under the acute inpatient prospective payment system for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare peer groups of hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions. We refer readers to section IV.E.1. of the preamble of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and section V.I.1. of the preamble of the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401);
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676);
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048);
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543);
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979); and
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240).

These rules describe the general framework for the implementation of the Hospital Readmissions Reduction Program, including: (1) The selection of measures for the applicable conditions/procedures; (2) the calculation of the excess readmission ratio, which is used,

in part, to calculate the payment adjustment factor; (3) beginning in FY 2018, the calculation of the proportion of ''dually eligible'' Medicare beneficiaries (described below) which is used to stratify hospitals into peer groups and establish the peer group median excess readmission ratios (ERRs); (4) the calculation of the payment adjustment factor, specifically addressing the base operating DRG payment amount, aggregate payments for excess readmissions (including calculating the peer group median ERRs), aggregate payments for all discharges, and the neutrality modifier; (5) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on *Hospital Compare;* (6) the adoption of an extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (7) the clarification that the public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* website as soon as is feasible following the Review and Correction period; and (8) the specification that the definition of ''applicable hospital'' does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and hospitals in Puerto Rico.

We also have codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154.

The Hospital Readmissions Reduction Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians, using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces costs and allows clinicians to focus on providing high quality health care for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital Readmissions Reduction Program incentivizes hospitals to improve health care quality and value, while giving patients the tools and information needed to make the best decisions for them.

We note that we received public comments on the effectiveness and design of the Hospital Readmissions Reduction Program in response to the FY 2019 IPPS/LTCH PPS proposed rule. While we appreciate the commenters' feedback, because we did not include in the proposed rule any proposals related to these topics, we consider the public comments to be out of the scope of the proposed rule. Therefore, we are not addressing most of these comments in this final rule. All other topics that we consider to be out of scope of the proposed rule will be taken into consideration when developing policies and program requirements for future years.

Comment: Several commenters requested that CMS study the continued viability of the Hospitals Readmissions Reduction Program. Some commenters believed that certain level of readmissions may be necessary for patient care as defined by medical research on this subject, which means some of the program's measures may have reached the point of diminishing returns. Other commenters expressed concerns about the possibility of unintended patient consequences resulting from the Hospital Readmissions Reduction Program, such as the potential for mortality to increase as readmissions decrease. Some commenters requested that CMS and/or AHRQ undertake a study on any unintended consequences arising from the program.

Response: We believe that the Hospital Readmissions Reduction Program has successfully reduced readmissions which are both harmful to patients and costly for the health care system. Patient well-being is one of our highest priorities, and we welcome any research reports pertaining to the unintended consequences of the program. We are committed to monitoring any unintended consequences over time, such as the inappropriate shifting of care or increased patient morbidity and mortality, to ensure that the Hospital Readmissions Reduction Program improves the lives of patients and reduces cost.

Comment: Some commenters suggested that CMS review the Hospital Readmissions Reduction Program in the context of all quality improvement programs, determine whether the program is worth retaining, and assess whether the program has achieved its purpose or should give way to a new approach.

Response: As part of the Meaningful Measures Initiative, which we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20404) and in greater detail below, we have taken a holistic approach to evaluating the appropriateness of the Hospital Readmissions Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs. The focus of the Hospital Readmissions Reduction Program is on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. In addition, we will continue to monitor the program to ensure that each program is meeting its intended goals within the larger context of CMS' value-based purchasing programs.

We would like to clarify for the commenters that the Hospital Readmissions Reduction Program is required by statute, and we cannot decline to administer it.

Comment: Several commenters expressed concern that, under the Hospital Readmissions Reduction Program, hospitals can undertake and perform reasonable acts to avoid readmissions, but still be penalized because their performance might remain relatively worse when compared to peer group hospitals' performance.

Response: We understand the commenters' concern. We continue to encourage hospitals to reduce avoidable readmissions through proven care coordination and communications quality improvement tools, such as CMS Quality Improvement and Innovation Network efforts (*https://qioprogram.org/qionews/topics/care-coordination*).

However, we note that the basic readmissions payment adjustment formula for assessing readmissions and penalties under the Hospital Readmissions Reduction Program are specified in the Act, and we are required to implement the statute as written. In particular, the 21st Century Cures Act, which amended section 1886(q) of the Act, directs the Hospital Readmissions Reduction Program to develop a transitional methodology based on dual-eligible beneficiaries that allows for separate comparisons for hospitals within peer groups to determine a hospital's payment adjustment factor. It also allows the program to consider other risk-adjustment methodologies, taking into account studies conducted and recommendations made by the Secretary in reports required under section 2(d)(1) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), Public Law 113–185. We will continue to review our risk-adjustment methodologies and monitor

our quality reporting and incentive programs for any unintended and negative consequences, and we will take the commenters' views into account when reviewing Hospital Readmissions Reduction Program data.

3. Summary of Policies for the Hospital Readmissions Reduction Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20403 through 20407), we proposed to: (1) Establish the applicable period for FY 2019, FY 2020 and FY 2021; (2) codify the previously adopted definition of ''dual-eligible''; (3) codify the previously adopted definition of ''proportion of dual-eligibles''; and (4) codify the previously adopted definition of ''applicable period for dual-eligibility.''

These proposals are described in more detail below.

4. Current Measures for FY 2019 and Subsequent Years

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia; total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG).

By publicly reporting quality data, we strive to prioritize patients by ensuring that they, along with their clinicians, are empowered to make decisions about their own healthcare using information aligned with meaningful quality measures. The Hospital Readmissions Reduction Program, together with the Hospital VBP Program and the HAC Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing to the inpatient care setting. We have undertaken efforts to review the existing measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative that we described in section I.A.2. of the preambles of the proposed rule (82 FR 20167 through 20168) and this final rule.

As part of this review, we have taken a holistic approach to evaluating the appropriateness of the Hospital Readmissions Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital VBP Program and the HAC Reduction Program), as well as the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable,—but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.

As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

Measures in the Hospital Readmissions Reduction Program are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting. By including these measures in the Program, we seek to encourage hospitals to address the serious problems indicated by the necessity of a hospital readmission and to reduce them and improve care coordination and communication. Therefore, after thoughtful review, we have determined that the six readmission measures in the Hospital Readmissions Reduction Program, which we proposed for removal from the Hospital IQR Program as discussed in section VIII.A.5.b.(3) of the preambles of the proposed rule and this final rule, are nevertheless appropriately included as part of the Hospital Readmissions Reduction Program.

We continue to believe that the measures that we have adopted adequately address the conditions and procedures specified in the Hospital Readmissions Reduction Program statute. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20404), we did not propose to adopt any new measures.

We note that we received public comments on the program's measures and our holistic approach to the value-based purchasing program and the program's measures. Because we did not propose any measure changes to the program in the FY 2019 IPPS/LTCH PPS proposed rule, we consider these public comments out of the scope of the proposed rule and, therefore, we are not addressing most of them in this final rule. All other topics that we consider to be out of the scope of the proposed rule will be taken into consideration when developing policies and program requirements for future years. However, we address some public comments pertaining to our holistic review of the value-based purchasing programs below.

Comment: Some commenters supported CMS' holistic view of the various hospital value-based purchasing programs and quality reporting programs in an effort to ease provider reporting burden and better focus quality and patient safety efforts. The commenters agree that the reduction of duplicative measures across various programs will help streamline quality measure reporting for hospitals, enhance provider focus on important clinical outcomes, and reduce cost. Other commenters appreciated and encouraged the greater focus on outcome focus rather than process.

Response: We thank the commenters for their support.

Comment: One commenter requested that CMS ensure ample time is provided to the organizations for implementation of new processes such as data collection measures/processes, operations change to align with the Meaningful Measures Initiative, and CMS' holistic approach to the value-based purchasing programs.

Response: We thank the commenter for its comment. As changes occur to implement these initiatives, we will, to the greatest extent possible, work to operationalize our policies in the most seamless way possible. In instances where we expect disruption to stakeholders, we will welcome an ongoing conversation to ensure that providers can continue to focus on patients.

Comment: One commenter opposed removing Hospital Readmissions Reduction Program measures from the Hospital IQR Program because the commenter believed that measures should be initially adopted into the Hospital IQR Program to allow for a period of measure validation, and for health systems to gain familiarity with the measures before they are moved into value-based programs. Other commenters requested that CMS require that any measures newly added to the Hospital Readmissions Reduction Program be publicly reported either in the Hospital IQR Program or within the program without penalty implications for at least 1 year to ensure that hospitals have time to familiarize themselves with the measure and that there are no adverse unintended consequences of the measure use. One commenter urged CMS to not introduce measures with financial impact on providers until after an initial transition period that allows hospitals and CMS to become accustomed to reporting and measuring these items.

Response: We are cognizant of stakeholder concerns and understand the importance of providing hospitals with an opportunity to gain familiarity with a quality measure prior to its implementation in a payment program. We will consider how to best implement new measures in the payment programs before proposing additional measures for the programs, but we do not believe it is appropriate to address how we would adopt new measures into the program at this time. We note also that we did not propose to add any measures to the Hospital Readmissions Reduction Program in the FY 2019 IPPS/LTCH PPS proposed rule.

We received numerous comments from stakeholders regarding our holistic approach to evaluating the appropriateness of measures previously adopted under the Hospital Readmissions Reduction Program, the Hospital VBP Program, the HAC Reduction Program, and the Hospital IQR Program and our vision for the future of these programs. While program-specific comments and policies are discussed in more detail in each program-specific section of this final rule, we would like to clarify that, in light of our mission to prioritize patients in the provision of services, we are expanding the stated scope of the Hospital VBP Program to include patient safety measures. While we initially sought to delineate measure focus areas between the Hospital VBP Program and the HAC Reduction Program, we agree with commenters that patient safety is a critical component of quality improvement efforts. Therefore, we believe it is appropriate and important to provide incentives under more than one program to ensure that hospitals take every reasonable precaution to avoid adverse patient safety events. In addition, we believe including patient safety measures in both the HAC Reduction Program and the Hospital VBP Program will best promote transparency through publicly reporting hospital performance on these measures, as stakeholders will be able to see both hospitals' performance compared to all other hospitals and hospitals' performance improvement over time. Finally, we note that this approach will also reduce provider burden associated with safety measure data collection and reporting because these measures are being finalized for removal from the Hospital IQR Program, as discussed in section VIII.A.5.b.(2) of the preamble of this final rule.

Comment: One commenter expressed concern about unintended consequences of making care coordination the sole feature of the Hospital Readmissions Reduction Program and not related measures in an incentive program. This commenter believed that, without the possibility of receiving an incentive payment for performing well, hospitals outside of the penalty portion of the programs would cease trying to improve.

Response: We thank the commenter for its comment. The Hospital Readmissions Reduction Program scores a hospital's performance in relation to its peer institutions' performance. We believe that peer comparison provides appropriate incentives for hospitals to strive for continuous improvement in readmission rates, while also recognizing the impacts of hospital case-mix and other characteristics on a hospital's performance rates.

5. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our website in the Measure Methodology Reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet website on the Resources page at: *http://www.qualitynet.org/dcs/ContentServer?=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995*.

6. Applicable Periods for FY 2019, FY 2020 and FY 2021

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of ''applicable period'' in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and payment adjustment factors for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The applicable period for dual-eligibles is the same as the applicable period that we otherwise adopt for purposes of the Program.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20405), for FY 2019, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2014 through June 30, 2017. In other words, we proposed that the proportion of dual-eligibles, excess readmissions ratios and the payment adjustment factors (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2019 would be calculated using data for

discharges occurring during the 3-year period of July 1, 2014 through June 30, 2017.

In the FY 2019 IPPS/LTCH PPS proposed rule, for FY 2020, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2015 through June 30, 2018. As noted earlier, we define the applicable period for dual-eligibles as the applicable period that we otherwise adopted for purposes of the Program; therefore, for FY 2020, the applicable period for dual-eligibles would be the 3-year period from July 1, 2015 through June 30, 2018.

In addition, in the FY 2019 IPPS/LTCH PPS proposed rule, for FY 2021, consistent with the definition specified at § 412.152, we proposed that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2016 through June 30, 2019. The applicable period for dual-eligibles for FY 2021 would similarly be the 3-year period from July 1, 2016 through June 30, 2019.

Comment: Some commenters supported the applicable periods for FY 2019, FY 2020, and FY 2021 as proposed.

Response: We thank commenters for their support.

Comment: Some commenters expressed concern about the proposed performance period for FY 2019 because it combines data collected under both the ICD–9 and ICD–10 coding sets. Commenters also requested that CMS provide further empirical analysis in the final rule to show that measure reliability and validity are not compromised by using two different coding systems and ensure that the ICD–10 versions of the measures in the Hospital Readmissions Reduction Program are NQF-endorsed as soon as practicable.

Response: As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38223), the readmission measures in the Hospital Readmissions Reduction Program all completed ''maintenance of endorsement,'' a periodic evaluation of measures to assess impact and potential unintended consequences, in December 2016 and are NQF-endorsed. The NQF requires developers to submit all ICD–9 and ICD–10 diagnosis and procedure codes used to define the measure cohorts. We identified all ICD–10 codes that corresponded with ICD–9 codes used in the measure cohort definitions using the General Equivalence Mappings tool (GEMs). The ICD–10 codes identified using GEMs were reviewed by measure and clinical experts and made public as a part of the maintenance of endorsement process. We will submit testing results in claims data coded with ICD–10 in future cycles of NQF endorsement maintenance.

In addition, we have examined changes in risk-standardized readmission rates at the hospital level and the distribution of changes in rates for all claims-based readmission measures, comparing the results of the 2015, 2016, 2017, and 2018 reporting periods. These analyses suggest no more than typical year-to-year variability in hospital-level rates before and after the introduction of ICD–10 codes for most measures. Year-to-year changes between 2015 and 2016, which both contained only ICD–9 claims, are similar to year-to-year changes for the following years, which included a mix of ICD–9 and ICD–10 claims. Risk-standardized readmission rates for 2018 public reporting are similar to those for 2015, 2016, and 2017 public reporting, which also indicates that the results using ICD–9 codes and ICD–10 codes are comparable. Overall, these results suggest that we have successfully created measure specifications in ICD–10 that align with the intent of the measure, which allows us to compare rates with measures calculated using ICD–9 codes and ICD–10 codes.

We will continue to use a 3-year measurement period rather than a 1-year measurement period, despite the implementation of ICD–10. We use a 3-year measurement period because some small and rural hospitals do not have at least 25 admissions for Medicare FFS patients who are 65 years and older for each of the measure conditions in a single year or even over the course of 2 years. The 3-year period allows us to include the maximum possible number of hospitals in scoring and public reporting.

Comment: One commenter encouraged CMS to include feedback from providers and other stakeholders through previewing model results prior to releasing hospital-specific reports.

Response: We thank commenter for its input. We agree with the need for transparency and providing stakeholders with data to confirm their dual proportion assignment. We also are seeking input from stakeholders and considering different options to provide hospitals with early individualized feedback regarding their peer grouping and payment adjustment.

Comment: One commenter believed that a 1-year performance period is more appropriate than the 3-year period because a 3-year performance period is too long, as some hospitals may demonstrate significant improvement year-over-year and it requires the combination of data from ICD–9 and ICD–10. Another commenter believed the lag time between actual performance and public reporting is troublesome as patients and hospitals may be relying on stale data. This commenter further recommended the consideration of electronic health records (EHRs) to derive more accurate and timely metrics.

Response: We continue to believe the 3-year period as codified at 42 CFR 412.152 is appropriate. We use a 3-year period of index admissions to increase the number of cases per hospital used for measure calculation, which improves the precision of each hospital's readmission estimate. While this approach utilizes older data, it also identifies more variation in hospital performance and still allows for improvement from one year of reporting to the next. We are maintaining the 3-year period as previously adopted because we continue to believe it balances the needs for the most recent claims and for sufficient time to process the claims data and calculate the measures to meet the program implementation timeline. With respect to EHRs, the Hospital Readmissions Reduction Program relies on claims data; therefore, we question whether EHRs would provide much more timely information.

After consideration of the public comments we received, we are finalizing as proposed, without modification, the applicable period of the 3-year time period of July 1, 2014 through June 30, 2017 for FY 2019; the applicable period of the 3-year time period July 1, 2015 through June 30, 2018 for FY 2020; and the applicable period of the 3-year time period of July 1, 2016 through June 30, 2019 for FY 2021 to calculate readmission payment adjustment factor for FYs 2019, FY 2020, and FY 2021, respectively, under the Hospital Readmissions Reduction Program.

7. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for such condition/procedure, using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each

Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2019 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–9–CM or ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, because diagnoses and procedure codes for discharges occurring prior to October 1, 2015 were reported under the ICD–9–CM code set, while discharges occurring on or after October 1, 2015 (FY 2016) were reported under the ICD–10–CM and ICD–10–PCS code sets.

We only identify Medicare FFS claims that meet the criteria described above for each applicable condition/procedure to calculate the aggregate payments for excess readmissions (that is, claims paid for under Medicare Part C or Medicare Advantage, are not included in this calculation). This policy is consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2019, we proposed to continue to exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20405), for FY 2019, we proposed to determine aggregate payments for excess readmissions, aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2014, and no later than June 30, 2017. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we will determine the neutrality modifier using the most recently available full year of MedPAR data. However, we noted that, for the purpose of modeling the proposed FY 2019 readmissions payment adjustment factors for the proposed rule, we used the proportion of dual-eligibles, excess readmissions ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2018 Hospital Readmissions Reduction Program applicable period. For the FY 2019 program year, applicable hospitals will have the opportunity to review and correct calculations based on the proposed FY 2019 applicable period of July 1, 2014 to June 30, 2017, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

In the proposed rule, for FY 2019, we proposed to use MedPAR data from July 1, 2014 through June 30, 2017 for FY 2019 Hospital Readmissions Reduction Program calculations. Specifically, for the final rule, we proposed to use the following MedPAR files—

- March 2015 update of the FY 2014 MedPAR file to identify claims within FY 2014 with discharges dates that are on or after July 1, 2014;
- March 2016 update of the FY 2015 MedPAR file to identify claims within FY 2015;
- March 2017 update of the FY 2016 MedPAR file to identify claims within FY 2016;
- March 2018 update of the FY 2017 MedPAR file to identify claims within FY 2017.

We did not receive any public comments on our proposal to use of the above stated MedPAR files, and therefore are finalizing as proposed, without modification, the use of the above listed MedPAR files to identify claims.

As discussed earlier, the final FY 2019 readmissions payment adjustment factors are not available at this time because hospitals have not yet had the opportunity to review and correct the data (program calculations based on the FY 2019 applicable period of July 1, 2014 to June 30, 2017) before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2019, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2019 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2018. We expect Table 15 will be posted on the CMS website in the fall of 2018.

8. Calculation of Payment Adjustment Factors for FY 2019 and Codification of Certain Definitions

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019.

To implement this provision, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237), we finalized several changes to the payment adjustment methodology for FY 2019. First, we finalized that an individual would be counted as a full-benefit dual-eligible patient if the beneficiary was identified as full-benefit dual status in the State Medicare Modernization Act (MMA) files for the month he/she was discharged from the hospital (82 FR 38226 through 38228). Second, we finalized our policy to define the proportion of full benefit dual-eligible beneficiaries as the proportion of dual-eligible patients among all Medicare FFS and Medicare Advantage stays (82 FR 38226 through 38228). Third, we finalized our policy to define the data period for determining dual-eligibility as the 3-year data period corresponding to the Program's applicable period (82 FR 38229). Fourth, we finalized our policy to stratify hospitals into quintiles, or five peer groups, based on their proportion of dual-eligible patients (82 FR 38229 through 38231). Finally, we finalized our policy to use the median Excess Readmission Ratio (ERR) for the hospital's peer group in place of 1.0 in the payment adjustment formula and apply a uniform modifier to maintain budget neutrality (82 FR 38231 through 38237). The payment adjustment formula would then be:

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM * Payment(dx) * \max\{(\text{ERR(dx)} - \text{Median peer group ERR(dx)}),0\})}{All\ payments}\}$$

where dx is AMI, HF, pneumonia, COPD, THA/TKA or CABG and payments refers to the base operating DRG payments. The payment reduction (1–P) resulting from use of the median ERR for the peer group is scaled by a

neutrality modifier (NM) to achieve budget neutrality. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the changes to the payment adjustment methodology, including alternatives considered, for FY 2019. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20406), we did not propose any changes to the methodology for FY 2019 or subsequent years. However, we proposed to codify our previously finalized definitions of ''applicable period for dual-eligibility'', ''dual-eligible'', and ''proportion of dual-eligibles'' at 42 CFR 412.152. The definitions which we proposed to codify are as follows:

- ''Applicable period for dual-eligibility'' is the 3-year data period corresponding to the applicable period as established by the Secretary for the Hospital Readmissions Reduction Program.
- ''Dual-eligible'' is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State MMA files for the month the beneficiary was discharged from the hospital.
- ''Proportion of dual-eligibles'' is the number of dual-eligible patients among all Medicare FFS and Medicare Advantage stays during the applicable period.

Comment: One commenter supported the proposal to codify the previously finalized definitions of applicable period for dual-eligibility, dual-eligible, and proportion of dual-eligibles. Several commenters supported the codification of previously adopted definitions for dual-eligibles to better assess disparate outcomes across patient populations at a given hospital.

Response: We thank commenters for their support.

Comment: Some commenters opposed the use of Medicare Advantage (MA) patients in the proportion of dual-eligibles definition and stated that CMS should base the peer group only on the share of FFS patients that are fully dual eligible, not on the share of all (FFS and MA) patients because the penalty does not apply to readmissions of MA patients. The commenters asserted that their risk characteristics could distort the risk profiles of hospitals because the income characteristics of FFS and MA patients may differ for particular hospitals. Other commenters opposed the use of dual-eligible as the basis for determining socioeconomic status because it does not necessarily reflect demographic or economic factors and conditions where the hospital is located or the patient resides.

Response: We would like to clarify that we did not propose any changes to the definition of dual-eligible; we merely proposed to codify it. As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221), we finalized using FFS and MA patients because calculating the dual proportion among all Medicare FFS and managed care patients more accurately represents the dual status of the hospital, particularly for hospitals in States with high managed care penetration rates. This approach enables more accurate and complete risk profiles for hospitals. There is a strong relationship between dual proportion and penalties under both the current methodology and proposed approaches, whether hospitals are stratified based on Medicare FFS patients only or based on both Medicare FFS and managed care patients. In general, this relationship is similarly positive; hospitals with higher dual proportions by either definition incur larger penalties, on average. However, the relationship between the penalty share of payments and dual proportion among FFS and managed care patients exhibits a slightly stronger upward trend. We refer readers to FY 2018 IPPS/LTCH PPS final rule (82 FR 38228 through 38229) for more information. Further, the statute directs the Secretary to use dual-eligibles to assign the peer groups during this transitional phase of risk-adjustment.

We did not propose changes with respect to our previously finalized proposals. However, commenters provided many suggestions on the Hospital Readmissions Reduction Program's risk-adjustment methodology. While we appreciate the commenters' feedback, we consider these topics to be out of the scope of the proposed rule. Therefore, we are not addressing most of them in this final rule. However, because there is stakeholder interest in this topic, we have included summaries of some of these comments with responses below. All other topics that we consider to be out of the scope of the proposed rule, even if not addressed below, will be taken into consideration when developing policies and program requirements for future years.

Comment: Some commenters supported the previously adopted payment adjustment methodology for FY 2019, which implemented the transitional methodology required by the 21st Century Cures Act. Commenters supported appropriate risk-adjustment methodology for the Hospital Readmissions Reduction Program. Commenters also supported organizing hospitals into peer groups and evaluating their performance in comparison to similar hospitals.

Response: We thank the commenters for their support.

Comment: Some commenters supported accounting for social risk factors in quality programs through peer grouping.

Response: We thank the commenters for their support.

Comment: One commenter recommended that, instead of peer groups, CMS find ways to direct additional resources to hospitals that serve the most disadvantaged populations to achieve health equity.

Response: We do not believe there is a provision in the statute that authorizes the Program to provide direct resources to hospitals. However, subparagraphs (D) and (E) to section 1886(q)(3) of the Act direct the Secretary to assign hospitals to peer groups, develop a methodology that allows for separate comparisons for hospitals within these groups, and allows for changes in the risk adjustment methodology. Following this transitional methodology, the Secretary is allowed to consider the recommendations in the reports required by the IMPACT Act related to risk adjustment and social risk factors to determine improved risk adjustment, but is not authorized to provide direct support to hospitals. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38222) for more information. We also note that many programs throughout HHS, run by CMS and other agencies, provide funding and support for ''safety net hospitals.''

Comment: Some commenters questioned whether five peer groups were the appropriate number of peer groups and whether there should be more peer groups. One commenter reiterated its recommendations to use statistical analysis to create what it posits as a more natural distribution of provider performance than quintiles. Another commenter provided a different statistical approach to determine hospital groupings. Commenters urged CMS to continuously evaluate this peer groupings to avoid unintended consequences.

Response: We would like to clarify that we did not propose any changes to the policy for five peer groups. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38229 through 38231), we finalized stratifying hospitals into quintiles (five peer groups) because that policy creates peer groups that accurately reflect the relationship between the proportion of dual-eligible patients in the hospital's population without the disadvantage of establishing a larger number of peer groups. We continue to believe

preselecting peer groups of equal size and choosing the size that best meets these objectives is transparent and effective. In the future, more flexible methods for peer group formation may be considered for implementation. Any approach must be evaluated based on multiple criteria, including those described above and proposed through the rulemaking process.

Comment: Some commenters supported assignment of hospitals to peer groups (quintiles) as a first step of accounting for social risk factors, but encouraged CMS to continue to work with stakeholders to develop appropriate risk-adjustment methodologies. Commenters believed that stratifying performance by the hospital's number of dual-eligible patients is only a temporary solution, and recommended that CMS take steps to ensure that individual measures account for socio-demographic status (SDS) in the measure level risk adjustment model. Commenters asked CMS to consider whether it should continue to use dual-eligibility as an adjustment variable and whether it should move from the current peer grouping approach to one that incorporates one or more socioeconomic variables into the risk-adjustment model of Hospital Readmissions Reduction Program measures. Commenters supported CMS' efforts to adjust for socioeconomic factors. However, these commenters urged continued refinements to stay current with evolving measurement science around accounting for social risk factors.

Response: As required by the 21st Century Cures Act, we are stratifying hospitals based on dual-eligible proportion and modifying the payment adjustment factor formula to assess a hospital's performance relative to other hospitals in its peer group. This approach is transparent. We believe this approach achieves both the goal of holding all hospitals to a high standard while also ensuring we are not disproportionally penalizing hospitals serving an at-risk population. Section 1886(q)(3)(E)(i) of the Act allows the Secretary to consider studies conducted and recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act in the application of risk adjustment methodologies. We will continue to monitor the progress and findings of research the Assistant Secretary for Planning and Evaluation (ASPE) is conducting as part of its IMPACT Act study and the National Quality Forum's trial period and will consider their recommendations. We also will continue to monitor the impact of accounting for dual-eligible patients in the Hospital Readmissions Reduction Program and evaluate whether future changes to include other variables or adjustments are needed. For more information, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38222).

Comment: Some commenters believed that peer grouping by dual-eligibility has limitations or flaws limitations as a risk-adjustment method, and urged CMS to consider whether it should continue to use dual-eligibility as the adjustment variable and whether to move from the current peer grouping approach to one in which it incorporates one or more socioeconomic variables into the risk adjustment models of the Hospital Readmissions Reduction Program measures (that is, direct risk adjustment). Commenters encouraged CMS to review the evolving measurement science continually and consider NQF and National Academy of Medicine concepts as it considers best ways to risk-adjust quality measures for social factors. Other commenters urged CMS to include factors related to a patient's background—including SDS, language, and post-discharge support structure—in measure development and risk-adjustment methodology. Still other commenters recommended that CMS use census data, distressed community index, or location information to determine socioeconomic adjustment.

Response: We will continue to monitor the impact of accounting for dual-eligible patients in the Hospital Readmissions Reduction Program and evaluate whether future changes to include other variables or adjustments are needed. As we have previously noted, the Hospital Readmissions Reduction Program is required by section 1886(q)(3)(D) of the Act to use dual-eligible beneficiaries for hospital's adjustment factor beginning in FY 2019, and until the application of section 1886(q)(3)(E)(i) of the Act, at which point the Secretary may consider other risk-adjustment methodologies, taking into account the reports mandated by the IMPACT Act. The second and final report is scheduled for release in October 2019. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38222) for more information.

Comment: One commenter urged CMS to not use social risk factors to adjust quality measures for transparency and payment.

Response: We thank the commenter for its comment. However, we note Congress mandated that the Hospital Readmissions Reduction Program account for social risk factors when it added subparagraphs (D) and (E) to section 1886(q)(3) of the Act directing the Secretary to assign hospitals to peer groups, develop a methodology that allows for separate comparisons for hospitals within these groups, and allows for changes in the risk adjustment methodology. As we have noted previously, the goal of risk adjustment is to account for factors that are inherent to the patient at the time of admission, such as severity of disease to put hospitals on a level playing field. The measures should not be risk-adjusted to account for differences in practice patterns that lead to lower or higher risk for patients to be readmitted. The measures aim to reveal differences related to the patterns of care.

After consideration of the public comments we received, we are finalizing as proposed, without modification, our decision to codify the definitions of ''applicable period for dual-eligibility''; ''dual-eligible''; and ''proportion of dual-eligibles'' as stated above at 42 CFR 412.152.

9. Calculation of Payment Adjustment for FY 2019

Section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions, and (ii) the aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified in our regulations at § 412.154(c)(2), for FY 2019, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2019, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

Comment: One commenter supported budget neutral adjustment approach directed by the 21st Century Cures Act.

Response: We thank the commenter for its support.

Comment: Another commenter addressed what it believed is a methodological flaw in the statutory design of the penalty calculation. However, this commenter agreed that only Congress has the authority to amend the statute to correct the calculations.

Response: We thank the commenter for the feedback. As the commenter noted, we are bound by the statute's direction.

After consideration of the public comments we received, we are finalizing as proposed, without modification, the calculation of payment adjustment for FY 2019.

10. Accounting for Social Risk Factors in the Hospital Readmissions Reduction Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20406 through 20407), we discussed accounting for social risk factors in the Hospital Readmissions Reduction Program.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237 through 38239), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[230] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[231] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[232] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[233] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

While we did not specifically request public comment on social risk factors in the FY 2019 IPPS/LTCH PPS proposed rule, we received a number of comments with respect to social risk factors. We thank commenters for sharing their views and their willingness to support the efforts of CMS and NQF on this important issue. We will take this feedback into account as we continue to review social risk factors on an ongoing and continuous basis. In addition, we both welcome and appreciate stakeholder feedback as we continue our work on these issues.

[230] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[231] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[232] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[233] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

I. Hospital Value-Based Purchasing (VBP) Program: Policy Changes

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 57011); the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38240 through 38269).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2019 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details.

Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2019 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2019 is approximately $1.9 billion, based on the March 2018 update of the FY 2017 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2019, on a per-claim basis. We published proxy value-based incentive payment adjustment factors in Table 16 associated with the FY 2019 IPPS/LTCH PPS proposed rule (which is available via the internet on the CMS website). We are publishing updated proxy value-based incentive payment adjustment factors in Table 16A associated with this final rule (which is available via the internet on the CMS website). The proxy factors are based on the TPS from the FY 2018 program year. These FY 2018 performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. The updated slope of the linear exchange function used to calculate the proxy value-based incentive payment adjustment factors in Table 16A is 2.8887004713. This slope, along with the estimated amount available for value-based incentive payments, has been updated based on the March 2018 update to the FY 2017 MedPAR file and is also published in Table 16A (which is available via the internet on the CMS website).

After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2019, we will post Table 16B (which will be available via the internet on the CMS website) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2019 program year. We expect Table 16B will be posted on the CMS website in the fall of 2018.

2. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Clarification of the Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20408), we did not propose any changes to this policy.

In the FY 2019 IPPS/LTCH/PPS proposed rule (83 FR 20408), we proposed to revise our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program (that is, we have selected the measure from the Hospital IQR Program measure set and included data on that measure on *Hospital Compare* for at least one year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP statute does not require that the measure continue to remain in the Hospital IQR Program. We stated that the proposed revision to the regulation text would clarify that Hospital VBP Program measures will be selected from the measures specified under the Hospital IQR Program, but the Hospital VBP Program measure set will not necessarily be a subset of the Hospital IQR Program measure set. As discussed in section I.A.2. of the preamble of this final rule, we are engaging in efforts aimed at evaluating and streamlining regulations with the goal to reduce unnecessary costs, increase efficiencies, and improve beneficiary experience. In the FY 2019 IPPS/LTCH PPS proposed rule, we stated that this proposal would reduce costs, such as those discussed in section IV.I.2.b. of the preamble of the proposed rule, by allowing us to remove duplicative measures from the Hospital IQR Program that are retained in the Hospital VBP Program.

Comment: A number of commenters supported CMS' proposal to revise its regulations to clarify that once CMS has complied with the statutory prerequisites for the Hospital VBP Program, the Hospital VBP Program statute does not require that a measure continue to remain in the Hospital IQR Program. These commenters agreed that clarifying these statutory requirements would reduce the complexity and costs associated with maintaining duplicative measures across CMS quality programs.

One commenter also expressed its belief that this clarification would allow for more focused quality improvement efforts by hospitals and result in streamlined public reporting, which would be easier for the public to understand.

Response: We thank the commenters for their support.

Comment: Some commenters did not support CMS' proposal to clarify the Hospital VBP Program's regulations. These commenters expressed their belief that CMS lacks the statutory authority to remove a measure from the Hospital IQR Program that is being used in the Hospital VBP Program, and further asserted that removing such a measure would undermine the statutory requirements that created and preserve the Hospital IQR Program. Other commenters stated that initially adopting measures into the Hospital IQR Program allows for a period of measure validation and for health systems to gain familiarity with the measures before they are moved into value-based purchasing programs, and expressed concern CMS' ''holistic'' view would allow new measures to be adopted immediately into the value-based purchasing programs without this time for familiarization and validation. These commenters stated their belief that adopting measures directly into the value-based purchasing programs would result in significant harm, undue hardship, and potentially financial penalties on healthcare systems.

Other commenters expressed confusion regarding the proposed revisions to the Hospital VBP Program's regulatory text, and requested clarification about whether measures would continue to be adopted in the Hospital IQR Program and publicly reported on *Hospital Compare* for one year prior to adoption in the Hospital VBP Program.

Response: We thank the commenters for their comments, but emphasize that our proposal to revise the Hospital VBP Program regulations at 42 CFR 412.164(a) does not affect the underlying statutory requirements of the Hospital VBP or Hospital IQR Programs. As required under sections 1886(o)(2)(A) and 1886(o)(2)(C)(i) of the Act, we will continue to select measures for the Hospital VBP Program that have been specified for the Hospital IQR Program and refrain from beginning the performance period for any new measure until the data on that measure have been posted on *Hospital Compare* for at least one year. We note the statute does not require a measure that has met these statutory requirements to remain in the Hospital IQR Program at the same time as the Hospital VBP Program. The proposed revisions to the regulatory text only clarify that after a measure has met the above requirements and been adopted into the Hospital VBP Program measure set, it can be removed from the Hospital IQR Program measure set. We, therefore, disagree that this revision could result in harm, undue hardship, or financial penalties to hospitals because it does not alter the processes associated with adopting a new measure into the Hospital VBP Program.

We also disagree that removing measures from the Hospital IQR Program after adoption by the Hospital VBP Program undermines the Hospital IQR Program's statutory requirements or purpose. The Hospital IQR Program will continue to serve as the primary quality reporting program for the inpatient hospital setting of care, and its authority to collect and report data is unaffected by this revision to the Hospital VBP Program's regulatory text. We believe removing certain measures from the Hospital IQR Program that have transitioned to the Hospital VBP Program will better enable the Hospital IQR Program to consider new quality measures and collect and publicly report these data for both patients and providers without imposing an unduly high burden on providers.

Comment: A number of commenters did not support CMS' proposal to clarify the Hospital VBP Program's regulations due to concerns this clarification would reduce transparency in public reporting. Some commenters noted that the Hospital IQR Program publicly reports measure performance data but the Hospital VBP Program only reports program-specific performance scores for its measures and domains, which are not meaningful to consumers and are only indirectly tied to actual data. These commenters, therefore, expressed concern that the Hospital VBP Program's current public reporting is an insufficient substitute for the Hospital IQR Program's measure-specific reporting. A few commenters also noted that the Hospital IQR Program and *Hospital Compare* have a carefully outlined process for reviewing measure data with hospitals before releasing that data to the public, and expressed their belief that measures must be in the Hospital IQR Program in order to undergo this process. One commenter observed that the Hospital VBP Program is built around the Hospital IQR Program reporting infrastructure to establish a progression of measures to promote higher quality of care, and should be maintained as such. A number of commenters requested CMS ensure that measure-level results continue to be reported on *Hospital Compare* for all measures in the Hospital VBP program to ensure that there is no loss of information to the public. One commenter further requested that CMS consider the impact of measure removals from the Hospital IQR Program for hospitals that do not participate in the Hospital VBP Program and the potential effect on public reporting of data for these hospitals.

Response: We thank commenters for sharing their concerns, and clarify that we will continue to report measure-level data for all of CMS' quality programs in a manner that is transparent and easily understood by patients. We note that section 1886(o)(10)(A) of the Act requires the Hospital VBP Program to make information available to the public regarding the performance of individual hospitals, including performance with respect to each measure, on the *Hospital Compare* website in an easily understandable format. We currently publicly report hospital-specific measure-level information from the Hospital VBP Program along with program-specific scores, and we will continue to solicit input from and share updates with stakeholders as we move forward with plans to publicly report Hospital VBP Program data in order to ensure the publicly reported information is sufficiently streamlined to avoid confusion while also providing the information necessary to assist patients in making decisions about their care. We therefore clarify that we will continue to publicly report the quality measure data for those measures removed from the Hospital IQR Program but kept in the Hospital VBP program on the *Hospital Compare* website in a manner similar to the way the data have previously been reported under the Hospital IQR Program. We will also take commenters' concerns regarding public reporting of data for hospitals not included or not participating in the Hospital VBP Program into account as we continue to assess public reporting options.

After consideration of the public comments we received, we are finalizing the proposed revisions to our regulations at 42 CFR 412.164(a).

b. Measure Removal Factors for the Hospital VBP Program

As discussed earlier, we have adopted a policy to generally retain measures from prior year's Hospital VBP Program for subsequent years' measure sets unless otherwise proposed and finalized. We have previously removed measures from the Hospital VBP Program for reasons such as being topped out (80 FR 49550), the measure

does not align with current clinical guidelines or practices (78 FR 50680 through 50681), a more applicable measure was available (82 FR 38242 through 38244), there was insufficient evidence that the measure leads to better outcomes (78 FR 50680 through 50681), another measure was more closely linked to better outcomes (77 FR 53582 through 53584, and 53592), the measure led to unintended consequences (82 FR 38242 through 38244), and impossibility of calculating a score (82 FR 38242 through 38244).

The reasons we cited above to support the removal of measures from the Hospital VBP Program generally align with measure removal factors that have been adopted by the Hospital IQR Program. We believe that these factors are also applicable in evaluating Hospital VBP Program quality measures for removal, and that their adoption in the Hospital VBP Program will help ensure consistency in our measure evaluation methodology across our programs. Accordingly, in the FY 2019 IPPS/LTCH/PPS proposed rule (83 FR 20408 through 20409), we proposed to adopt the Hospital IQR Program measure removal factors that we finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and further refined in the FY 2015 IPPS/LTCH PPS and FY 2016 IPPS/LTCH PPS final rules (79 FR 50203 through 50204 and 80 FR 49641 through 49643, respectively) for use in determining whether to remove Hospital VBP Program measures:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures), defined as: Statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10; [234]
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings or populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- Factor 7. It is not feasible to implement the measure specifications.

We noted that these removal factors would be considerations taken into account when deciding whether or not to remove measures, not firm requirements. We continue to believe that there may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure.

Also, in alignment with proposals that were made for other quality reporting and value-based purchasing programs, we proposed to adopt the following additional factor to consider when evaluating measures for removal from the Hospital VBP Program measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of the preamble of the proposed rule with respect to our new Meaningful Measures Initiative and in this final rule, we are engaging in efforts to ensure that the Hospital VBP Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the Hospital VBP Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the Hospital VBP Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the Hospital VBP Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

Comment: Several commenters supported the adoption of the seven measure removal factors previously adopted by the Hospital IQR Program into the Hospital VBP Program. A few commenters stated that adoption of these factors would allow for consistency in measure evaluation methodology across programs. One commenter believed that the factors are well-established and ensure that a variety of valid reasons to remove a measure are considered by CMS. Another commenter agreed the seven measure removal factors improve the

[234] We previously adopted the two criteria for determining the ''topped-out'' status of Hospital VBP Program measures in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50055).

usefulness of accepted quality measures included in the Hospital VBP Program (that is, they make them align with clinical practice, relate to good patient outcomes, do not lead to unintended adverse consequences, are feasible, and have room for improvement) and uphold the purpose behind the program to improve patient care and reduce Medicare costs. A third commenter expressed appreciation that these factors are guidelines and not firm requirements.

Response: We thank commenters for their support.

Comment: One commenter did not support adoption of measure removal Factor 1, ''measure performance among hospitals is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made (''topped out'' measures)'' because the commenter believed removal of a measure immediately upon a ''topped out'' analysis would eliminate the ability to determine whether performance regresses or that the removal of the measure may result in lower quality of care over the long term. The commenter recommended CMS either consolidate measures that meet the ''topped out'' criteria but are still considered meaningful to stakeholders into a composite measure or include them as an evidence-based standard in a verification program. The commenter further recommended that CMS ask measure stewards for different data sources which may demonstrate a gap in performance, as well as assess whether a measure is topped-out across all provider types and all sub-groups of patients to identify any potential gaps before proposing to remove the measure.

Response: We thank commenter for its recommendations. As we discussed in the proposed rule, the removal factors are intended to be considerations taken into account when deciding whether or not to remove measures, but are not firm requirements. There may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure. We intend to take multiple considerations into account when determining whether to propose a measure for removal under Factor 1 or any of the other removal factors.

Comment: A few commenters did not support the adoption of measure removal Factor 4, ''performance or improvement on a measure does not result in better patient outcomes'' for the Hospital VBP Program because the commenters were concerned the factor could be used as a reason to remove any measure that is not directly linked to clinical outcomes. These commenters asserted there is value in including multiple types of measures in the Hospital VBP Program, not just outcomes-related measures.

Response: As we discussed in the proposed rule, the removal factors are intended to be considerations taken into account when deciding whether or not to remove measures, but are not firm requirements. There may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure. Although we strive to have measures in our programs that can drive improvement in patient health outcomes, we agree that other types of measures may be of value to the program as well.

Comment: A few commenters did not support the adoption of measure removal Factor 6, ''collection or public reporting of a measure leads to negative unintended consequences other than patient harm,'' because the commenters believed hospitals often claim unintended consequences as a reason to oppose quality measurement without offering evidence to support such claims. The commenters therefore recommended that CMS require documented evidence of real consequences as opposed to potential or speculative consequences before removing a measure under this factor.

Response: We thank commenters for their recommendation. We intend to take multiple sources of evidence into account when proposing to remove measures under any of the removal factors and always welcome stakeholder input.

Comment: Many commenters supported the addition of measure removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program'' to the Hospital VBP Program. Several commenters supported the adoption of measure removal Factor 8 for the Hospital VBP Program because they believe it is appropriate for CMS to consider the costs to providers and the agency itself in considering whether to remove a measure under this factor. A number of commenters stated that they believed the proposed new removal factor will provide CMS the flexibility to streamline measures to meet the goals of the Meaningful Measures Initiative by reducing measures that are inappropriately burdensome and ensuring greater consistency in measure evaluation methodologies across programs. A few commenters expressed their agreement that the five types of costs outlined in the proposed rule are important to consider when creating new or revised meaningful measures for quality and value-based payment programs. Another commenter believed that eliminating measures that are costly and have a limited benefit to program objectives allows providers to focus more efforts on reporting and improving performance on measures that benefit provider patient populations.

Response: We thank commenters for their support. We note that the five types of costs listed in the FY 2019 IPPS/LTCH PPS proposed rule were intended to provide examples of costs we would assess when removing a measure under measure removal Factor 8, and were not intended to comprise an exhaustive list of cost types. Costs assessed under this measure removal factor would include direct and indirect costs, financial and otherwise, to stakeholders including but not limited to, patients, caregivers, providers, CMS, healthcare researchers, healthcare purchasers, and other entities. We also believe that while a measure's use in the Hospital VBP Program may benefit many entities, a key benefit is to patients and their caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available.

Comment: Several commenters that supported the adoption of measure removal Factor 8 also requested additional information and transparency on the factors used to determine costs and benefits, including factors that deem the cost to be burdensome, whether the costs exceed the benefits, the nature of the burden that the removal of a measure relieves, and methods or criteria used to assess when the measure cost or burden outweighs the benefits of retaining it. One commenter supported measure removal Factor 8, but did not agree with how CMS applied its cost assumptions, questioning how costs can be reduced for hospitals by removing a measure from one program when the measure remains in another program.

Response: We intend to be transparent in our assessment of measures under this measure removal factor. As described above, there are various considerations of costs and benefits, direct and indirect, financial and otherwise, that we will evaluate in applying removal Factor 8, and we will take into consideration the perspectives of multiple stakeholders. However, because we intend to evaluate each

measure on a case-by-case basis, and each measure has been adopted to fill different needs in the Hospital VBP Program, we do not believe it would be meaningful to identify a specific set of assessment criteria to apply to all measures. We believe costs include costs to stakeholders such as patients, caregivers, providers, CMS, and other entities. In addition, we note that the benefits we will consider center around benefits to patients and caregivers as the primary beneficiaries of our quality reporting and value-based payment programs. When we propose to remove a measure under this measure removal factor, we will provide information on the costs and benefits we considered in evaluating the measure.

We also recognize that hospitals would still be required to monitor measures removed from one program but retained in another quality program. However, we believe that the simplification benefits hospitals because they will no longer be required to identify discrepancies in reporting and identify whether those discrepancies are due to differing measure specifications or due to potential CMS measure calculation error. Furthermore, we believe this simplification will benefit patients and caregivers because they will not need to review data submitted on the same or similar metrics through multiple programs to compare quality of care across multiple providers.

Comment: Several commenters supported the adoption of measure removal Factor 8 but also recommended specific things the commenters believed CMS should consider in the assessment of costs and benefits, including: The mode of data collection and reporting; input from relevant clinical experts and patient perspectives; the value of consistency in program measure sets; whether removing measures creates a gap in the measure set; resources required for providers to perform well on the measure; costs associated with contracting out or otherwise paying external vendors; costs associated with adding processes to collect data to inform the measure; whether new processes added to collect data on the measure will duplicate efforts with existing tasks; and whether the process involves completing more steps or tasks as it produces outputs for measurement. Commenters also requested that CMS clarify the process for seeking input of stakeholders in the decision-making process.

Response: We note that in our proposal to adopt this measure removal factor (83 FR 20409), we stated that we will evaluate costs and benefits on a case-by-case basis and identified several types of costs to provide examples of costs which we would evaluate in this analysis. These costs include, but are not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including maintenance and public display; and/or (5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable). This was not intended to be a complete list of the potential factors to consider in evaluating measures.

The other factors suggested by commenters are additional factors that we will consider in evaluating the costs and benefits of each measure on a case-by-case basis under measure removal Factor 8. For example, resources for quality improvement is an example of a cost that would be evaluated on a case-by-case basis because we believe that investing resources in quality improvement is an inherent part of delivering high-quality, patient-centered care, and is therefore, generally not considered a part of the quality reporting program requirements. However, there may be cases where a measure would require such a specific quality improvement initiative that it would be appropriate to consider this cost to be associated with the measure. We also value transparency in our processes, and continually seek stakeholder input through education and outreach activities, such as webinars and national provider calls, stakeholder listening sessions, through rulemaking, and other collaborative engagements with stakeholders.

Comment: Several commenters did not support the adoption of proposed measure removal Factor 8 because commenters believed the factor may not adequately consider the value a measure holds for beneficiaries or consumers, and other commenters requested additional information about how the calculation applies to beneficiaries. Some commenters recommended that CMS develop a standardized evaluation and scoring system with multi-stakeholder input to ensure measure removal Factor 8 appropriately balances the needs of all healthcare stakeholders, and to consider how beneficiary decision-making occurs and ensure that policies do not demand beneficiaries make life-altering decisions based on scant information, inadequate tools, or insufficient assistance. A few commenters requested that CMS adopt a more inclusive process that accounts for the perspective of both patients and clinicians when making measure removal determinations.

Response: We believe that various stakeholders may have different perspectives on how to define costs as well as benefits. Because of these challenges, we intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs (financial and otherwise) of maintaining the specific measure in the Hospital VBP Program. However, we also agree that while a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing high-quality care and providing publicly reported data regarding the quality of care available. We note that we intend to assess the costs and benefits to program stakeholders, including but not limited to, those listed above.

Comment: A few commenters that did not support adoption of removal measure removal Factor 8 expressed concern that the proposal does not define how burden and benefits would be evaluated or weighted. One commenter asked how that definition is to be tested and what results will empirically determine whether there is, or is not, a cost-benefit of the measure.

Response: We believe that various stakeholders may have different perspectives on how to define costs as well as benefits. Because of these challenges, we intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs, financial and otherwise, of maintaining the specific measure in the Hospital VBP Program. We note that we intend to assess the costs and benefits to all program stakeholders, including but not limited to, those listed above. We do not believe it is necessary to

empirically test measure removal factors. These factors are part of a coordinated approach to developing a balanced measure set, and may affect measures in different programs differently because of the specific needs of each program

Comment: A few commenters that did not support removal Factor 8 expressed concern that the proposal did not reference the cost to patients or to the Medicare program for the treatment people may need following events. One commenter asserted it is difficult to measure the benefits to Medicare beneficiaries (such as good quality of care, timely care, good communication between providers and individuals and their family caregivers, and quality of life) using a dollar metric. Another commenter recommended that CMS also consider whether a more efficient alternative reporting method is available to collect the performance data under this analysis. This commenter further stated that any assessments of the benefits of continued use of a given measure must account for the public's right to quality and cost transparency and consumers' reliance on publicly available information to make important healthcare decisions, in addition to the potential impact of the measure on improving care quality (for example, size of performance gap).

Response: We do intend to assess the costs and benefits to a variety of program stakeholders, including but not limited to, those listed above. As noted, the list of potential costs we described in the proposed rule was not intended to be a complete list of the potential factors to consider in evaluating measures. The other factors suggested by commenters are additional factors that we will consider in evaluating the costs and benefits of each measure on a case-by-case basis under measure removal Factor 8. We also agree with the commenter that it is useful to consider whether a more efficient alternative is available to collect performance data and believe it would be appropriate to consider this in our evaluation of measures under measure removal Factor 8. While a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing provision of high quality care and through providing publicly reported data regarding the quality of care available. Therefore, we intend to consider the benefits, especially those to patients and their families, when evaluating measures under this measure removal factor.

Comment: A few commenters that did not support measure removal Factor 8 expressed concern that focusing on cost alone may be problematic and does not reflect the potential for assessing or improving care quality that are important to patients and families.

Response: We intend to balance the costs with the benefits to a variety of stakeholders. These stakeholders include, but are not limited to, patients and their families or caregivers, providers, the healthcare research community, healthcare purchasers, and patient and family advocates. Because for each measure the relative benefit to each stakeholder may vary, we believe that the benefits to be evaluated for each measure are specific to the measure and the original rationale for including the measure in the program.

We also understand that while a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted, and are illustrated through the domains of the Meaningful Measures Initiative. When the costs associated with a measure outweigh the evidence supporting the benefits to patients with the continued use of a measure in the Hospital VBP Program we believe it may be appropriate to remove the measure from the program.

Comment: One commenter expressed its belief that a fair and appropriate number of measures should be retained in the Hospital VBP Program and that measure removals and adoptions should take into account the time and resources required to adjust and adapt to changing program requirements. The commenter specifically recommended that CMS implement a standard 24-month timeline for measure adoptions and removals in order to allow hospitals time to budget, plan, adopt, and operationalize any necessary changes to their plans and workflows.

Response: We attempt to ensure that a fair and appropriate number of measures are retained in the Hospital VBP Program. We note that in our proposal to adopt this measure removal factor (83 FR 20409), we stated that we will evaluate costs and benefits on a case-by-case basis and identified several types of costs to provide examples of costs which we would evaluate in this analysis. These costs include, but are not limited to, those listed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20409). This was not intended to be a complete list of the potential factors to consider in evaluating measures. The other factors suggested by commenters are additional factors that we will consider in evaluating the costs and benefits of each measure on a case-by-case basis under measure removal Factor 8. Regarding commenter's recommendation to implement a 24-month timeline for measure adoptions and removals, we do not believe such a timeline is necessary to adopt a measure given that hospitals would have been reporting measure data under the Hospital IQR Program prior to adoption into the Hospital VBP Program. We also believe it is important to retain flexibility in the timing of removing measures from the program, especially when we have determined that the costs of continued use in the program outweigh the benefits.

Comment: One commenter recommended that CMS adopt an additional removal factor addressing measure reliability and/or validity, under which CMS would remove an existing measure from the program when a new measure that provides results which are more reliable and/or valid becomes available. The commenter expressed its belief that such a factor would better recognize that as measure development and implementation become more sophisticated, these new measures are better able to precisely and accurately represent the quality of care provided to patients.

Response: We thank the commenter for its suggestion and will take this under consideration when considering future policies for the program. We consider validity and reliability in determining whether to adopt a measure and will continue to do so as we evaluate the ongoing measure sets.

Comment: One commenter recommended that the Hospital VBP Program also adopt measure retention factors, such as: (1) Measure aligns with other CMS and HHS policy goals; (2) measure aligns with other CMS programs, including other quality reporting programs; and (3) measure supports efforts to move the program towards reporting electronic measures.

Response: We note that the Hospital VBP Program currently has a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. We thank commenter for their suggestions and also note that under the Meaningful Measures Initiative, as described in section I.A.2. of the preambles of the proposed rule and in this final rule, we will take into

consideration measures that could allow us to align across programs and/or with other payers, as well as to minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures).

After consideration of the public comments we received, we are finalizing our proposals to adopt for the Hospital VBP Program the measure removal factors currently in the Hospital IQR Program, and a measure removal Factor 8, where ''the costs associated with a measure outweigh the benefit of its continued use in the program'' beginning with FY 2019 program year.

In addition to the proposals discussed above, to further align with policies adopted in the Hospital IQR Program (74 FR 43864), we proposed that if we believe continued use of a measure in the Hospital VBP Program poses specific patient safety concerns, we may promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure along with the reasons for its removal through routine communication channels to hospital, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website. We would then confirm the removal of the measure from the Hospital VBP Program measure set in the next IPPS rulemaking. In circumstances where we do not believe that continued use of a measure raises specific patient safety concerns, we would use the regular rulemaking process to remove a measure.

Comment: Several commenters supported the proposal to remove a measure from the Hospital VBP Program without rulemaking if it poses a patient safety concern.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS be transparent in the process for determining if a measure meets this criterion and to promptly respond to stakeholders' concerns when potential patient safety concerns are identified. One commenter recommended use of the rulemaking process and stakeholder input wherever possible because partnership in reaching measure consensus will help to avoid unintended consequences for all. Another commenter requested clarification on the level of evidence needed to rapidly remove a measure from a program without rulemaking. A third commenter recommended that CMS continuously monitor the impact of measures and emerging literature to better position itself to remove measures proactively before widespread patient harm occurs rather than after harm has already occurred.

Response: We thank commenters for their recommendations. We intend to be transparent about our concerns and seek input from relevant stakeholders when possible, depending on the urgency of the patient safety concern. While we do not believe it is possible to anticipate the exact level of evidence that would be required to take such action, we would take such considerations seriously and do not anticipate making such a decision based on scant evidence. Rather, we believe that a high level of evidence would be required in most circumstances, depending on the patient safety concern at issue, such as consistent evidence from multiple sources. We currently monitor various sources to assess impacts and effects of measures and plan to continue doing so.

Comment: A few commenters did not support CMS' proposal to remove measures for patient safety concerns without rulemaking. Other commenters expressed concern with circumventing the rulemaking process and delaying opportunity for public comment from multiple stakeholders. One commenter expressed concern because numerous public and private purchasers have come to employ measures from the Hospital VBP Program in their own accountability strategies. Another commenter expressed concern with how this approach may impact a hospital's overall performance score and payment adjustment, especially for safety-net hospitals and those operating in underserved areas that treat a disproportionate share of high risk patients. A third commenter recommended that this authority should be used narrowly and rarely, if at all, and only in the most urgent of circumstances. This commenter also recommended that it be exercised transparently in ways that prioritize beneficiary safety and access to information, and, if it is used, to seek public comment, at that time, on continued use of this authority.

Response: We thank the commenters for their input. We intend to use this authority narrowly and in only those circumstances that pose specific and serious patient safety concerns. Although we may take this action outside of rulemaking, we intend to be transparent about concerns and seek input from relevant stakeholders to the extent possible, depending on the urgency of the concern. We also appreciate commenter's concern regarding the impact of a measure removal under this policy on a hospital's overall performance score and payment adjustment, and will attempt to mitigate such impacts to the extent program requirements may allow. While we note that we would remove a measure under this policy based on specific patient safety concerns, we would also analyze the potential impacts on scoring and payment adjustments. However, any changes to program requirements, including any potential changes to the minimum number of measures required for a domain score, would be proposed through rulemaking. We will also consider commenters' other suggestion regarding transparency, for the future.

After consideration of the public comments we received, we are finalizing our proposal to allow the Hospital VBP Program to promptly remove a measure without rulemaking if we believe the measure poses specific patient safety concerns.

c. Removal of Ten Measures From the Hospital VBP Program

By publicly reporting quality data, we strive to put patients first, ensuring they, along with their clinicians, are empowered to make decisions about their own healthcare using information that are aligned with meaningful quality measures. The Hospital VBP Program, together with the Hospital Readmissions Reduction Program and the HAC Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing to the inpatient care setting. We have undertaken efforts to review the existing Hospital VBP Program measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative we described in section I.A.2. of the preambles of the proposed rule and in this final rule.

As part of this review, we stated in the proposed rule that we have taken a holistic approach to evaluating the appropriateness of the Hospital VBP Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital Readmissions Reduction Program and the HAC Reduction Program), as well as in the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing

programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable, but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.

As part of this holistic quality payment program strategy, we stated in the proposed rule that we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. We stated that the Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We stated that we believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

In the FY 2019 IPPS/LTCH/PPS proposed rule (83 FR 20409 through 20412), we proposed to remove the following 10 measures previously adopted for the Hospital VBP Program:

- Elective Delivery (NQF #0469) (PC–01);
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (CAUTI);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (CLABSI);
- American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSI);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (MRSA Bacteremia);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDI);
- Patient Safety and Adverse Events (Composite) (NQF #0531) (PSI 90); [235]
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment);
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579) (PN Payment).

In addition to the measure-specific comments discussed below, we received a number of comments addressing all measures proposed for removal as a single set.

Comment: Many commenters expressed general support for CMS' proposals to remove 10 measures that are duplicative, burdensome, or otherwise do not meet the goals of CMS' Meaningful Measure Initiative from the Hospital VBP Program. Many of these commenters expressed particular support for these measure removals because they would reduce the number of duplicative measures used across CMS' quality programs and thereby increase program alignment. Some commenters noted that removing these measures would simplify program participation requirements and reduce the time and resources required to track performance across multiple programs, and in turn allow hospitals more time to focus on implementing quality care improvements. A few commenters stated this program alignment will also reduce confusion for patients and providers associated with each program's respective focus and purpose. One commenter expressed general support for these measure removals as a way to streamline and align CMS' quality programs, but asserted the removals will not have any actual impact on the burden of reporting as the measures will continue to be used in other programs.

Response: We thank commenters for their support. We recognize that hospitals would still be required to monitor measures removed from one program, but retained in another quality program. However, we believe this simplification benefits hospitals because they will reduce the burden associated with identifying discrepancies in reporting and determining whether those discrepancies are due to differing measure specifications or due to CMS measure calculation error. Furthermore, we believe this simplification will benefit patients and caregivers because they will not need to review data submitted on the same or similar metrics through multiple programs to compare quality of care across multiple providers.

Comment: One commenter expressed particular support for a smaller set of measures in the Hospital VBP Program because the commenter believed this would enable hospitals that have historically fared poorly in the Hospital VBP Program to improve performance and potentially earn an incentive payment.

Response: We thank the commenter for its support.

Comment: A few commenters did not support CMS' proposal to remove any measures from the Hospital VBP Program. Some of these commenters asserted the measures proposed for removal are all valid for use in a value-based purchasing program and therefore did not support their removal.

Response: We agree with commenters that the measures proposed for removal from the Hospital VBP Program are valid measures; for this reason, we are not proposing to remove the measures from all of CMS' quality programs, only to reduce instances where the same measure is used in multiple programs

[235] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS programs.

such that the costs outweigh the benefits of their continued use. We note that the AMI Payment, HF Payment, PN Payment, and PC–01 measures will continue to be used in the Hospital IQR Program. While the Hospital IQR Program is not a value-based purchasing program, we believe continued public reporting of these measures will appropriately incentivize continued high performance or improvement on these measures. We further note that, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, below, we are not finalizing the removal of six safety measures and note that those measures will continue to be used both in the Hospital VBP Program and in the HAC Reduction Program.

(1) Removal of PC–01: Elective Delivery (NQF #0469)

We proposed to remove the Elective Delivery (NQF #0469) (PC–01) measure beginning with the FY 2021 program year because the costs associated with the measure outweigh the benefit of its continued use in the program—proposed removal Factor 8. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38262), we finalized both the benchmark at 0.000000 and the achievement threshold at 0.000000 for the PC–01 measure for the FY 2020 program year, meaning that at least 50 percent of hospitals that met the case minimum performed 0 elective deliveries for the measure during the baseline period of CY 2016. We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50080 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. Based on past performance on the measure, we anticipate that continued use of the PC–01 measure in the Hospital VBP Program would result in more than half of hospitals with a calculable score for this measure earning the maximum 10 achievement points. We anticipate that the remaining hospitals with a calculable score would be awarded points based on improvement only because they will not have met the achievement threshold, earning zero to nine improvement points. Therefore, we believe the measure no longer meaningfully differentiates performance among most participating hospitals for scoring purposes in the Hospital VBP Program.

We continue to believe that avoiding early elective delivery is important; however, because overall performance on the PC–01 measure has improved over time and we anticipate the measure will have little meaningful effect on the TPS for most hospitals, we believe the measure is no longer appropriate for the Hospital VBP Program. In order to continue tracking and reporting rates of elective deliveries to incentivize continued high performance on the measure, this measure would remain in the Hospital IQR Program. We believe that maintaining the measure in the Hospital IQR Program, which publicly reports measure performance, will be sufficient to incentivize continued high performance or improvement on the measure. At the same time, we believe that removing the measure from the Hospital VBP Program will reduce costs and potential confusion for providers and clinicians to track the measure in both the Hospital IQR and Hospital VBP Programs, which may include reviewing different reports and tracking slightly different measure rates across programs.

Based on the reasons described above, we believe that under the measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, which we are finalizing in section IV.I.2.b. of the preamble of this final rule, the costs of keeping the PC–01 measure in the Hospital VBP Program outweigh the benefits because the measure is costly for health care providers and clinicians to review multiple reports on this measure that is being retained in the Hospital IQR Program and our analyses show that the measure no longer meaningfully differentiates performance among participating hospitals for scoring purposes in the Hospital VBP Program.

Therefore, we proposed to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year, with data collection on this measure for purposes of the Hospital VBP Program ending with December 31, 2018 discharges, based on proposed removal Factor 8—because the costs associated with the measure outweigh the benefit of its continued use in the program.

Comment: The majority of commenters that specifically commented on the proposed removal of PC–01 supported removal of PC–01 from the Hospital VBP Program. One commenter supported the removal of PC–01 because although hospitals should continue to strive for 100 percent of early elective deliveries to have a valid clinical indication, performance on this measure should not be expected to reach zero percent, nor should hospital payments in value-based purchasing programs be based on this benchmark. One commenter supported removal because the measure no longer meaningfully differentiates hospitals for purposes of Hospital VBP Program scoring. One commenter supported removal but believed unintended patient harm is a more appropriate rationale because the commenter believed striving for zero percent performance is not a safe practice as it may inadvertently prevent a medically indicated delivery from being performed prior to 39 weeks due to facilities trying to reach a zero percent performance threshold.

Response: We thank commenters for their support. We agree that with both the benchmark at 0.000000 and the achievement threshold at 0.000000 for the PC–01 measure for the FY 2020 program year, we believe the measure no longer meaningfully differentiates performance among most participating hospitals for Hospital VBP scoring purposes. We lack data or anecdotal evidence indicating use of this measure in CMS' quality programs is causing unintended consequences. However, because this measure will remain in the Hospital IQR Program, we will continue to monitor for any unintended consequences associated with its continued use in a CMS reporting program.

Comment: One commenter did not support CMS' proposal to remove the PC–01 measure from the Hospital VBP Program because it could detract focus from this important (as indicated by CMS) measure, thus the commenter recommended that the PC–01 measure be retained but allow its collection via electronic means (that is, as an eCQM) for the Hospital VBP Program, the Hospital IQR Program, and Medicare and Medicaid Promoting Interoperability Programs and, where possible, allow organizations to elect (as resources and systems allow) the ability to submit the measures electronically or via manual abstraction.

Response: As discussed in section VIII.A.5.b.(9)(e) of the preamble of this final rule, the chart-abstracted version of the PC–01 measure will be retained in the Hospital IQR Program for public reporting, which we believe will be sufficient to incentivize continued high performance or improvement on the measure. We note that the eCQM version of the PC–01 measure has not been adopted into the Hospital VBP Program. We also refer readers to sections VIII.A.5.b.(9)(e) and VIII.D.8.b. of the preamble of this final rule for a discussion about our decisions to finalize removal of the eCQM version of PC–01 from the Hospital IQR Program and the Medicare and Medicaid Promoting Interoperability Programs.

Comment: One commenter disagreed with applying measure removal Factor 8 as a rationale for CMS' proposal to remove the PC–01 measure from the Hospital VBP Program because the commenter believed removing the measure from the Hospital VBP Program while retaining it in the Hospital IQR Program is inconsistent with measure removal Factor 8.

Response: We do not agree that removing the measure from the Hospital VBP Program while retaining it in the Hospital IQR Program is inconsistent with measure removal Factor 8. We believe the costs and benefits of a measure should be evaluated on a program by program basis because the costs and benefits of continued use of a measure in one program may be different than the costs and benefits of continued use in another program. As discussed in the proposed rule (83 FR 20410), we believe that the costs associated with retaining the PC–01 measure outweigh the benefits associated with its continued use in the Hospital VBP Program because we believe the measure no longer meaningfully differentiates performance among most participating hospitals for scoring purposes in the Hospital VBP Program. We believe removing PC–01 from the Hospital VBP Program while maintaining it in the Hospital IQR Program will reduce costs and potential confusion for providers to review different reports and track slightly different measure rates across programs, while continuing to incentivize continued high performance through public reporting in the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing our proposal to remove the Elective Delivery (NQF #0469) (PC–01) measure from the Hospital VBP Program beginning with the FY 2021 program year.

(2) Maintenance of Healthcare-Associated Infection (HAI) Measures and the Patient Safety and Adverse Events (Composite) Measure

We proposed to remove the following five measures of healthcare-associated infections (HAIs) from the Hospital VBP Program beginning with the FY 2021 program year because the costs associated with the measures outweigh the benefit of their continued use in the program—proposed removal Factor 8:

- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (CAUTI);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (CLABSI);
- American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSI);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (MRSA Bacteremia); and
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDI).

We also proposed to remove the Patient Safety and Adverse Events (Composite) (PSI 90) (NQF #0531) because the costs associated with the measure outweigh the benefit of its continued use in the program—proposed removal Factor 8.

As discussed in section IV.I.2.b. of the preamble of the proposed rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures available to track patient outcomes and impact. While we continue to consider patient safety and reducing HAIs as high priorities (as reflected in the Meaningful Measures Initiative quality priority of making care safer by reducing harms caused in the delivery of care), the six measures listed above are all used in the HAC Reduction Program, which specifically focuses on reducing hospital-acquired conditions and improving patient safety outcomes. While there are differences in the scoring methodology between the Hospital VBP Program and the HAC Reduction Program, the HAC Reduction Program's incentive payment structure, like the Hospital VBP Program, ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected measures, thereby incentivizing performance improvement on these measures among participating hospitals. In the proposed rule, we stated that we believe removing these measures from the Hospital VBP Program would reduce costs and complexity for hospitals to separately track the confidential feedback, preview reports, and publicly reported information on these measures in both the Hospital VBP and HAC Reduction Programs. We further stated that we believe retaining these measures in the HAC Reduction Program and removing them from the Hospital VBP Program would best support the holistic approach to the measures used in the three quality payment programs as described above, while continuing to keep patient safety and improvements in patient safety as high priorities. We refer readers to section IV.J.4.b., d. and h. of the preambles of the proposed rule and this final rule for how data for the same HAI measures in the HAC Reduction Program will continue to be reported by hospitals to CMS via the CDC's NHSN and posted on our *Hospital Compare* website. In the proposed rule, we stated that we believe removing these measures from the Hospital VBP Program, but retaining them in the HAC Reduction Program, would strike an appropriate balance of benefits and costs associated with these measures across payment programs.

Therefore, we proposed to remove the CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measures from the Hospital VBP Program beginning with the FY 2021 program year, with data collection on these measures for purposes of the Hospital VBP Program ending with December 31, 2018 discharges, based on proposed removal Factor 8—because the costs associated with the measures outweigh the benefit of their continued use in the program. We also proposed to remove the PSI 90 measure from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule based on proposed removal Factor 8—because the costs associated with the measure outweigh the benefit of its continued use in the program.[236] As the PSI 90 measure would not be incorporated into TPS calculations until the FY 2023 program year, we stated in the proposed rule that we could operationally remove this measure from the program sooner than the HAI measures. We also refer readers to section IV.I.4.a.(2) and b. of the preamble of the proposed rule, where we discussed our proposals to remove the Safety domain from the Hospital VBP Program and to increase the weight of the Clinical Care domain (which we proposed to rename as the Clinical Outcomes domain) if our proposals to remove all of the current Safety domain measures were adopted, beginning with the FY 2021 program year.

Comment: Many commenters did not support CMS' proposals to remove the five HAI measures and PSI 90 from the

[236] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256), we finalized the adoption of the PSI 90 measure beginning with the FY 2023 program year. We proposed to remove this measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measure would not be used in calculating hospitals' TPS for any program year.

Hospital VBP Program because the commenters believe patient safety measures should remain in all payment programs to sufficiently incentivize continued improvement on these measures and prioritize practices that ensure safe care. A number of commenters expressed concern that the HAC Reduction Program payment penalty does not sufficiently incentivize medium- and high-performing hospitals to continue to strive for continuous improvement. A few commenters expressed concern that removal of the HAI measures from the Hospital VBP Program sends a message to hospitals that mediocre performance on hospital safety measures is acceptable, and could result in hospitals receiving incentive payments under the Hospital VBP Program despite having a high rate of preventable infections. One commenter expressed concern that even with the HAI measures being used in both the Hospital VBP Program and HAC Reduction Program, some data may indicate hospitals have performed worse over time on four of these measures (MRSA, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI). Another commenter expressed concern that retaining the measures in only the HAC Reduction Program might result in continually penalizing hospitals that serve predominantly high-risk patients even if a hospital's individual performance improves from year to year. Another commenter expressed concern that the penalty only structure of the HAC Reduction Program could create a defeatist attitude and recommended that CMS examine ways to use simple, rationalized, and appropriately-incented payment structures to encourage quality improvement within hospitals.

Response: We agree that patient safety is a high priority focus of CMS' quality programs and, as part of the Meaningful Measures Initiative, we strive to put patients first. Within the framework of the Meaningful Measures and Patients Over Paperwork initiatives, we seek to ensure quality measurement is simultaneously useful and impactful for patients and not overly burdensome on providers such that it takes time and resources away from providing quality care to patients. In evaluating the costs and benefits of keeping certain measures in more than one CMS quality program, we found determining the right balance in using these patient safety measures in our programs a challenge with various stakeholders who may have different perspectives.

We appreciate the many commenters who provided feedback and recommendations on this important topic. In particular, we appreciate commenters who conveyed the multifaceted benefits of retaining the safety measures in more than one value-based purchasing program, and we agree that while a measure's use in the Hospital VBP Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing the provision of high quality care. While we initially sought to clearly delineate the safety focus between the Hospital VBP Program and the HAC Reduction Program for program simplification, we agree with commenters that these measures cover topics of critical importance to quality improvement and patient safety in the inpatient hospital setting. These measures track infections and adverse events that could cause significant health risks and other costs to Medicare beneficiaries; therefore, we agree it is appropriate and important to provide appropriate incentives for hospitals to avoid them through inclusion in more than one program.

In addition, regarding performance over time on the HAI measures, we refer readers to recently updated AHRQ/CMS results that show continued improvement on several hospital acquired conditions.[237] This report indicates that national efforts to reduce hospital-acquired conditions, such as adverse drug events and injuries from falls, helped prevent an estimated 8,000 deaths and saved approximately $2.9 billion between 2014 and 2016. We believe these findings further support retaining the HAI measures and PSI 90 measure in both the Hospital VBP and HAC Reduction Programs, as both programs provide hospitals different but complimentary incentives to continually strive for improvement and high performance on these measures. Importantly, the Hospital VBP Program provides an incentive for hospitals to achieve high performance on these measures, with both positive as well as negative payment adjustments available based on each hospital's Total Performance Score; whereas the HAC Reduction Program imposes a payment reduction on only the lowest quartile of hospitals.

For these reasons, we are not finalizing our proposal to remove the five HAI measures or the PSI 90 measure from the Hospital VBP Program. We will retain the HAI measures and PSI 90 measure in both the Hospital VBP and HAC Reduction Programs. However, in order to reduce some cost and burden for providers in having to track these safety measures in multiple programs, while maintaining a strong financial incentive to perform well on the measures, we are finalizing our proposal to remove these measures from the Hospital IQR Program. We refer readers to section VIII.A.5.b.(2) of the preamble of this final rule where we discuss these measures in the Hospital IQR Program.

Comment: A number of commenters stated their belief that incentivizing performance improvement is preferable to the penalty-only structure of the HAC Reduction Program and therefore recommended that CMS should retain the HAI measures and the PSI 90 measure in the Hospital VBP Program and eliminate them from the HAC Reduction Program, or modify the HAC Reduction Program to incorporate positive payment incentives like those currently used in Hospital VBP Program. A few of these commenters expressed concern that risk adjustment strategies within the HAC Reduction Program are limited and do not always account for facility-specific populations (for example, trauma or other facilities with a high percentage of high risk or vulnerable patients), which might result in continually penalizing hospitals that serve predominantly high-risk patients even if a hospital's individual performance improves from year to year, while the Hospital VBP Program provides incentives for each facility's performance improvement as well as penalties for poor performance.

One commenter specifically recommended retaining the PSI 90 measure in the Hospital VBP Program because the commenter believes the specific measures in the composite target the most important quality priorities, directly address patient outcomes that impact vulnerable Medicare beneficiaries, and encourage hospitals to prioritize the prevention of adverse events that are costly to treat. Another commenter expressed concern that removing these measures from the Hospital VBP Program will also eliminate hospitals' ability to receive positive incentive payments for HAI measure performance in the Hospital VBP Program. A third commenter noted the importance of recognizing that each

[237] Agency for Healthcare Research and Quality (AHRQ), ''Declines in Hospital-Acquired Conditions Save 8,000 Lives and $2.9 Billion in Costs,'' News release, (June 5, 2018). Available at: *https://www.ahrq.gov/news/newsroom/press-releases/declines-in-hacs.html?utm_source=ahrq&utm_medium=en-3&utm_term=&utm_content=3&utm_campaign=ahrq_en6_5_2018*; AHRQ. *National Scorecard on Hospital-Acquired Conditions: Updated Baseline Rates and Preliminary Results 2014–2016.* (June 2018). Available at: *https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/natlhacratereport-rebaselining2014-2016_0.pdf.*

of these programs is structured differently, with different goals and policy mechanisms, and therefore recommended that CMS retain patient safety measures in the quality program that will have the most potential to influence provider behavior.

Response: We thank the commenters for their recommendations. We agree with commenters that the HAC Reduction Program and Hospital VBP Program apply different scoring methodologies and different incentive structures. The HAC Reduction Program, as outlined in section 1886(p) of the Act, reduces payments to the lowest quartile of hospitals for excess hospital-acquired conditions in order to increase patient safety in hospitals. The Hospital VBP Program, on the other hand, is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on a variety of measures. All hospitals in the program are incentivized to achieve high performance on all the measures, and hospitals may receive positive as well as negative payment adjustments based on their overall performance. As stated above, we believe the critical importance of these measures to patient safety and maintaining a strong financial incentive to perform well on the measures warrant their continued inclusion in both programs.

Therefore, although these measures will continue to exist in more than one program, we clarify that they will be used and calculated under different scoring methodologies. Because we continue to consider patient safety and reducing hospital-acquired conditions high priorities (as reflected in the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care), we will continue to monitor the HAC Reduction and Hospital VBP Programs and analyze the impact of our program policies, including any unintended consequences associated with continuing to use these measures in more than one program. We refer readers to section VIII.A.5.b.(2) of the preamble of this final rule where we discuss finalizing our proposals to remove these measures from the Hospital IQR Program. We also refer readers to section IV.J.4.b., e. and h. of the preamble of this final rule for additional discussion of how the measures in the HAC Reduction Program will continue to be reported by hospitals, validated, and posted on the *Hospital Compare* website.

We note that all of these safety measures apply risk adjustment methodologies that have been reviewed by the NQF and are endorsed measures. We will continue to consult with the CDC and take feedback about measure risk adjustment into consideration for measure maintenance and future refinement of measure specifications.

Comment: A few commenters recommended that CMS explore other solutions to address duplication of safety measures across CMS quality programs, including adjusting reporting periods or allow hospitals to report on a measure once for use in multiple accountability programs. A few commenters believed that consolidating the measures in only a single program does not relieve a significant burden on facilities because data are submitted in the same way to be used for the various programs. One commenter noted that the costs associated with even one additional HAI in any of the impacted facility types far outweighs the estimated annual savings associated with removing the HAI measures from the Hospital VBP Program. One commenter believed that as many as 440,000 Americans die from preventable hospital errors each year.

Response: We thank commenters for their input. We recognize that there are many factors to be considered in assessing the costs and benefits of a measure under removal Factor 8. We will continue to monitor the HAC Reduction and Hospital VBP Programs and analyze the impact of our program policies, including the impact on patient safety and the reduction of preventable errors and HAIs.

Comment: Numerous commenters supported CMS' proposals to remove the five HAI measures and PSI 90 measure from the Hospital VBP Program because it would eliminate duplication of the measures with the HAC Reduction Program and thereby reduce the possibility of double penalties in two separate pay-for-performance programs. Some commenters specifically supported removing these measures because they believed the duplicative and overlapping penalties are detrimental to hospitals serving vulnerable populations. Some of these commenters also supported removing these measures because doing so would reduce the potential for conflicting signals on performance. One commenter specifically expressed its belief that removing these measures will lead to greater alignment and consistency across programs.

Response: We thank the commenters for their support of our proposals. However, for the reasons discussed above, we are not finalizing removal of these measures from the Hospital VBP Program. We believe retaining these safety measures in two value-based purchasing programs (and removing them from the Hospital IQR Program, as finalized in section VIII.A.5.b.(2) of this final rule) will at least partly address the concerns of both commenters who want to retain these measures and commenters who supported their removal and de-duplication.

Comment: Several commenters stated that transparency through continued public reporting of performance data for the HAI measures is important. One commenter recommended that CMS make public additional information demonstrating the progress made in quality, patient safety, and patient outcomes since the implementation of the Hospital VBP and HAC Reduction Programs.

Response: We agree with commenters that maximizing transparency through public reporting of performance data is a critical component of CMS' quality programs, which is why we intend to continue publicly reporting the five HAI measures and the PSI 90 measure on the *Hospital Compare* website in a consumer-friendly manner, and data will continue to be available at: *https://data.medicare.gov/*. We reiterate that removing these measures from the Hospital IQR Program will not cease or otherwise interfere with collection or public reporting of these data. The HAI data will continue to be made publicly available on a quarterly basis and the PSI 90 data on an annual basis in a consumer-friendly manner and also through downloadable files. We note that section 1886(p)(6) of the Act requires the HAC Reduction Program to make information available to the public regarding hospital-acquired conditions of each applicable hospital on the *Hospital Compare* website in an easily understandable format.

We further note that section 1886(o)(10)(A) of the Act requires the Hospital VBP Program to make information available to the public regarding the performance of individual hospitals, including performance with respect to each measure, on the *Hospital Compare* website in an easily understandable format. We currently publicly report hospital-specific measure-level information from the Hospital VBP Program along with program-specific scores, and we will continue to solicit input from and share updates with stakeholders as we move forward with plans to publicly report Hospital VBP Program data in order to ensure the publicly reported information is sufficiently streamlined to avoid confusion while also providing the information necessary to assist

patients in making decisions about their care.

After consideration of the public comments we received, we are not finalizing our proposals to remove the CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measures from the Hospital VBP Program or our proposal to remove the PSI 90 measure from the Hospital VBP Program.

(3) Removal of Condition-Specific Payment Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20411 through 20412), we proposed to remove the following three condition-specific payment measures from the Hospital VBP Program, effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, because the costs associated with the measures outweigh the benefit of their continued use in the program—proposed removal Factor 8:

- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment);
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579) (PN Payment).

As discussed in section IV.I.2.b. of the preamble of this final rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures. We also seek to reduce costs and complexity across the hospital quality programs.

Currently, the Hospital IQR and Hospital VBP Programs both include the Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158) (MSPB) measure, as well as the three condition-specific payment measures listed above. We continue to believe the condition-specific payment measures provide important data for patients and hospitals, and we will continue to use these measures in the Hospital IQR Program along with the Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip and/or Total Knee Arthroplasty measure, to provide more granular information to hospitals for reducing costs and resource use while maintaining quality care. However, we believe that continuing to retain the AMI Payment, HF Payment, and PN Payment measures in both the Hospital VBP and Hospital IQR Programs no longer aligns with current CMS and HHS policy priorities for reducing program costs and complexity. We believe the Hospital IQR Program's public reporting of these condition-specific payment measures provide hospitals and patients with sufficient information to make decisions about care and to drive resource use improvement efforts, while removing them from the Hospital VBP Program would reduce the costs and complexity for hospitals to separately track the confidential feedback, preview reports, and publicly reported information on these measures in both programs. We note that the Hospital VBP Program would still retain the MSPB measure, which is an overall hospital efficiency measure required under section 1886(o)(2)(B)(ii) of the Act. We also refer readers to section VIII.A.5.b.(6) of the preamble of this final rule, where we discuss finalizing our proposal to remove the MSPB measure from the Hospital IQR Program.

Therefore, we proposed to remove the AMI Payment, HF Payment, and PN Payment measures from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule based on proposed removal Factor 8—because the costs associated with the measures outweigh the benefit of their continued use in the program. As the AMI Payment and HF Payment measures [238] would not be incorporated into TPS calculations until the FY 2021 program year and the PN Payment measure [239] would not be incorporated into TPS calculations until the FY 2022 program year, we can operationally remove these measures from the program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

Comment: Many commenters specifically supported CMS' proposals to remove the three condition-specific payment measures from the Hospital VBP Program due to their overlap with the MSPB measure and the potential for this overlap to lead to unnecessary confusion among hospitals and patients. A number of commenters specifically noted the potential for these measures to double-count services that are already captured under the MSPB measure. One commenter expressed its belief that the condition-specific payment measures are no more actionable for providers than the MSPB measure because the measures themselves do not provide any insight into where improvements should be made in the delivery of care across the continuum. However, a number of these commenters also expressed support for the use of well-designed measures of cost and resource use and their ability to assist in assessing the value of care provided to patients. One commenter expressed particular support for CMS' proposal to remove the HF Payment measure.

Response: We thank the commenters for their support.

Comment: Several commenters supported CMS' proposals to remove the condition-specific payment measures, but expressed concern about continued use of the current MSPB measure. A few commenters noted findings from ASPE's Report to Congress indicating that differences in MSPB measure performance were driven, in part, by the higher likelihood of dual-enrolled beneficiaries to use more expensive post-acute care settings, and to have higher charges during their stays in these settings. These commenters therefore urged CMS to improve the predictive power of the MSPB measure and ensure the MSPB measure can stand alone as a reliable and valid measure of efficiency and cost reduction in the Hospital VBP Program.

Response: We thank the commenters for their support, and note the MSPB measure is a valid and reliable measure of Medicare spending that was recently re-endorsed by the NQF.[240] As part of this endorsement review, we submitted both sociodemographic and socioeconomic status adjustment measure testing indicating such adjustments had a minimal impact on hospitals' measure scores, as well as demonstrating that dual eligibility had a low impact on MSPB measure scores and hospitals on the tails of score distributions were not disproportionately affected.[241] The NQF Cost and Resource Use Workgroup also acknowledged ASPE's findings, stating ''the analysis in the appendix's

[238] In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56992), we adopted the AMI Payment and HF Payment measures in the Hospital VBP Program beginning with the FY 2021 program year. We proposed to remove these measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measures would not be used in calculating hospitals' TPS for any program year.

[239] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251), we adopted the PN Payment measure in the Hospital VBP Program beginning with the FY 2022 program year. We proposed to remove this measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measure would not be used in calculating hospitals' TPS for any program year.

[240] Medicare Spending Per Beneficiary (MSPB)—Hospital, National Quality Forum, *http://www.qualityforum.org/QPS/QPSTool.aspx?m=2158&e=1.* The MSPB Measure was re-endorsed as specified on September 11, 2017.

[241] National Quality Forum, *Cost and Resource Use 2016–2017 Final Technical Report* (August 20, 2017). Available at: *http://www.qualityforum.org/Publications/2017/08/Cost_and_Resource_Use_2016-2017_Final_Technical_Report.aspx.*

Supplementary Table 7 suggest that these differences may be that measure scores are high for both duals and non-duals in these hospitals. This suggests that these hospitals are relatively higher-cost for all types of patients.'' [242] For these reasons, we continue to believe the MSPB measure is an appropriate, reliable, and valid measure of Medicare spending, and is therefore appropriate for use in the Hospital VBP Program.

Comment: Some commenters did not support CMS' proposals to remove the AMI Payment, HF Payment, and PN Payment measures because the commenters believed these measures serve as strong indicators of hospital efficiency and are key factors in ensuring hospital accountability. These commenters also noted that each of these measures, when paired with a corresponding quality measure, could provide a clear, meaningful picture of value-based care delivery. A few of these commenters also expressed concern that removing the condition-specific payment measures would revert the Hospital VBP Program to assessing efficiency and cost reduction using only the MSPB measure, which the commenters believe does not provide actionable or meaningful data to patients or providers and is difficult to operationalize at the service line level. One commenter expressed further concern that removing these measures from the Hospital VBP Program would reduce hospitals' incentives to provide quality care by reducing transparency in public reporting. Another commenter believed that although these measures cannot currently provide a full vision of the value of care because they are not linked to corresponding quality measures, the condition-specific payment measures have the potential to improve coordination and transitions of care and provide patients with more contextual data for using in medical decision-making, thereby increasing the efficiency of care across the full care continuum.

Response: We acknowledge commenters' concerns, and thank the commenters for their recommendations. Section 1886(o)(2)(B)(ii) of the Act requires that the Hospital VBP Program ''include efficiency measures, including measures of 'Medicare spending per beneficiary.' '' While we agree that condition-specific payment measures can provide hospitals with important data on payments associated with an episode of care, we continue to believe the MSPB measure also provides hospitals with valuable information because this measure captures a wide range of services provided in the inpatient hospital setting. In addition, we note the MSPB measure has been NQF-endorsed and is considered to be a valid, reliable measure of Medicare spending.

We disagree with commenters' suggestions that removing these condition-specific payment measures from the Hospital VBP Program would reduce hospitals' incentive to provide quality care by reducing transparency in public reporting or reduce patients or providers from receiving actionable or meaningful data. As listed in the tables of previously adopted measures for the Hospital IQR Program in sections VIII.A.7. and 8. of the preamble of this final rule, these three measures will remain in the Hospital IQR Program. Therefore, these three measures will continue to be publicly reported under the Hospital IQR Program. In addition, we proposed to remove these measures before they have been incorporated into hospitals' Total Performance Scores (TPS) or public reporting under the Hospital VBP Program. Therefore, removing these measures at this time will not change performance scoring or public reporting under the Hospital VBP Program.

We continue to believe that using condition-specific payment measures that can be paired directly with clinical quality measures, aligned by comparable populations, performance periods, or risk-adjustment methodologies will help move toward enabling patients, payers, and providers to better assess the overall value of care provided at a hospital. However, we believe retaining MSPB, an overall hospital efficiency measure, while removing these condition-specific payment measures will allow for reduced costs and complexity from the Hospital VBP Program and across the hospital quality programs.

After consideration of the public comments we received, we are finalizing our proposals to remove the AMI Payment, HF Payment, and PN Payment measures from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

d. Summary of Previously Adopted Measures for the FY 2020 Program Year

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38244), we finalized the following measure set for the Hospital VBP Program for the FY 2020 program year. We note that we did not propose any changes to this measure set.

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PROGRAM YEAR

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Clinical Outcomes Domain*	
MORT–30–AMI	Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550

[242] Ibid.

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PROGRAM YEAR—Continued

Measure short name	Domain/measure name	NQF #
	Safety Domain	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
PC–01	Elective Delivery	0469
	Efficiency and Cost Reduction Domain	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

e. Summary of Measures for the FY 2021, FY 2022, and FY 2023 Program Years

We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20413 through 20414) for tables showing summaries of measures for the FY 2021, FY 2022, and FY 2023 program years if the measure removals proposed in the proposed rule were finalized. Set out below are summaries of measures for the FY 2021, FY 2022, and FY 2023 program years based on our finalized policies in this final rule.

SUMMARY OF MEASURES FOR THE FY 2021 PROGRAM YEAR

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Safety Domain*	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
	Clinical Outcomes Domain**	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550

SUMMARY OF MEASURES FOR THE FY 2021 PROGRAM YEAR—Continued

Measure short name	Domain/measure name	NQF #
	Efficiency and Cost Reduction Domain* **	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, or the Safety domain.

** In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

*** As discussed in sections IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year.

SUMMARY OF MEASURES FOR THE FY 2022 PROGRAM YEARS

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Safety Domain*	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
	Clinical Outcomes Domain**	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Efficiency and Cost Reduction Domain***	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, or the Safety domain.

** In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

*** As discussed in sections IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year, and one measure (PN Payment) which would have entered the program beginning with the FY 2023 program year.

SUMMARY OF MEASURES FOR THE FY 2023 PROGRAM YEAR

Measure short name	Domain/measure name	NQF #
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	Safety Domain*	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure.	1717
PSI 90**	Patient Safety and Adverse Events (Composite)**	0531
	Clinical Outcomes Domain* **	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Efficiency and Cost Reduction Domain** **	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia, and PSI 90 measures, or the Safety domain.

** In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251 through 38256), we finalized adoption of the PSI 90 measure beginning with the FY 2023 program year.

*** In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

**** As discussed in sections IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year and one measure (PN Payment) which would have entered the program beginning with the FY 2023 program year.

3. Accounting for Social Risk Factors in the Hospital VBP Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38241 through 38242), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[243] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[244] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in

[243] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[244] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

the FY 2018 IPPS/LTCH PPS final rule (82 FR 38241), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[245] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[246] allowing further examination of social risk factors in outcome measures.

In the FY 2018 IPPS/LTCH PPS and CY 2018 OPPS/ASC proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS: To explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: Many commenters recommended that CMS risk-adjust quality and cost measures (including Medicare Spending per Beneficiary—MSPB) for social risk factors because these factors are outside of a provider's control and affect patient outcomes. Several commenters expressed that risk adjustment for social risk factors is critical because public reporting of performance on measures that have not been adjusted for social risk factors may lead consumers to conclude that providers with a high-risk patient population provide lower quality care. Other commenters noted that public reporting of performance on measures that have not been risk-adjusted may lead policy makers to not address the underlying health disparities. Some commenters recommended specific factors for risk adjustment, including: (1) Elements in the ASPE, NQF, and NAM reports; (2) availability of primary care; (3) availability of physical therapy; (4) access to medications; (5) access to appropriate food; (6) access to support services; (7) dual eligibility; (8) income; (9) education; (10) neighborhood deprivation; (11) marital status; (12) access to transportation; (13) homelessness; (14) type of residence; (15) local crime rates; (16) employment status; (17) race/ethnicity; and (18) primary language.

Response: We thank these commenters for their support and will consider these topics in our future analyses of social risk factors.

Comment: Several commenters recommended specific methods of risk adjustment to evaluate performance and calculate payment adjustments, including: (1) Risk adjustment at the domain level; (2) risk adjustment at the measure level, including requiring measures developers to build the risk adjustment in from the start through testing; (3) peer grouping of similar facilities, at either the domain or measure level; (4) stratification for public reporting; (5) confidential stratification reports; and (6) reporting hospital-specific disparities.

Response: We thank these commenters for their input and will consider these topics in our future analyses of accounting for social risk factors.

Comment: Several commenters provided recommendations for adopting processes for accounting for social risk factors. Some of these commenters recommended that CMS allow providers time to review and analyze confidential stratified measure results prior to making these data public. These commenters recommended use of the rulemaking process to identify measures for which these reports would be generated, and for which data would be publicized. Other commenters recommended that CMS perform analyses to ensure that providers are not penalized for treating disadvantaged populations. Some commenters observed that there is inconsistent data collection regarding social risk factors and recommended that CMS address this (potentially through a pilot program centered on EHR use for data collection). Some commenters requested that CMS develop and publicize a work plan and timeline for accounting for social risk factors within CMS quality reporting and value-based purchasing programs. Other commenters encouraged CMS to continue monitoring and evaluation to identify potential unintended consequences of quality reporting and value-based purchasing programs on vulnerable populations.

Response: We thank these commenters for their input and will consider these topics in our future analyses of social risk factors.

Comment: One commenter expressed concern that accounting for social risk factors in quality reporting and value-based purchasing programs minimizes incentives to improve outcomes for

[245] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[246] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

high-risk patients and therefore does not address the underlying disparities.

Response: We agree with the commenter that accounting for social risk factors should not come at the cost of minimizing incentives to improve outcomes for high-risk patients. We note that among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. These are the objectives that we are seeking to achieve in evaluating methods to account for social risk factors in our programs.

We thank the commenters for their views and will take them into consideration as we continue our work on these issues.

4. Scoring Methodology and Data Requirements

a. Changes to the Hospital VBP Program Domains

(1) Domain Name Change for the FY 2020 Program Year and Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49553 through 49554), we renamed the Clinical Care—Outcomes subdomain as the Clinical Care domain beginning with the FY 2018 program year. As discussed in the section I.A.2. of the preamble of this final rule, we strive to have measures in our programs that can drive improvement in patients' health outcomes. We also strive to align quality measurement and value-based payment programs with other national strategies, such as the Meaningful Measures Initiative. As discussed in section IV.I.2.c. of the preamble of this final rule, we believe that one of the primary areas of focus for the Hospital VBP Program should be on measures of clinical outcomes, such as measures of mortality and complications, which address the Meaningful Measures Initiative quality priority of promoting effective treatment. The Clinical Care domain currently contains these types of measures; therefore, to better align the name of the domain with our priority area of focus, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20415), we proposed to change the domain name from Clinical Care to Clinical Outcomes, beginning with the FY 2020 program year. We believe this proposed domain name better captures our goal of driving improvement in health outcomes and focusing on those outcomes that are most meaningful to patients and their providers.

Comment: One commenter supported CMS' proposal to rename the Clinical Care domain to the Clinical Outcomes domain.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern about the proposed change of the domain name from Clinical Care to Clinical Outcomes due to a perceived lack of outcome measures that meet all the criteria of strong evidence; measurable with a high degree of precision; risk-adjustment methodology including, and accurately measuring the risk factors most strongly associated with the outcome; and having little chance of inducing unintended adverse consequences. The commenter stated the importance of continuing to report good process measures that give hospitals specific data on their performance that is actionable.

Response: As discussed in section IV.I.2.b. of the preambles of the proposed rule and this final rule, we strive to have measures in our programs that can drive improvement in patients' health outcomes. We believe changing the name to the Clinical Outcomes domain better aligns with this priority. While we recognize that the measures in the Clinical Care (newly finalized as the Clinical Outcomes) domain do not account for every potential risk factor, the measures are risk adjusted and NQF-endorsed. As part of our measure maintenance process, we welcome specific feedback from stakeholders regarding ways to improve risk adjustment for the measures in the hospital programs. We refer readers to the measure methodology reports available at: *https://www.qualitynet.org*. Regarding the importance to continue reporting process measures, we agree that some process measures are valuable and may warrant inclusion in CMS' value-based purchasing programs. Currently, there are no process measures in the Clinical Care (Clinical Outcomes) domain; however, we may consider adding additional measures to the domain in the future that can drive improvement in outcomes, including process measures that can be directly linked to outcomes.

After consideration of the public comments we received, we are finalizing our proposal to change the domain name from Clinical Care to Clinical Outcomes, beginning with the FY 2020 program year.

(2) Maintenance of the Safety Domain for the FY 2021 Program Year and Subsequent Years

We previously adopted five HAI measures and the PC–01 measure for the Safety domain (82 FR 38242 through 38244). We also previously adopted PSI 90 as a measure in the Safety domain beginning with the FY 2023 program year (82 FR 38251 through 38256). However, as discussed in section IV.I.2.c.(1) and (2) of the preambles of the proposed rule and this final rule, above, we proposed to remove the PC–01 measure and the five HAI measures from the Hospital VBP Program beginning with the FY 2021 program year and to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, as the PSI 90 measure and all five of the HAI measures will be retained in the HAC Reduction Program. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20415 through 20416), we did not propose any new measures for the Safety domain. In addition, as discussed in section IV.I.2.c. of the preamble of the proposed rule, we stated that by taking a holistic approach to evaluating the appropriateness of the measures used in the three hospital value-based purchasing programs—the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs—we believed the HAC Reduction Program is the primary part of the quality payment framework that should focus on the safety aspect of care quality for the inpatient hospital setting (Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care). We stated we believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce the costs of duplicative measures and program complexity.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50056) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49546), we noted that hospital acquired condition measures comprise some of the most critical patient safety areas, therefore justifying the use of the measures in more than one program. However, we have also stated that we will monitor the HAC Reduction and Hospital VBP Programs and analyze the impact of our measures selection, including any unintended consequences with having a measure in more than one program, and will revise the measure set in one or both programs if needed (79 FR 50056). In the proposed rule, we stated that we have continued to receive stakeholder feedback expressing concern about overlapping measures amongst different payment programs, such as the Hospital VBP and HAC Reduction Programs. We further stated that for the Hospital VBP Program, specifically, we believed

removing the measures in the Safety domain and retaining them in the HAC Reduction Program would address the concerns expressed by these stakeholders about the costs to hospitals participating in these programs so that the costs of participation do not outweigh the benefits of improving beneficiary care.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20415 through 20416), we proposed to remove the Safety domain from the Hospital VBP Program, beginning with the FY 2021 program year, because there would no longer be any measures in that domain if our measure removal proposals are finalized. We acknowledged that by removing the Safety domain and its measures from the Hospital VBP Program, the overall effect would be to decrease the total percent of hospital payment at risk that is based on performance on these measures (by no longer tying performance on them to Hospital VBP Program reimbursement), and that it might reduce the current incentive for hospitals to perform as well on them. However, we stated we believed hospitals would still be sufficiently incentivized to perform well on the measures even if they are only in one value-based purchasing program, and we intended to monitor the effects of this proposal, if finalized, as the patient safety measures would be maintained in the HAC Reduction Program, validated, and publicly reported on the *Hospital Compare* website.

We also referred readers to section IV.I.4.b.(2) of the preamble of the proposed rule, where we discussed how we considered keeping the Safety domain and the current domain weighting of 25 percent weight for each of the four domains with proportionate reweighting if a hospital has sufficient data on only three domains, which would include retaining in the Hospital VBP Program one or more of the measures in the Safety domain (such as measures which are also used in the HAC Reduction Program). However, based on the considerations discussed above, we decided to propose removal of the Safety domain measures and the Safety domain from the Hospital VBP Program. If our proposals to remove the Safety domain measures (PC–01, the five HAI measures, and PSI 90) were adopted, there would be no measures left in the Safety domain beginning with the FY 2021 program year.

Therefore, we proposed to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year.

Comment: A number of commenters did not support CMS' proposal to remove the Safety domain because they believe its removal would detract from the previously increasing focus on safety within inpatient hospitals. One commenter further stated that safe care is the foundation of high-value care and measuring hospitals' overall quality performance—and financially rewarding them based on this—is incomplete without accounting for the degree to which hospitals are safely providing care.

Response: We agree with commenters that patient safety is a high priority focus of CMS' quality programs and, as part of the Meaningful Measures Initiative, we strive to put patients first. As discussed in sections IV.I.2.c.(1) and (2) of the preamble of this final rule, above, while we are finalizing removal of the PC–01 measure from the Safety domain, we are not finalizing removal of the five HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, CDI) or the removal of the Patient Safety and Adverse Events (Composite) Measure (PSI 90). For this reason, we are not finalizing removal of the Safety domain.

Comment: Many commenters supported CMS' proposal to remove the Safety domain. A few commenters supported CMS' proposal to remove the Safety domain because there would be no measures in the domain. One commenter asserted the measures currently included in the Hospital VBP Program Safety domain are adequately represented in other Medicare quality programs.

Response: We thank the commenters for their input regarding the proposed removal of the Safety domain from the Hospital VBP Program. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, above, we are not finalizing our proposal to remove the five HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, CDI) or to remove the Patient Safety and Adverse Events (Composite) Measure (PSI 90). For this reason, we are not finalizing our proposal to remove the Safety domain.

Comment: One commenter recommended that even if the measures currently in the Safety domain are removed, the Safety domain should remain in the Hospital VBP Program and CMS should adopt a number of eCQMs for this domain.

Response: We thank the commenter for their suggestion. As stated above, we are not finalizing our proposal to remove the Safety domain. Regarding the adoption of eCQMs for the Hospital VBP Program, we continue to evaluate our measure sets and may consider proposing the incorporation of eCQMs into the program in the future.

After consideration of the public comments we received, we are not finalizing our proposal to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year.

b. Maintenance of Existing Domain Weighting for the FY 2021 Program Year and Subsequent Years

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. For the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085).

In the FY 2019 IPPS/LTCH PPS proposed rule, we discussed our proposal to remove the Hospital VBP Program Safety domain beginning with the FY 2021 program year in connection with our proposal to remove all of the measures previously adopted for the Safety domain. We stated that if these proposals are adopted, there would be only three domains remaining in the Hospital VBP Program, beginning with the FY 2021 program year—Clinical Outcomes (currently referred to as the Clinical Care domain), Person and Community Engagement, and Efficiency and Cost Reduction. The Clinical Outcomes domain would have five measures of mortality and complications for the FY 2021 program year and 6 measures beginning with the FY 2022 program year, the Person and Community Engagement domain would have the HCAHPS survey with its eight dimensions of patient experience, and the Efficiency and Cost Reduction domain would include only the MSPB measure. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing the removal of the 5 HAI measures or the PSI 90 measure from the Safety domain, and as discussed in section IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing removal of the Safety domain from the Hospital VBP Program. Therefore, we are not finalizing any changes to the Hospital VBP Program domain weighting policies in this final rule, as further discussed below.

In the proposed rule, we discussed that to account for these proposed changes, we assessed the weighting of scores on the three remaining domains in constituting each hospital's TPS. Specifically, we considered: (1) Weighting the Clinical Outcomes domain at 50 percent of a hospital's TPS, and to weight the Person and Community Engagement and Efficiency and Cost Reduction at 25 percent each; and (2) weighting all three domains equally, each as one-third (⅓) of a hospital's TPS. Because there would have been only three domains if our proposals to remove the Safety domain and all of the Safety domain measures were adopted, we did not propose any changes to the requirement that a hospital must receive domain scores on at least three domains to receive a TPS. Historically, when the Hospital VBP Program had three domains, scores in all three were required to receive a TPS (76 FR 74534; 76 FR 74544). We also discussed in the proposed rule that we considered keeping the current domain weighting (25 percent for each of the four domains—Safety, Clinical Outcomes, Person and Community Engagement, and Efficiency and Cost Reduction—with proportionate reweighting if a hospital has sufficient data on only three domains), which would require keeping at least one or more of the measures in the Safety domain and the Safety domain itself.

(1) Proposed Domain Weighting With Increased Weight to Clinical Outcomes

For the reasons discussed in the proposed rule, we proposed to weight the domains as follows beginning with the FY 2021 program year:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS

Domain	Weight (percent)
Clinical Outcomes*	50
Person and Community Engagement	25
Efficiency and Cost Reduction	25

*In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

In the proposed rule, we stated that we believe the proposed domain weighting best aligns with our emphasis on clinical outcomes, which address the Meaningful Measures Initiative quality priority of promoting effective treatment, and would provide a greater weight for the domain with the greatest number of measures (Clinical Outcomes), while providing appropriate weighting to the domains that focus on patient experience and cost reduction commensurate with their continued importance. In proposing to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of hospitals' TPSs, we stated that we took into account that the Clinical Outcomes domain will include five outcome measures for the FY 2021 program year (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN (updated cohort), and THA/TKA) and six outcome measures for the FY 2022 program year (MORT–30–CABG, MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN (updated cohort), and THA/TKA), while the Person and Community Engagement domain includes the HCAHPS survey measure, and the Efficiency and Cost Reduction domain would include only one measure (MSPB) if our proposals to remove the condition-specific payment measures, discussed in section IV.I.2.c.(3) of the preamble of the proposed rule, were adopted.

Under the proposed domain weighting, each measure in the Clinical Outcomes domain (measures of mortality and complications) would have comprised 10 percent of each hospital's TPS for the FY 2021 program year and 8.33 percent for the FY 2022 program year and subsequent years, if a hospital met the case minimum for each measure in the domain, and no more than 25 percent for each measure if a hospital could only meet the minimum two measure scores for the Clinical Outcomes domain. The MSPB measure would continue to be weighted at 25 percent, if our proposals to remove the condition specific payment measures are adopted; and each of the eight HCAHPS dimensions would continue to be weighted at 3.125 percent for a total of 25 percent for the Person and Community Engagement domain. In the proposed rule, we stated that we believed the proposed domain weighting would better balance the contributing weights of each individual measure that would be retained in the Hospital VBP Program (assuming there were no Safety domain measures) compared to the alternative weighting we considered of equal weights (one-third (⅓) for each domain), as discussed in more detail below.

In the proposed rule, we stated that we also believed the proposal to increase the weight of the Clinical Outcomes domain would help address concerns expressed by the Government Accountability Office (GAO) in a June 2017 report.[247] In the report, GAO observed that high scores in the Efficiency and Cost Reduction domain resulted in positive payment adjustments for some hospitals that had composite quality scores below the median (the GAO assessed each hospital's composite quality score as its TPS minus its weighted Efficiency and Cost Reduction domain score). GAO also expressed concern that proportionate reweighting of the Efficiency and Cost Reduction domain (for example, from 25 percent to one-third (⅓) of a hospital's TPS in FY 2016), due to a missing domain score for another domain, amplified the contribution of the Efficiency and Cost Reduction domain to the TPS. GAO recommended that CMS take action to avoid disproportionate impact of the Efficiency and Cost Reduction domain on the TPS, and to change the proportionate reweighting policy so it does not facilitate positive payment adjustments for hospitals with lower quality scores. Other stakeholders and researchers have expressed similar concerns.[248]

Using actual FY 2018 program data,[249] we analyzed the estimated potential impacts to hospital TPSs and payment adjustment. Based on this analysis, we estimated that with the proposed domain weighting, approximately 200 hospitals with composite quality scores below the median composite quality score for all Hospital VBP Program-eligible hospitals would no longer receive a positive payment adjustment mainly driven by their high performance on the Efficiency and Cost Reduction domain. This represents an approximate 50 percent reduction in the percent of hospitals receiving positive payment adjustments that have composite quality scores below the median (from 21 percent of hospitals receiving payment adjustments to 11 percent). We refer

[247] *Hospital Value-Based Purchasing: CMS Should Take Steps to Ensure Lower Quality Hospitals Do Not Qualify for Bonuses: Report to Congressional Committees.* (GAO Publication No. GAO–17–551) Retrieved from U.S. Government Accountability Office: Available at: *https://www.gao.gov/assets/690/685586.pdf.*

[248] For example, Ryan AM, Krinsky S, Maurer KA, Dimick JB. Changes in Hospital Quality Associated with Hospital Value-Based Purchasing. N Engl J Med. 2017 June 15;376(24):2358–2366.

[249] Only eligible hospitals were included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the State of Maryland) were removed from this analysis.

readers to the table in section IV.I.4.b.(3) of the preamble of this final rule, below summarizing the results of this analysis.

In further analyzing the potential impacts of the proposed domain weighting on hospitals' TPSs using actual FY 2018 program data, our analysis showed that, on average, hospitals with large bed size, hospitals in urban areas, teaching hospitals, and safety net status hospitals,[250] which have historically received lower overall TPSs on average (generally due to lower average performance on the Efficiency and Cost Reduction and Patient and Community Engagement domains), moved closer to the average TPS under the proposed domain weighting (generally due to their higher average performance on the Clinical Outcomes domain). With average scores for these types of hospitals moving closer to the average TPS for all hospitals, this would increase their TPSs, on average, and thereby increase their chances for a positive payment adjustment.

On average, hospitals with small bed size, rural hospitals, and non-teaching hospitals, which were historically high scorers on average (generally due to higher average performance on the Efficiency and Cost Reduction and Patient and Community Engagement domains), also moved closer to the average TPS under the proposed domain weighting (generally due to lower average performance on the Clinical Outcomes domain). With average scores for these types of hospitals also moving closer to the average TPS for all hospitals, this would decrease their TPSs, on average, and thereby decrease their chances for a positive payment adjustment. This would also be consistent with our analysis discussed above that the proposed domain weighting would better address GAO's recommendations for the Hospital VBP Program by reducing the percent of hospitals receiving positive payment adjustments that have composite quality scores below the median.

Our analysis also simulated that removing the Safety domain and increasing the weight of the Clinical Outcomes domain would have decreased the slope of the linear exchange function from 2.89 (actual FY 2018) to 2.78 (estimated using actual FY 2018 program data) and would have decreased the percent of hospitals receiving a positive payment adjustment from 57 percent to 45 percent. We believe this is mainly due to hospitals with greater total MS–DRGs payments (such as larger hospitals that generally have higher average performance on the Clinical Outcomes domain) earning higher TPSs relative to hospitals with smaller total MS–DRGs payments in this estimated budget-neutral program. We refer readers to the tables in section IV.I.4.b.(3) of the preambles of the proposed rule and this final rule summarizing the results of these analyses.

(2) Alternatives Considered

In the proposed rule, we stated that as an alternative, we also considered weighting each of the three domains equally, meaning that each domain (Clinical Outcomes, Person and Community Engagement, and Efficiency and Cost Reduction) would be weighted as one-third (⅓) of a hospital's TPS, which is similar to the proportionate reweighting policy when a hospital is missing one domain score due to insufficient cases to score enough measures for the domain. Our analysis showed that, on average, hospitals with small bed size, rural hospitals, non-teaching hospitals, and non-safety net status hospitals would earn TPSs relatively closer to or better than historic levels of performance, particularly with increased weighting of the Patient and Community Engagement and Efficiency and Cost Reduction domains from 25 percent each to one-third (⅓) each, domains in which these types of hospitals historically perform better than average compared to large bed size, hospitals in urban areas, teaching hospitals, and safety net status hospitals.[251] In addition, our analysis showed that equally weighting the domains does not address the GAO's concern of positive payment adjustments for hospitals with composite quality scores below the median. Based on our analyses, we estimated that approximately 20 percent of hospitals with composite quality scores below the median composite quality score for all Hospital VBP Program-eligible hospitals would receive a positive payment adjustment mainly driven by their high performance on the Efficiency and Cost Reduction domain, if we weighted the domains equally. This is approximately double the number of hospitals that we estimate would receive a positive payment adjustment with composite quality scores below the median as compared to our proposed domain weighting of increasing the Clinical Outcomes domain to 50 percent and keeping the Patient and Community Engagement and Efficiency and Cost Reduction domains at 25 percent each. We refer readers to the tables in section IV.I.4.b.(3) of the preambles of the proposed rule and this final rule summarizing the results of these analyses.

In the proposed rule, we stated that we also considered keeping the Safety domain and the current domain weighting (25 percent weight for each of the four domains with proportionate reweighting if a hospital has sufficient data on only three domains), which would include retaining in the Hospital VBP Program one or more of the measures in the Safety domain (such as measures which are also used in the HAC Reduction Program). As discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposal to remove the PSI 90 and five HAI measures from the Hospital VBP Program.

(3) Analysis

In the proposed rule, we stated that our priority is to adopt a domain weighting policy that appropriately reflects hospital performance under the Hospital VBP Program, aligns with CMS policy goals, including the more holistic quality payment program strategy for hospitals discussed in the proposed rule, and continues to incentivize quality improvement. As noted in the proposed rule, to understand the potential impacts of the proposed domain weighting on hospitals' TPSs, we conducted analyses using FY 2018 program data that estimated the potential impacts of our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS and an alternative weighting policy we considered of equal weights whereby each domain would constitute one-third (⅓) of a hospital's TPS. The table below provided an overview of the estimated impact on hospitals' TPS by certain hospital characteristics and as they would compare to actual FY 2018 TPSs, which included scoring on four domains, including the Safety domain, and applying proportionate reweighting if a

[250] For purposes of this analysis, ''safety net'' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.*

[251] For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS final rule impact file, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.*

hospital had sufficient data on only three domains.

COMPARISON OF ESTIMATED AVERAGE TPSs AND UNWEIGHTED DOMAIN SCORES *

Hospital characteristic	Actual FY 2018 average clinical care domain score	Actual FY 2018 average person and community engagement domain score	Actual FY 2018 average efficiency and cost reduction domain score	Actual FY 2018 average TPS (4 domains) +	Proposed increased weighting of clinical care domain: Estimated average TPS	Alternative weighting: Estimated average TPS
All Hospitals **	43.2	33.5	18.8	37.4	34.6	31.8
Bed Size:						
1–99	33.4	46.0	35.7	44.6	37.2	38.4
100–199	42.2	34.5	21.0	39.2	35.0	32.6
200–299	44.5	27.9	12.9	34.4	32.4	28.4
300–399	48.2	27.3	10.0	33.3	33.4	28.5
400+	50.9	26.9	7.6	31.9	34.1	28.5
Geographic Location:						
Urban	46.8	30.7	13.7	35.7	34.5	30.4
Rural	33.7	40.5	31.7	41.9	34.9	35.3
Safety Net Status: ***						
Non-Safety Net	42.7	35.4	19.0	37.9	34.9	32.4
Safety Net	45.1	25.7	18.1	35.6	33.5	29.6
Teaching Status:						
Non-Teaching:	39.9	36.7	22.9	39.4	34.9	33.2
Teaching	48.7	27.9	11.8	34.1	34.3	29.5

* Analysis based on FY 2018 Hospital VBP Program data.

** Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

+ Based on FY 2018 program year policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

*** For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*.

The table below provided a summary of the estimated impacts on average TPSs and payment adjustments for all hospitals,[252] including as they would compare to actual FY 2018 program results under current domain weighting policies.

Summary of estimated impacts on average TPS and payment adjustments using FY 2018 program data	Actual (4 domains) +	Proposed increased weight for clinical outcomes (3 domains)	Equal weighting alternative (3 domains)
Total number of hospitals with a payment adjustment	2,808	2,701	2,701
Number of hospitals receiving a positive payment adjustment (percent)	1,597 (57%)	1,209 (45%)	1,337 (50%)
Average positive payment adjustment percentage	0.60%	0.58%	0.70%
Estimated average positive payment adjustment	$128,161	$233,620	$204,038
Number of hospitals receiving a negative payment adjustment (percent)	1,211 (43%)	1,492 (55%)	1,364 (50%)
Average negative payment adjustment percentage	−0.41%	−0.60%	−0.57%
Estimated average negative payment adjustment	$169,011	$189,307	$200,000
Number of hospitals receiving a positive payment adjustment with a composite quality score * below the median (percent)	341 (21%)	134 (11%)	266 (20%)
Average TPS	37.4	34.6	31.8
Lowest TPS receiving a positive payment adjustment	34.6	35.9	30.9
Slope of the linear exchange function	2.8908851882	2.7849297316	3.2405954322

+ Based on FY 2018 program year policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

* ''Composite quality score'' is defined as a hospital's TPS minus the hospital's weighted Efficiency and Cost Reduction domain score.

The estimated total number of hospitals with a payment adjustment was lower under the proposed domain weighting and equal weighting alternative considered (2,701), compared to the current four domain policy (2,808), because under the proposed domain weighting and equal weighting alternative, scores would be

[252] Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the State of Maryland) were removed from this analysis.

required on all three domains (Clinical Outcomes, Person and Community Engagement, and Efficiency and Cost Reduction) to receive a TPS and hence, a payment adjustment, whereas under the current scoring policy, if a hospital has sufficient data on any three of the four domains it can receive a TPS and payment adjustment. For example, under the FY 2018 program year scoring policy, if a hospital did not have sufficient data for a score on the Clinical Outcomes domain, but received a score on the other three domains (Safety, Person and Community Engagement, and Efficiency and Cost Reduction), the hospital could have had its domain scores proportionately reweighted and received a TPS and payment adjustment, whereas under the proposed domain weighting and equal weighting alternative considered (which do not include the Safety domain and retain the requirement for at least three domain scores to receive a TPS), a hospital that does not have sufficient data for a score on the Clinical Outcomes domain would not receive a TPS or payment adjustment.

We also refer readers to section I.H.6.b. of Appendix A of the proposed rule (83 FR 20620 through 20621) for detailed discussions regarding the estimated impacts of the proposed domain weighting and equal weighting alternative on hospital percentage payment adjustments.

(4) Summary

In the proposed rule, we stated that based on our analyses and all of the other considerations discussed above, we believed our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS would best align with the goal of the Hospital VBP Program to make value-based incentive payment adjustments based on hospitals' performance on quality and cost, as well as emphasizes the Meaningful Measures Initiative's focus on high impact areas that are meaningful to patients and providers.

Because we proposed to remove the Safety domain and its measures from the Hospital VBP Program, we considered the two options for weighting the three remaining domains. Increasing the weight of the Clinical Outcomes domain from 25 percent to 50 percent of each hospital's TPS emphasizes our priority and focus on improving patients' health outcomes, without decreasing the weight of the Efficiency and Cost Reduction or Person and Communities Engagement domains. By contrast, equally weighting each of the three domains at one-third (⅓) of each hospital's TPS would result in the MSPB measure and the HCAHPS survey measure together accounting for two-thirds (⅔) of each hospital's TPS. In the proposed rule, we stated that if our proposal to remove the Safety domain beginning with the FY 2021 program year is adopted, we proposed to weight the three remaining domains as follows: Clinical Outcomes domain—50 percent; Person and Community Engagement domain—25 percent; and Efficiency and Cost Reduction domain—25 percent—beginning with the FY 2021 program year. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing the removal of the 5 HAI measures or the PSI 90 measure from the Safety domain. Therefore, we are not finalizing the removal of the Safety domain from the Hospital VBP Program, as further discussed below.

Comment: A few commenters expressed concern that ongoing changes to the program's scoring and weighting methodology create volatility for providers and do not allow for assessments of hospital performance over time. These commenters recommended that CMS create stability for the program going forward to afford providers a level of predictability and allow for comparison across time.

Response: We appreciate commenters' concerns, and will take this into account as we continue to move forward with the holistic approach to program and measure evaluation across CMS' quality programs. We note that as discussed in section IV.I.2.c.(2) of the preamble of this final rule, above, we are not finalizing the removal of the 5 HAI measures or the PSI 90 measure from the Safety domain, and as discussed in section IV.I.4.a.(2) of the preamble of this final rule, above, we are not finalizing our proposal to remove the Safety domain, and are therefore not finalizing any changes to the Hospital VBP Program domain weighting policies in this final rule.

We note that in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49568 through 49570), we adopted equal weights of 25 percent for each of the four domains in the FY 2018 program year for hospitals that receive a score in all domains. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57009 through 57010), for the FY 2019 program year, we retained this domain weighting. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38265 through 38266) we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. Because we did not propose to change the domain weighting policies based on consideration of four domains (including retention of the Safety domain) in the FY 2019 IPPS/LTCH PPS proposed rule, and in response to stakeholder concerns of changes to the program's scoring and weighting methodology creating volatility for providers, we are not making changes to the previously finalized equal weight of 25 percent for each of the four domains for hospitals that receive a score in all domains in this final rule.

Comment: Many commenters supported the proposed increased weight to the Clinical Outcomes domain because they believed it would most fairly weight the individual measures within the program, given that the distribution of measures across the three domains. Some commenters recommended delaying implementation of the proposed domain weighting to allow hospitals time to shift quality improvement focus toward the Clinical Outcomes domain. A number of commenters recommended adopting the alternative domain weighting proposal, where each remaining domain would be weighted equally at one-third of a hospital's TPS, because it would result in a roughly equal distribution of gains and losses across hospitals participating in the Hospital VBP Program and thereby provide hospitals an opportunity to be rewarded for good performance on any one of the measure domains. A few commenters expressed concern about increasing the weight of the Clinical Outcomes domain to 50 percent because the commenters believed the domain does not provide an accurate, comprehensive view of hospital performance. Some commenters did not support adoption of any domain weighting methodology where the Safety domain is removed.

Response: We thank the commenters for their input regarding the proposed domain weighting policies for the Hospital VBP Program. As discussed in section IV.I.4.a.(2) of the preamble of this final rule, above, we are not finalizing our proposal to remove the Safety domain. For this reason, as stated above, we are not finalizing any changes to the current domain weighting in this final rule. However, we will take commenters' feedback into consideration in evaluating any potential future changes to the domain weights.

Comment: Several commenters did not support weighting the Efficiency and Cost Reduction domain at 25 percent because this domain would include only the MSPB measure and

therefore recommended reducing its weight. A few commenters recommended that CMS consider further deemphasizing the weight of the Efficiency and Cost Reduction domain if it continues to observe that hospitals that perform below the national average on the clinical quality measures but perform well on the MSPB measure receive an incentive payment under the proposed approach. Other commenters recommended reducing the weight of the Efficiency and Cost Reduction domain and increasing the weight of the Person and Community Engagement domain.

Response: We thank commenters for their input, and note that the previously finalized weight of the Efficiency and Cost Reduction domain for the FY 2019 and FY 2020 program years, which contains only the MSPB measure, is 25 percent. Because we did not consider a weight for the Efficiency and Cost Reduction domain below 25 percent in our analyses of the domain weighting options discussed in the FY 2019 IPPS/LTCH PPS proposed rule, we are not revising the previously finalized weighting of the Efficiency and Cost Reduction domain in this final rule. However, will take commenters' recommendations into consideration as we continue evaluating our domain weighting policies, including ways to address concerns about hospitals that perform below the national average on quality measures receiving incentive payments.

Comment: One commenter expressed concern about the weight placed on the Person and Community Engagement domain because it is based on only the HCAHPS patient experience survey measures, which the commenter believes are subjective, can force hospitals to overemphasize experience as opposed to making improvements to clinical care, and could lead to unintended consequences.

Response: We thank the commenter for its input, and will take this recommendation into consideration for future years of the program as we continue evaluating our domain weighting policies. Because we did not consider a weight for the Person and Community Engagement domain below 25 percent in our analyses of the domain weighting options discussed in the FY 2019 IPPS/LTCH PPS proposed rule, we are not revising the previously finalized weighting of the Person and Community Engagement domain in this final rule. As previously finalized, we believe weighting the Person and Community Engagement domain at 25 percent of hospitals' TPSs is appropriate for the domain that measures important elements of the patient's experience of inpatient care. We have adjusted HCAHPS scores for certain patient-level factors that are beyond the hospital's control but which affect survey responses. These factors include patient severity, as indicated by self-reported overall health, and patient's highest level of education, considered the most accurate single measure of socioeconomic status for older adults. We also note that AHRQ carried out a rigorous, scientific process to develop and test the HCAHPS instrument. This process entailed multiple steps, including: A public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking. The HCAHPS Survey is NQF-endorsed and is currently the only measure in the program which uses information collected directly from patients.

Comment: One commenter specifically recommended further development of the Person and Community Engagement domain and then increasing the weight of that domain. Another commenter recommended that CMS reevaluate the measures in the program to encompass a more holistic view of quality, including improving patient's quality of life, because the commenter believed that while experience and cost are important measures of quality, they are not necessarily equivalent to high quality. A third commenter recommended that if measures are added to or removed from these domains, CMS should examine the weighting and make appropriate adjustments.

Response: We thank the commenters for their recommendations, and will take these recommendations into consideration for future years of the program.

After consideration of the public comments we received, we are not finalizing our proposal to use three domains, beginning with the FY 2021 program year, with the Clinical Outcomes domain weighted at 50 percent; the Person and Community Engagement domain weighted at 25 percent; and the Efficiency and Cost Reduction domain weighted at 25 percent. We are also not finalizing our proposal to remove the Safety domain because we are not removing all of the measures in that domain. Therefore, in accordance with our current policy, we will maintain four domains in the Hospital VBP Program, each with a weight of 25 percent, for hospitals that receive a score in all domains, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted.

c. Minimum Numbers of Measures for Hospital VBP Program Domains for the FY 2021 Program Year and Subsequent Years

Based on previously finalized policies (82 FR 38266), for a hospital to receive a domain score for the FY 2021 program year and subsequent years:

- A hospital must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Person and Community Engagement domain score.
- A hospital must receive a minimum of two measure scores within the Clinical Outcomes domain (currently referred to as the Clinical Care domain).
- A hospital must receive a minimum of one measure score within the Efficiency and Cost Reduction domain.

As discussed in section IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposal to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year. Therefore, based on previously finalized policies (82 FR 38266), we are clarifying in this final rule that additionally:

- A hospital must receive a minimum of two measure scores within the Safety domain.

We note that we are finalizing our proposal to remove the condition-specific payment measures from the Hospital VBP Program and, therefore, a hospital's Efficiency and Cost Reduction domain score would be based solely on its MSPB measure score. In the proposed rule (83 FR 20420), we did not propose any changes to this policy.

d. Minimum Numbers of Cases for Hospital VBP Program Measures for the FY 2021 Program Year and Subsequent Years

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608

through 53609); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267).

(2) Clinical Care Domain/Clinical Outcomes Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a minimum number of 25 cases for the MORT–30–AMI, MORT–30–HF, and MORT–30–PN measures. We adopted the same 25-case minimum for the MORT–30–COPD measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570), and for the MORT–30–CABG, MORT–30–PN (updated cohort), and THA/TKA measures in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011).

In the proposed rule (83 FR 20420), we did not propose any changes to these policies.

(3) Person and Community Engagement Domain

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we adopted a minimum number of 100 completed HCAHPS surveys for a hospital to receive a score on the HCAHPS measure.

In the proposed rule (83 FR 20420), we did not propose any changes to this policy.

(4) Efficiency and Cost Reduction Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53609 through 53610), we adopted a minimum of 25 cases in order to receive a score for the MSPB measure. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086), we retained the same MSPB measure case minimum for the FY 2016 program year and subsequent years. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38267), we adopted a policy that hospitals must report a minimum number of 25 cases per measure in order to receive a measure score for the condition-specific payment measures (namely, the AMI Payment, HF Payment, and PN Payment measures), for the FY 2021 program year, FY 2022 program year, and subsequent years.

In the proposed rule (83 FR 20420), we did not propose any changes to these policies for the MSPB measure; however, as discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposals to remove the three condition-specific payment measures (AMI Payment, HF Payment, and PN Payment) from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

(5) Summary of Previously Adopted Minimum Numbers of Cases for the FY 2021 Program Year and Subsequent Years

The previously adopted minimum numbers of cases for these measures are set forth in the table below.

As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposals to remove the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia) beginning with the FY 2021 program year, or to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. Therefore, previously adopted minimum numbers of cases for those measures are also set forth in the table below. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a minimum of one predicted infection for NHSN-based surveillance measures (that is, the CAUTI, CLABSI, CDI, MRSA, and SSI measures) based on CDC's minimum case criteria. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085), we adopted this case minimum for the NHSN-based surveillance measures for the FY 2016 Hospital VBP Program and subsequent years. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38267), beginning with the FY 2023 program year, we adopted a policy that hospitals must report a minimum of three eligible cases on any one underlying indicator during the baseline period in order to receive an improvement score and three eligible cases on any one underlying indicator during performance period in order to receive an achievement score on the Patient Safety and Adverse Events (Composite) (PSI 90) measure. For the purposes of the PSI 90 measure, a case is ''eligible'' for a given indicator if it meets the criterion for inclusion in the indicator measure population.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS

Measure short name	Minimum number of cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain*	
MORT–30–AMI	Hospitals must report a minimum number of 25 cases.
MORT–30–HF	Hospitals must report a minimum number of 25 cases.
MORT–30–PN (updated cohort).	Hospitals must report a minimum number of 25 cases.
MORT–30–COPD	Hospitals must report a minimum number of 25 cases.
MORT–30–CABG	Hospitals must report a minimum number of 25 cases.
THA/TKA	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI.	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Measure short name	Minimum number of cases
Patient Safety and Adverse Events (Composite) #.	Hospitals must report a minimum of three eligible cases on any one underlying indicator.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

* In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize our proposal to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38242 through 38244, 38251 through 38256), we removed the former PSI 90 measure beginning with the FY 2019 program year. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251 through 38256), we adopted the Patient Safety and Adverse Events (Composite) (PSI 90) measure beginning with the FY 2023 program year.

5. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for baseline and performance periods that we have adopted for the FY 2019, FY 2020, FY 2021, and FY 2022 program years. In the same rule, we finalized a schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261) for additional baseline and performance periods that we have adopted for the FY 2022, FY 2023, and subsequent program years.

b. Person and Community Engagement Domain

Since the FY 2015 program year, we have adopted a 12-month baseline period and 12-month performance period for measures in the Person and Community Engagement domain (previously referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the Person and Community Engagement domain that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and subsequent years.

In the proposed rule (83 FR 20421), we did not propose any changes to these policies.

c. Efficiency and Cost Reduction Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). In the FY 2017 IPPS/LTCH PPS final rule, we finalized our proposal to adopt a 12-month performance period for the MSPB measure that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent years (81 FR 56998).

In the proposed rule (83 FR 20421), we did not propose any changes to these policies.

d. Clinical Care Domain/Clinical Outcomes Domain

For the FY 2020 and FY 2021 program years, we adopted a 36-month baseline period and 36-month performance period for measures in the Clinical Outcomes domain (currently referred to as the Clinical Care domain) (78 FR 50692 through 50694; 79 FR 50073; 80 FR 49563).[253] In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized our proposal to adopt a 36-month performance period and 36-month baseline period for the FY 2022 program year for each of the previously finalized measures in the Clinical Outcomes domain—that is, the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, THA/TKA, and MORT–30–CABG measures. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we also adopted a 22-month performance period for the MORT–30–PN (updated cohort) measure and a 36-month baseline period for the FY 2021 program year. In the same final rule, we adopted a 34-month performance period and 36-month baseline period for the MORT–30–PN (updated cohort) measure for the FY 2022 program year.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38259), we adopted a 36-month performance period and 36-month baseline period for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort), and THA/TKA measures for the FY 2023 program year and subsequent years. Specifically, for the mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, and MORT–30–PN (updated cohort)), the performance period runs for 36 months from July 1, five years prior to the applicable fiscal program year, to June 30, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from July 1, ten years prior to the applicable fiscal program year, to June 30, seven years prior to the applicable fiscal program year. For the THA/TKA measure, the performance period runs for 36 months from April 1, five years prior to the applicable fiscal program year, to March 31, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from April 1, ten years prior to the applicable fiscal program year, to March 31, seven years prior to the applicable fiscal program year.

In the proposed rule (83 FR 20421), we did not propose any changes to the length of these performance or baseline periods.

e. Safety Domain

In the FY 2017 IPPS/LTCH PPS final rule, we finalized our proposal to adopt a performance period for all measures in the Safety domain—with the exception of the PSI 90 measure—that runs on the calendar year two years prior to the applicable program year and a baseline

[253] The THA/TKA measure was added for the FY 2019 program year with a 36-month baseline period and a 24-month performance period (79 FR 50072), but we have since adopted 36-month baseline and performance periods for the FY 2021 program year (80 FR 49563).

period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent program years (81 FR 57000). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38242 through 38244, 38251 through 38256), we removed the former PSI 90 measure beginning with the FY 2019 program year, and adopted the Patient Safety and Adverse Events (Composite) (PSI 90) measure beginning with the FY 2023 program year, along with baseline and performance periods for the measure (82 FR 38258 through 38259).

As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposals to remove the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia) beginning with the FY 2021 program year, or to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

f. Summary of Previously Adopted Baseline and Performance Periods for the FY 2020 Through FY 2024 Program Years

The tables below summarize the baseline and performance periods that we have previously adopted. In the FY 2019 IPPS/LTCH PPS proposed rule, we did not summarize the previously adopted baseline and performance periods for the Safety domain or its measures for the FY 2021 program year or subsequent years due to our proposal to remove the Safety domain and its measures. However, because we are not finalizing our proposals to remove the five HAI measures, the PSI 90 measure, or the Safety domain as a whole, we are providing the previously adopted baseline and performance periods for those measures in this final rule, below.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; SAFETY; AND EFFICIENCY AND COST REDUCTION DOMAINS

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS	• January 1, 2016–December 31, 2016	• January 1, 2018–December 31, 2018.
Clinical Outcomes: *		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT-30–PN).	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
• THA/TKA	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
Safety:		
• PC–01 and NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia).	• January 1, 2016–December 31, 2016	• January 1, 2018–December 31, 2018.
Efficiency Cost Reduction:		
• MSPB	• January 1, 2016–December 31, 2016	• January 1, 2018–December 31, 2018.

* In section IV.I.4.a.(1) of the preamble of this final rule we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * SAFETY; ** AND EFFICIENCY AND COST REDUCTION DOMAINS

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
Clinical Outcomes: *		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD).	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2019.
• THA/TKA	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.
Safety: **		
• NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
Efficiency and Cost Reduction: ***		
• MSPB	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.

* In section IV.I.4.a.(1) of the preamble of this final rule we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, or the Safety domain.

*** As discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove the AMI Payment and HF Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * SAFETY; ** AND EFFICIENCY AND COST REDUCTION DOMAINS

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.
Clinical Outcomes: *		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG).	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2020.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2020.
• THA/TKA	• April 1, 2012–March 31, 2015	• April 1, 2017–March 31, 2020.
Safety: **		
• NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.
Efficiency and Cost Reduction: ***		
• MSPB	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.

* In section IV.I.4.a.(1) of the preamble of this final rule we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, or the Safety domain.

*** As discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove the AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2023 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * SAFETY; ** AND EFFICIENCY AND COST REDUCTION DOMAINS

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS	• January 1, 2019–December 31, 2019	• January 1, 2021–December 31, 2021.
Clinical Outcomes: *		
• Mortality (MORT-30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort).	• July 1, 2013–June 30, 2016	• July 1, 2018–June 30, 2021.
• THA/TKA	• April 1, 2013–March 31, 2016	• April 1, 2018–March 31, 2021.
Safety:		
• NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2019–December 31, 2019	• January 1, 2021–December 31, 2021.
• Patient Safety and Adverse Events (Composite) (PSI 90).	• October 1, 2015–June 30, 2017	• July 1, 2019–June 30, 2021.
Efficiency and Cost Reduction: ***	• January 1, 2019–December 31, 2019	• January 1, 2021–December 31, 2021
• MSPB.		

* In section IV.I.4.a.(1) of the preamble of this final rule we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, PSI 90 measure, or the Safety domain.

*** As discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2024 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * SAFETY; ** AND EFFICIENCY AND COST REDUCTION DOMAINS

Doman	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS	• January 1, 2020–December 31, 2020	• January 1, 2022–December 31, 2022.
Clinical Outcomes: *		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort).	• July 1, 2014–June 30, 2017	• July 1, 2019–June 30, 2022.
• THA/TKA	• April 1, 2014–March 31, 2017	• April 1, 2019–March 31, 2022.
Safety: **		
• NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2020–December 31, 2020	• January 1, 2022–December 31, 2022.
• Patient Safety and Adverse Events (Composite) (PSI 90).	• July 1, 2016–June 30, 2018	• July 1, 2020–June 30, 2022.
Efficiency and Cost Reduction: ***		

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2024 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * SAFETY; ** AND EFFICIENCY AND COST REDUCTION DOMAINS—Continued

Doman	Baseline period	Performance period
• MSPB	• January 1, 2020–December 31, 2020	• January 1, 2022–December 31, 2022.

* In section IV.I.4.a.(1) of the preamble of the proposed this final rule we discuss our decision, to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in section IV.I.2.c.(1) of the preamble of this final rule, we are finalizing our proposal to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year. However, as discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of the preamble of this final rule, we are not finalizing our proposals to remove CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures, PSI 90 measure, or the Safety domain.

*** As discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

6. Previously Adopted and Newly Finalized Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50080 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program.

b. Previously Adopted and Newly Finalized Performance Standards for the FY 2021 Program Year

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38263), we summarized the previously adopted performance standards for the FY 2021 program year for the Clinical Care domain (proposed Clinical Outcome domain) measures (MORT–30–HF, MORT–30–AMI, MORT–30–COPD, THA/TKA, and MORT–30–PN (updated cohort)) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. The previously adopted performance standards for the measures in the Clinical Care (proposed Clinical Outcome domain) and Efficiency and Cost Reduction domains for the FY 2021 program year are set out in the tables below. As discussed in sections IV.I.2.c.(2) and IV.I.4.a.(2) of this final rule, we are not finalizing our proposals to remove the five HAI measures, the PSI 90 measure, or the Safety domain from the Hospital VBP Program; therefore, below we are displaying newly finalized performance standards for the following Safety domain measures for the FY 2021 program year: CAUTI, CLABSI, CDI, MRSA Bacteremia, Colon and Abdominal Hysterectomy SSI.

PREVIOUSLY ADOPTED AND NEWLY DISPLAYED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR: SAFETY, CLINICAL OUTCOMES, ∧ AND EFFICIENCY AND COST REDUCTION DOMAINS #

Measure short name	Achievement threshold	Benchmark
Safety Domain		
CAUTI	0.774	0.
CLABSI	0.687	0.
CDI	0.748	0.067.
MRSA Bacteremia	0.763	0.
Colon and Abdominal Hysterectomy SSI	• 0.754	• 0.
	• 0.726	• 0.
Clinical Outcomes Domain ∧ *		
MORT–30–AMI	0.860355	0.879714.
MORT–30–HF	0.883803	0.906144.
MORT–30–PN (updated cohort)	0.836122	0.870506.
MORT–30–COPD	0.923253	0.938664.
THA/TKA **	0.031157	0.022418.

PREVIOUSLY ADOPTED AND NEWLY DISPLAYED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR: SAFETY, CLINICAL OUTCOMES, ∧ AND EFFICIENCY AND COST REDUCTION DOMAINS #—Continued

Measure short name	Achievement threshold	Benchmark
Efficiency and Cost Reduction Domain		
MSPB**	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

∧ In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize changing the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

As discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove the AMI Payment and HF Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance standards for those measures are not included in this table.

* We note that the mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.

** Lower values represent better performance.

The eight dimensions of the HCAHPS measure are calculated to generate the HCAHPS Base Score. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight, thus the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement Domain score that ranges from 0 to 100 points.

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), we proposed to adopt performance standards for the FY 2021 program year for the Person and Community Engagement domain. In the proposed rule, we noted that the numerical values for the proposed performance standards displayed in the proposed rule represent estimates based on the most recently available data, and that we intended to update the numerical values in the FY 2019 IPPS/LTCH PPS final rule.

Although we invited public comment on the proposed performance standards for the eight HCAHPS survey dimensions, we did not receive any public comments on the proposed performance standards, and are adopting the performance standards listed in the table below. These HCAHPS survey dimension performance standards in the table below have been updated from the FY 2018 IPPS/LTCH PPS proposed rule and represent the most recently available data.

NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN ±

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	42.06	79.06	87.36
Communication with Doctors	41.99	79.91	88.10
Responsiveness of Hospital Staff	33.89	65.77	81.00
Communication about Medicines	33.19	63.83	74.75
Hospital Cleanliness & Quietness	30.60	65.61	79.58
Discharge Information	66.94	87.38	92.17
Care Transition	6.53	51.87	63.32
Overall Rating of Hospital	34.70	71.80	85.67

± The performance standards displayed in this table were calculated using four quarters of CY 2017 data in this final rule.

c. Previously Adopted Performance Standards for Certain Measures for the FY 2022 Program Year

We have adopted certain measures for the Clinical Care domain (newly finalized as the Clinical Outcomes domain) and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57009), we adopted performance standards for the FY 2022 program year for the Clinical Care domain (newly finalized as the Clinical Outcomes domain) measures (THA/TKA, MORT–30–HF, MORT–30–AMI, MORT–30–PN (updated cohort), MORT–30–COPD, and MORT–30–CABG) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. The previously adopted performance standards for these measures are set out in the table below.

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain ∧ *		
MORT–30–AMI	0.861793	0.881305.
MORT–30–HF	0.879869	0.903608.
MORT–30–PN (updated cohort)	0.836122	0.870506.
MORT–30–COPD	0.920058	0.936962.
MORT–30–CABG †	0.968210	0.979000.
THA/TKA **	0.029833	0.021493.
Efficiency and Cost Reduction Domain #		
MSPB **	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

∧ In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize our proposal to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

† After publication of the FY 2017 IPPS/LTCH PPS final rule, we determined there was a display error in the performance standards for this measure. Specifically, the Achievement Threshold and Benchmark values, while accurate, were presented in the wrong categories. We corrected this issue in the FY 2018 IPPS/LTCH PPS final rule, and the correct performance standards are displayed here in the table above.

* The mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.

** Lower values represent better performance.

As discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove the AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance standards for those three measures are not included in this table.

d. Previously Adopted and Newly Displayed Finalized Performance Standards for Certain Measures for the FY 2023 Program Year

In the proposed rule (83 FR 20425 through 20426), we noted that we have adopted certain measures for the Clinical Care domain (newly finalized as the Clinical Outcomes domain) and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38264 through 38265), we adopted the following performance standards for the FY 2023 program year for the Clinical Care domain (newly finalized as the Clinical Outcomes domain) measures (THA/TKA, MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, and MORT–30–CABG) and for the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38264), we stated our intent to propose performance standards for the PSI 90 measure in this year's rulemaking.

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20425 through 20426), we proposed to remove the PSI 90 measure from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. For this reason, we did not include proposed performance standards for this measure in the proposed rule. However, as discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposal to remove the PSI 90 measure from the Hospital VBP Program. Therefore, we are displaying newly finalized performance standards for the PSI 90 measure for the FY 2023 program year, in the table below. We note that the performance standards for the MSPB measure are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. The previously adopted and newly displayed performance standards for the other measures are also set out in the table below.

PREVIOUSLY ADOPTED AND NEWLY DISPLAYED FINALIZED PERFORMANCE STANDARDS FOR THE FY 2023 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Safety Domain		
PSI 90 **	0.972658	0.760882.
Clinical Outcomes Domain ∧ *		
MORT–30–AMI	0.866548	0.885499.
MORT–30–HF	0.881939	0.906798.
MORT–30–PN (updated cohort)	0.840138	0.871741.
MORT–30–COPD	0.919769	0.936349.
MORT–30–CABG	0.968747	0.979620.
THA/TKA **	0.027428	0.019779.

PREVIOUSLY ADOPTED AND NEWLY DISPLAYED FINALIZED PERFORMANCE STANDARDS FOR THE FY 2023 PROGRAM YEAR—Continued

Measure short name	Achievement threshold	Benchmark
Efficiency and Cost Reduction Domain #		
MSPB **	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

∧ In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize our proposal to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

* The mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.

** Lower values represent better performance.

As discussed in section IV.I.2.c.(3) of the preamble of this final rule, we are finalizing our proposal to remove the AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance standards for those three measures are not included in this table.

e. Performance Standards for Certain Measures for the FY 2024 Program Year

We have adopted certain measures for the Clinical Care domain (newly finalized as the Clinical Outcomes domain) and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20427), we proposed the following performance standards for the FY 2024 program year for the Clinical Care domain (newly finalized as the Clinical Outcomes domain) and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. These newly proposed performance standards for these measures are set out in the table below.

Although we invited public comments on these proposed performance standards for the FY 2024 program year, we did not receive any public comments on the proposed performance standards for the FY 2024 program year, and are adopting the performance standards listed below.

NEWLY FINALIZED PERFORMANCE STANDARDS FOR THE FY 2024 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain ∧ *		
MORT–30–AMI	0.869247	0.887868.
MORT–30–HF	0.882308	0.907733.
MORT–30–PN (updated cohort)	0.840281	0.872976.
MORT–30–COPD	0.916491	0.934002.
MORT–30–CABG	0.969499	0.980319.
THA/TKA **	0.025396	0.018159.
Efficiency and Cost Reduction Domain		
MSPB **	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

∧ In section IV.I.4.a.(1) of the preamble of this final rule, we discuss our decision to finalize our proposal to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

* The mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.

** Lower values represent better performance.

J. Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the preamble of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program. For a detailed discussion of the statutory basis of the HAC Reduction Program, we refer readers to section V.I.2. of the preamble of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708 through 50709). For a further description of our previously finalized policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278). These policies describe the general framework for implementation of the HAC Reduction Program, including: (1) The relevant definitions applicable to the program; (2) the payment adjustment under the program; (3) the measure selection process and conditions for the program, including a risk-adjustment and scoring methodology; (4) performance scoring; (5) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and

(6) limitation of administrative and judicial review.

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

By publicly reporting quality data, we strive to put patients first by ensuring they, along with their clinicians, are empowered to make decisions about their own healthcare using information aligned with meaningful quality measures. The HAC Reduction Program, together with the Hospital VBP Program and the Hospital Readmissions Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing programs to the inpatient care setting. We have undertaken efforts to review the existing HAC Reduction Program measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative we described in section I.A.2. of the preambles of the proposed rule and this final rule.

As part of this review, as discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20426 through 20428), we took a holistic approach to evaluating the appropriateness of the HAC Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital VBP Program and the Hospital Readmissions Reduction Program), as well as in the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable—but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

As previously stated, the HAC Reduction Program focuses on making care safer by reducing harm caused in the delivery of care. Measures in the HAC Reduction Program, generally represent ''never events'' [254] and often, if not always, assess preventable conditions. By including these measures in the Program, we seek to encourage hospitals to address the serious harm caused by these adverse events and to reduce them. Therefore, after thoughtful review, we have determined that the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) and the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures (NHSN HAI measures) are most appropriately included as part of the HAC Reduction Program, and, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20474 through 20475; 20411), we proposed to remove these measures from the Hospital IQR and VBP Programs.[255] We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance while streamlining the measure sets.

The HAC Reduction Program has historically relied on Hospital IQR Program processes for administrative support; we therefore proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20429 through 20437) HAC Reduction Program specific healthcare-associated infection measure data collection and validation requirements, and scoring associated with data completeness, timeliness, and accuracy. Contingent upon the Hospital IQR Program finalizing its proposal to remove NHSN HAI measures from its program (section VIII.A.5.b.(2)(b) of the preamble of the proposed rule), the HAC Reduction Program proposed to formally adopt analogous processes and independently manage these administrative processes to receive CDC NHSN data and begin validation seamlessly with January 1, 2019 infectious events. In the proposed rule, we noted that if the Hospital IQR Program did not finalize its proposal to remove NHSN HAI measures from its program, then the HAC Reduction Program would subsequently not finalize its proposals to manage the associated administrative processes.

In the proposed rule (83 FR 20426 through 20437), for the HAC Reduction Program, we proposed to: (1) Establish administrative policies for the HAC Reduction Program to collect, validate, and publicly report quality measure data independently instead of conducting these activities through the Hospital IQR Program; (2) adjust the scoring methodology by removing domains and assigning equal weighting to each measure for which a hospital has a measure score in order to improve

[254] ''The term ''Never Event'' was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. The NQF initially defined 27 such events in 2002. The list has been revised since then, most recently in 2011, and now consists of 29 events grouped into 7 categories: Surgical, product or device, patient protection, care management, environmental, radiologic, and criminal.'' Never Events, Available at: *https://psnet.ahrq.gov/primers/primer/3/never-events.*

[255] We note that following the comment period, we determined that the Hospital VBP Program would retain NHSN HAI measures and its version of the CMS PSI–90. In order to facilitate the Hospital VBP Program's adoption of administrative requirements similar to requirements under the HAC Reduction Program, the Hospital IQR Program will retain NHSN HAI measures for additional year.

fairness across hospital types in the Program; (3) establish the data collection period for the FY 2021 Program Year; and (4) solicit stakeholder feedback regarding the potential future inclusion of additional measures, including eCQMs.

2. Accounting for Social Risk Factors in the HAC Reduction Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38273 through 38276), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[256] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[257] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38274), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[258] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[259] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

While we did not specifically request comment on social risk factors in the FY 2019 proposed rule, we received a number of comments with respect to social risk factors. We thank commenters for sharing their views and their willingness to support the efforts of CMS and NQF on this important issue. We take this feedback seriously and will continue to review social risk factors on an on-going and continuous basis. In addition, we both welcome and appreciate stakeholder feedback as we continue our work on these issues.

3. Previously-Adopted Measures for FY 2019 and Subsequent Years

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57013 through 57020), we finalized the CMS Patient Safety and Adverse Events Composite (CMS PSI 90)[260] measure for use in the FY 2018 program and subsequent years for Domain 1. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) measures for Domain 2 for use in the FY 2015 program and subsequent years.

[256] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[257] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[258] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[259] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

[260] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS quality programs.

Currently, the Program utilizes five NHSN measures: CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia. These previously finalized measures, with their full measure names, are shown in the table below.

HAC Reduction Program Measures for FY 2019

Short name	Measure name	NQF #
Domain 1:		
CMS PSI 90	Patient Safety and Adverse Events Composite	0531
Domain 2:		
CAUTI	NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716

4. Administrative Policies for the HAC Reduction Program for FY 2019 and Subsequent Years

a. Measure Specifications

As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) for the Hospital IQR Program and subsequently finalized for the HAC Reduction Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101), we will use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program and to use rulemaking to adopt substantive updates to measures. As with the Hospital IQR Program, we will determine what constitutes a substantive versus nonsubstantive change on a case-by-case basis. As we also stated in that rulemaking (79 FR 50100), examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe nonsubstantive changes may also include nonsubstantive updates to NQF-endorsed measures based upon changes to the measures' underlying clinical guidelines.

We will continue to use rulemaking to adopt substantive updates, and a subregulatory process to make nonsubstantive updates, to measures we have adopted for the HAC Reduction Program. As stated in past rules (78 FR 50776), examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus nonsubstantive would apply to all measures in the HAC Reduction Program.

We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process, which is available through its website at: *http://www.qualityforum.org/projectlisting.aspx*. We believe this policy adequately balances our need to incorporate updates to HAC Reduction Program measures in the most expeditious manner possible while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

Technical specifications for the CMS PSI 90 in Domain 1 can be found on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228695355425*. Technical specifications for the NHSN HAI measures in Domain 2 can be found at CDC's NHSN website at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html.* Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

b. Data Collection Beginning CY 2019

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20429 through 20430), we proposed to adopt data collection processes for the HAC Reduction Program to receive CDC NHSN data beginning with January 1, 2019 infection events to correspond with the Hospital IQR Program's calendar year reporting period and maintain the HAC Reduction Program's annual performance period start date. All reporting requirements, including quarterly frequency, CDC collection system, and deadlines would remain constant from current Hospital IQR Program requirements to aid continued hospital reporting through clear and consistent requirements. This proposed start date aligns with the effective date of the Hospital IQR Program's proposed removal of these measures beginning with CY 2019 reporting period/FY 2021 payment determination as discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule, and should allow for a seamless transition.

The HAC Reduction Program identifies the worst-performing quartile of hospitals by calculating a Total HAC Score derived from the CMS PSI 90 and NHSN HAI measures, which are derived from claims-based and chart-abstracted measures data, respectively. No additional collection mechanisms are required for the CMS PSI 90 measure because it is a claims-based measure calculated using data submitted to CMS by hospitals for Medicare payment, and therefore imposes no additional administrative or reporting requirements on participating hospitals. For the NHSN HAI measures, we proposed to adopt the NHSN HAI data collection process established in the Hospital IQR Program if the Hospital IQR Program removed the NHSN HAI

measures. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50190), where we finalized the CDC NHSN as the mechanism to submit data on the NHSN HAI measures to the Hospital IQR Program, and to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723), where the HAC Reduction Program stated that it would obtain HAI measure results that hospitals submitted to the CDC NHSN for the Hospital IQR Program. Hospitals would continue to submit data through the CDC NHSN portal located by selecting ''NHSN Reporting'' after signing in at: *https://sams.cdc.gov*, and the HAC Reduction Program would receive the NHSN data directly from the CDC instead of through the Hospital IQR Program as an intermediary.

We also proposed to adopt the Hospital IQR Program's exception policy to reporting and data submission requirements for the CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI measures. As noted in FY 2013 IPPS/LTCH PPS final rule (77 FR 53539) and in FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822) for the Hospital IQR Program and in FY 2015 IPPS/LTCH PPS final rule (79 FR 50096) for the HAC Reduction Program, CMS acknowledges that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting and that some hospitals may perform so few procedures requiring surveillance under the Colon and Abdominal Hysterectomy SSI measure that the data may not be meaningful for public reporting nor sufficiently reliable to be utilized for a program year. If a hospital does not have adequate locations or procedures, it should submit the Measure Exception Form to the HAC Reduction Program beginning on January 1, 2019. The IPPS Quality Reporting Programs Measure Exception Form is located using the link located on the QualityNet website under the Hospitals − Inpatient > Hospital Inpatient Quality Reporting Program tab at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*. As has been the case under the Hospital IQR Program, hospitals seeking an exception would submit this form at least annually to be considered.

Beginning in CY 2019,[261] the HAC Reduction Program would provide hospitals with the same NHSN HAI measures quarterly reports that stakeholders are accustomed to under the Hospital IQR Program. However, some hospitals that elected not to participate in the Hospital IQR Program may be unfamiliar with them. These reports, provided via the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*, provide hospitals with their facility's quarterly measure data as well as facility, State and national-level results for the measures. To access their reports, hospitals must register for a QualityNet Secure Portal Account. We anticipate the transition to occur without interruption, with the only change to stakeholders being that they would receive reports from both the HAC Reduction Program and the Hospital IQR Program for the respective measures adopted in each program.

Comment: Many commenters supported CMS' proposal to adopt a HAC Reduction Program-specific data collection process to receive NHSN HAI data from CDC.

Response: We thank the commenters for their support. As noted in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we are delaying removal of the NHSN HAI measures from the Hospital IQR Program until the CY 2020 reporting period/FY 2022 payment determination. For this reason, we are also delaying collection and reporting of this data under the HAC Reduction Program until CY 2020.

Comment: A commenter urged CMS to clearly communicate any administrative policies regarding the collection of quality measure data to stakeholders before the implementation of any finalized administrative policies to ensure a seamless, uninterrupted transition. Other commenters asked CMS to clarify that quality data would still be available on *Hospital Compare* and sought assurance that hospitals would still receive access to the data they were accustomed to receiving through the Hospital IQR Program.

Response: We thank the commenters for the comments. We do not expect hospitals to notice any changes in the submission of their NHSN HAI data. We are merely finalizing the CDC NHSN portal as the mechanism through which the HAC Reduction Program receives NHSN HAI data. We expect this process to occur seamlessly, but because of prior rulemaking, we needed to formally propose and adopt the CDC NHSN as the mechanism for the HAC Reduction Program to receive data. However, if we determine that any changes will impact how hospitals are able to view and report their data, we will clearly communicate any information regarding administrative actions through our established communication channels.

We received numerous comments from stakeholders regarding our holistic approach to evaluating the appropriateness of measures previously adopted under the Hospital Readmissions Reduction Program, Hospital VBP Program, HAC Reduction Program, and Hospital IQR Program and our vision for the future of these programs. While program-specific comments and policies are discussed in more detail in each program-specific section of the preamble of this final rule, we would like to clarify that in light of our mission to prioritize patients in the provision of services, we are expanding the stated scope of the Hospital VBP Program to include patient safety measures. While we initially sought to delineate measure focus areas between the Hospital VBP Program and HAC Reduction Program, we agree with commenters that patient safety is a critical component of quality improvement efforts, and we appreciate commenters who conveyed the multifaceted benefits of retaining the safety measures in more than one value-based purchasing program. Therefore, we believe it is appropriate and important to provide incentives under more than one program to ensure that hospitals take every precaution to avoid adverse patient safety events.

In addition, because the incentive payment structure is different under the HAC Reduction and Hospital VBP Programs, we believe including patient safety measures in both programs will provide hospitals with strong incentives to continually strive for both improvement and high performance on these measures. In addition, retaining the measures in both programs will best promote transparency through publicly reporting hospital performance on these measures, as stakeholders will continue to be able to see both hospitals' performance compared to all other hospitals and hospitals' performance improvement over time. Finally, we note this approach will also reduce provider burden associated with these measures because these measures are being finalized for removal from the Hospital IQR Program, as discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule.

[261] We note that in the FY 2019 IPPS/LTCH PPS proposed rule, we incorrectly stated that HAC Reduction Program would provide the same quarterly reports as stakeholders under Hospital IQR Program beginning in ''FY 2019'' as opposed to CY 2019, which aligned with the proposed removal of the NHSN HAI measures from the Hospital IQR Program. We intend to begin reporting data beginning with CY 2020 (January 1, 2020), which is when the HAC Reduction Program will begin collecting CDC NHSN data. This is 1 year after we initially proposed because the Hospital IQR Program is retaining these measures for an additional year.

As we discussed in the proposed rule, the reporting of NHSN HAI measures and the CMS PSI–90 will not change in any substantive way. The CMS PSI 90 measure is reported on the *Hospital Compare* web pages; however, the child measures (that is, the 10 individual indicators that comprise the CMS PSI 90 measure) are reported in the downloadable database on *Hospital Compare.* Similarly, we believe the NHSN HAI measures represent important quality data consumers of healthcare can use to make informed decisions. Therefore, we intend to continue making NHSN HAI data available to the public on a quarterly basis. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38324), our current policy has been to report data under the Hospital IQR Program as soon as it is feasible on CMS websites such as the *Hospital Compare* website, *http://www.medicare.gov/hospitalcompare*, after a 30-day preview period. Upon finalizing our policy for the HAC Reduction Program to collect NHSN HAI data, the HAC Reduction Program will continue to make data available in the same form and manner on the *Hospital Compare* website, and as it is currently displayed under the Hospital IQR Program.

Comment: A commenter strongly opposed CMS' proposal to have the HAC Reduction Program receive NHSN HAI data from the CDC NHSN portal because it did not believe the HAC Reduction Program should be separated from the Hospital IQR Program based on its concern separation of the programs will lead to patient harm, unfair scoring and inaccurate reporting of performance.

Response: We thank the commenter for this view. As we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20427), we have undertaken efforts to review the existing HAC Reduction Program measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. As part of this review, we took a holistic approach to evaluating the appropriateness of the HAC Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital VBP Program and the Hospital Readmissions Reduction Program), as well as in the Hospital IQR Program, and after thoughtful review as well as consideration of public comments, we have determined that the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) and the NHSN HAI measures are most appropriately included as part of the HAC Reduction Program and Hospital VBP Program.

In order for the HAC Reduction Program to continue to receive its NHSN HAI data following the removal of NHSN HAI measures from the Hospital IQR Program, the HAC Reduction Program must establish the CDC NHSN as its mechanism to receive the required data. We believe that the collection and reporting of safety and NHSN HAI data is essential to reducing hospital-acquired conditions and improving patient safety. We also note that the HAC Reduction Program proposed to adopt validation policies for NSHN HAI data to ensure accurate data is received and used in the program. We provide more information on our validation policies in section IV.J.4.e.(1) of the preamble of this final rule below.

After consideration of the public comments we received, we are finalizing our proposal to adopt the CDC NHSN as the mechanism by which hospitals will report NHSN HAI measures for the HAC Reduction Program. However, we are delaying implementation of these reporting requirements until January 1, 2020 in order to align with a corresponding delay in removing these NHSN HAI measures from the Hospital IQR Program. We are also finalizing our proposal to adopt the IPPS Quality Reporting Programs Measure Exception Form beginning on January 1, 2020.

c. Review and Correction of Claims Data Used in the HAC Reduction Program for FY 2019 and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727), we detailed the process for the review and correction of claims-based data, and we did not propose any changes. We calculate the measure in Domain 1 using a static snapshot (data extract) taken after the 90-day period following the last date of discharge used in the applicable period. We create data extracts using claims in CMS' Common Working File (CWF) 90 days after the last discharge date in the applicable period which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2018, we would create the data extract on September 30, 2018, and use those data to calculate the claims based measures for that applicable period.

Hospitals are not able to submit corrections to the underlying claims snapshot used for the Domain 1 measure calculations after the extract date, and are not be able to add claims to this data set. Therefore, hospitals are encouraged to ensure that their claims are accurate prior to the snapshot date. We consider hospitals' claims data to be complete for purposes of calculating the Domain 1 for the HAC Reduction Program after the 90-day period following the last date of discharge used in the applicable period.

For more information, we refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727). We reiterate that under this process, hospitals retain the ability to submit new claims and corrections to submitted claims for payment purposes in line with CMS' timely claims filing policies, but the administrative claims data used to calculate the Domain 1 measure and the resulting Domain Score reflect the state of the claims at the time of extraction from CMS' CWF.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20430), we did not propose any change to our current administrative policy regarding the submission, review, and correction of claims data.

d. Review and Correction of Chart-Abstracted NHSN HAI Data Used in the HAC Reduction Program for FY 2019 and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726), we stated that the HAC Reduction Program would use the same process as the Hospital IQR Program for hospitals to submit, review, and correct data for chart-abstracted NHSN HAI measures. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), we clarified that hospitals had an opportunity to submit, review, and correct any of the chart-abstracted information for the full 4½ months after the end of the reporting quarter. We also noted that for the purposes of fulfilling CMS quality measurement reporting requirements, each facility's data must be entered into NHSN no later than 4½ months after the end of the reporting quarter.

For a detailed description of the process, we refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50726) where we explained that hospitals can begin submitting data on the first discharge day of any reporting quarter. Hospitals are encouraged to submit data early in the submission schedule not only to allow them sufficient time to identify errors and resubmit data before the quarterly submission deadline, but also to identify opportunities for continued improvement. Users may view and make corrections to the data that they submit starting immediately following submission. The data are populated into reports that are updated immediately with all data that have

been submitted successfully. We believe that 4½ months is sufficient time for hospitals to submit, review, and make corrections to their HAI data. We also balance the correction needs of hospitals with the need to publicly report and refresh measure information on *Hospital Compare* in a timely manner. Historically, CMS has generally refreshed HAI data on a quarterly basis on *Hospital Compare* in the Hospital IQR Program.

We wish to clarify that this HAI review and correction process is intended to permit hospitals review of measure performance and data submission feedback. Hospitals can use the NHSN system during the quarterly data submission period to identify any errors made in the reporting of a patient's specific ''infection event,'' the denominator (that is, overall admissions data), and other NHSN protocol data used to calculate measure results before the quarterly submission deadline. The HAI review and correction process is different than and occurs prior to the annual Scoring Calculations Review and Correction Process, which is intended to ensure the accurate calculation of measure scoring used for payment, and was discussed in section IV.J.4.g. of the preamble of the proposed rule.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20430), we did not propose any changes to our current administrative policy regarding the submission, review, and correction of chart-abstracted HAI data.

e. Changes to Existing Validation Processes

As discussed in above in section IV.J.1. of the preamble of the proposed rule (83 FR 20431 through 20433), we proposed to adopt processes to validate the NHSN HAI measure data used in the HAC Reduction Program if the Hospital IQR Program finalizes its proposals to remove NHSN HAI measures from its program. While the HAC Reduction Program cannot adopt the Hospital IQR Program's process as is for various reasons as discussed below, we intend for the HAC Reduction Program's processes to reflect, to the greatest extent possible, the current processes previously established the Hospital IQR Program. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403) for detailed information on the Hospital IQR Program's validation processes.

Currently, CMS estimates accuracy for the hospital-reported data submitted to the clinical warehouse and data submitted to NHSN as reproduced by a trained abstractor using a standardized NHSN HAI measure abstraction protocol created by CDC and CMS and posted on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?cid=%201228776288808&;pagename=QnetPublic%2FPage%2FQnetTier3&c=Page.* We proposed to adopt the validation processes into the HAC Reduction Program as previously established by the Hospital IQR Program (with some exceptions as discussed below) in this section as follows: Section IV.J.4.e.(1) of the preamble of the proposed rule (proposed measures subject to validation); section IV.J.4.e.(2) of the preamble of the proposed rule (proposed provider selection); section (IV.J.4.e.(3) of the preamble of the proposed rule (proposed targeting criteria); section IV.J.4.e.(4) of the preamble of the proposed rule (proposed calculation of the confidence period); section IV.J.4.e.(5) of the preamble of the proposed rule (proposed educational review process); section IV.J.4.e.(6) of the preamble of the proposed rule (proposed application of validation penalty); and section IV.J.4.e.(7) of the preamble of the proposed rule (proposed validation period).

Comment: Commenters expressed understanding and support for CMS' proposal to adopt the Hospital IQR Program's NHSN HAI measure validation process to the greatest extent possible in the HAC Reduction Program. The commenters appreciated that the validation requirements and process for the Hospital IQR Program are well established, and supported CMS' efforts to maintain continuity as it removes the measures from the Hospital IQR Program, but retains them in the HAC Reduction Program.

Response: We thank the commenters for their support. As noted in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we are delaying removal of the NHSN HAI measures from the Hospital IQR Program until the CY 2020 reporting period/FY 2022 payment determination. For this reason, we are also delaying adoption of the NHSN HAI measure validation processes into the HAC Reduction Program as discussed in more detail below.

Comment: One commenter recommended that CMS work on a continuing basis with experts at CDC and others to improve surveillance case definitions and other measures in NHSN. The commenter also encouraged CMS to work with CDC's Division of Healthcare Quality Promotion, which funds HAI programs in State health departments on the validations of NHSN data, because it believed that State HAI programs are better positioned to conduct validations in more facilities and follow-up with them to improve the quality of data.

Response: We thank the commenter for its views. We will continue to work with CDC and our partner institutions to ensure that the HAC Reduction Program is continually improving case definitions to improve quality measurement through specific and clear data element definitions, reduce hospital-acquired conditions, and avoids any unintended consequences.

We also appreciate the comment concerning validation. Our validation process is designed to ensure nationwide accuracy across all States reporting NHSN data through objective, clear, and specific feedback to hospitals about their reported data. We use a single nationwide methodology for validating NHSN data, which ensures a uniform application to this CMS requirement. We also recognize that over 20 State health departments do not currently validate NHSN data for hospitals. Our validation is the only known process to ensure accuracy in these States with no current validation process.

Comment: One commenter opposed CMS' proposal for the HAC Reduction Program's validation because it believed data validation should remain within the Hospital IQR Program. The commenter believed that CMS' plan for validation only further convolutes the programs and will cause undue financial hardship for healthcare systems.

Response: We thank the commenter for its views. We believe that the validation processes for NHSN HAI measures are essential to ensure the HAC Reduction Program continues to receive reliable NHSN HAI measures data for use in the program and for reporting NHSN HAI data following the removal of the NHSN HAI measures from the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing our proposal to adopt a validation process for the NHSN HAI measures for the HAC Reduction Program as described in greater detail in the following sections of the preamble of this final rule. However, we are delaying adoption of this NHSN HAI measure validation process into the HAC Reduction Program until Q3 2020

discharges for FY 2023 in order to align with a corresponding delay in removing these NHSN HAI measures from the Hospital IQR Program.

(1) Measures Subject to Validation

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50828 through 50832) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50264 through 50265), the Hospital IQR Program identified the following chart-abstracted NHSN HAI measures submitted via NHSN as being subject to validation: CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia.

In the proposed rule, we proposed that chart-abstracted NHSN HAI measures submitted via NHSN would be subject to validation in the HAC Reduction Program beginning with the Q3 2019 discharges for FY 2022. As stated in section IV.J.3. of the preamble of the proposed rule, and as finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), the HAC Reduction Program currently includes five NHSN HAI measures: CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia.

Comment: Commenters generally understood and supported CMS' proposal to validate NHSN HAI measures upon their removal from the Hospital IQR Program.

Response: We appreciate the commenters' support. As noted in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we are delaying removal of the NHSN HAI measures from the Hospital IQR Program until the CY 2020 reporting period/FY 2022 payment determination. For this reason, we are also delaying adoption of the NHSN HAI measure validation processes into the HAC Reduction Program until Q3 2020 discharges for FY 2023.

Comment: One commenter, in addition to its general opposition to the HAC Reduction Program, more specifically opposed the HAC Reduction Program's validation proposals because it believed data validation and the NHSN HAI measures should remain within the Hospital IQR Program. The commenter believed that CMS' plan only further convolutes the programs and will cause undue financial hardship for healthcare systems.

Response: We thank the commenter for its comment. We believe that the validation processes for NHSN HAI measures are essential to ensure the HAC Reduction Program's continues to receive reliable NHSN HAI measures data for use in the program following removal of the NHSN HAI measures from the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing our proposal to validate chart-abstracted NHSN HAI measures (CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia) submitted via NHSN under the HAC Reduction Program, but are delaying implementation to begin with Q3 2020 discharges for FY 2023.

(2) Provider Selection

For chart-abstracted data validation in the Hospital IQR Program, CMS currently performs a random and targeted selection of participating hospitals on an annual basis, as initially set out in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50833 through 50834). For example, in December of 2017, CMS randomly selected 400 hospitals for validation for the FY 2020 payment determination. In April/May of 2018, an additional targeted provider sample of up to 200 hospitals are selected (78 FR 50833 through 50834). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20431), we stated that we intend to mirror these policies for the HAC Reduction Program, and thus, we proposed annual random selection of 400 hospitals and the annual targeted selection of 200 hospitals using the targeting criteria proposed below in section IV.J.4.e.(3) of the preamble of the proposed rule.

Unlike the Hospital IQR Program, which includes only hospitals with active Notices of Participation (77 FR 53536), we intend to include all subsection (d) hospitals in these proposed validation procedures, since all subsection (d) hospitals are subject to the HAC Reduction Program. Therefore, for the HAC Reduction Program, we proposed to include all subsection (d) hospitals in the provider sample for validation beginning with the Q3 2019 discharges for FY 2022. We believe this would be better representative of hospitals impacted by the Program. We note that for the FY 2018 HAC Reduction Program, which uses CY 2015 and 2016 NHSN HAI data, 44 hospitals were subject to the HAC Reduction Program, but chose not to participate in the Hospital IQR Program. These hospitals would be included in the validation process.

Comment: As noted above in section IV.J.4.e.(1) of the preamble of this final rule, commenters expressed understanding and support for CMS' proposal to adopt the Hospital IQR Program's NHSN HAI measure validation process to the greatest extent possible in the HAC Reduction Program. The commenters specifically appreciated that the validation requirements and that process for the Hospital IQR Program validation are well established, and CMS' efforts to maintain continuity as it removes the measures from the Hospital IQR Program, but retains them in the HAC Reduction Program.

Response: We interpret these general comments to include support for CMS' proposals regarding provider selection as well. We thank the commenters for their support.

Comment: A number of commenters understood the impetus for the HAC Reduction Program to adopt validation procedures, but expressed concern that as proposed, hospitals could be validated under both the Hospital IQR Program and the HAC Reduction Program during the same reporting period. These commenters urged CMS to enact a policy that prevents dual data validation selection for the same reporting period because the commenters were concerned about the potential for additional burden being imposed on participating hospitals. Some commenters suggested that CMS should align the random audits so that hospitals' audit frequency is unchanged. Other commenters suggested that a hospital should be ineligible for a random audit in a third year if they have been selected for audit in either the HAC Reduction Program or Hospital IQR Program in each year of the preceding two-year period. Other commenters encouraged CMS to finalize a policy under which a hospital selected for data validation under the Hospital IQR Program is not eligible for selection in that year for data validation in the HAC Reduction Program.

Response: We thank the commenters for sharing their concerns and suggestions. As part of our Meaningful Measures Initiative and Patients Over Paperwork initiative, our goal is to reduce provider burden and we are striving to ensure our processes are as least burdensome as possible. We are currently reviewing several options to address commenters' concerns and will provide more information in future rulemaking.

Comment: One commenter encouraged CMS to ensure that notices of inclusion and validation of results be located in a single interface and posted at the same time. Another commenter stated that CMS needs to provide the hospitals with unified case selection reports, records requests and submission processes that will cover both the Hospital IQR Program and the HAC Reduction Program validation.

Response: We are aware of hospitals' concerns. We thank the commenters for their suggestions, which we will take under advisement. We will work with our contractors to ensure that the information is provided in clearest and most convenient manner, so that hospitals can spend less time doing paperwork and more time with patients.

After consideration of the public comments we received, we are finalizing our proposal to randomly select 400 hospitals. Again, we note that we are delaying adoption of the Hospital IQR Program's NHSN HAI measure validation process to begin with Q3 2020 discharges for FY 2023.

(3) Targeting Criteria

As stated above, the Hospital IQR Program currently performs a random and targeted selection of hospitals for validation on an annual basis (78 FR 50833 through 50834). In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229), the Hospital IQR Program finalized that the targeted selection will include all hospitals that failed validation the previous year. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552 through 53553), the Hospital IQR Program finalized additional criteria for selecting targeted hospitals: Any hospital with abnormal or conflicting data patterns; any hospital with rapidly changing data patterns; any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed; any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated; any hospital that has not been randomly selected for validation in any of the previous 3 years; and any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent. In the FY 2014 IPPS/LTCH PPS final rule, the Hospital IQR Program expanded its targeting criteria to include any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort. We intend to propose similar policies for the HAC Reduction Program.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20431 through 20432). We proposed the following targeting criteria for the HAC Reduction Program beginning with the Q3 2019 discharges for FY 2022:

- Any hospital that failed validation the previous year;
- Any hospital that submits data to NHSN after the HAC Reduction Program data submission deadline has passed;
- Any hospital that not been randomly selected for validation in the past 3 years;
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent; [262] and
- Any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

Although we invited public comment on our proposals, because commenters did not specify whether their responses were directed to general provider selection, or the targeted selection proposals, we have included all validation selection comments under the provider selection section above, located at section IV.J.4.e.(2) of the preamble of this final rule.

After consideration of the public comments we received, we are finalizing our proposal to select 200 additional hospitals for targeted validation. Again, we note that we are delaying adoption of the Hospital IQR Program's NHSN HAI measure validation process to begin with Q3 2020 discharges for FY 2023.

(4) Calculation of the Confidence Interval

The Hospital IQR Program scores hospitals based on an agreement rate between hospital-reported infections compared to events identified as infections by a trained CMS abstractor using a standardized protocol (77 FR 53548). As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53550 through 53551), the Hospital IQR Program uses the upper bound of a two-tailed 90 percent confidence interval around the combined clinical process of care and HAI scores to determine if a hospital passes or fails validation; if this number is greater than or equal to 75 percent, then the hospital passes validation.

We believe that a similar computation of the confidence interval is appropriate for the HAC Reduction Program, but that it include only the NHSN HAI measures and not the clinical process of care measures, which are not a part of the Program's measure set. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20432), we proposed that for the HAC Reduction Program beginning in FY 2022: (1) We would score hospitals based on an agreement rate between hospital-reported infections compared to events identified as infections by a trained CMS abstractor using a standardized protocol; (2) we would compute a confidence interval; (3) if the upper bound of this confidence interval is 75 percent or higher, the hospital would pass the HAC Reduction Program validation requirement; and (4) if the upper bound is below 75 percent, the hospital would fail the HAC Reduction Program validation requirement.

Comment: One commenter supported CMS' proposals for computing the confidence interval.

Response: We thank the commenter for its support.

After consideration of the public comments we received, we are finalizing our proposals to score hospitals based on an agreement rate between hospital-reported infections compared to events identified as infections by a trained CMS abstractor using a standardized protocol by computing a confidence interval. If the upper bound of this confidence interval is 75 percent or higher, the hospital would pass the HAC Reduction Program validation requirement; if the upper bound is below 75 percent, the hospital would fail the HAC Reduction Program validation requirement. However, as discussed above, we are delaying adoption of the Hospital IQR Program's NHSN HAI measure validation process to begin with Q3 of FY 2020 discharges for FY 2023.

(5) Educational Review Process

Under the Hospital IQR Program, within 30 days of validation results being posted on the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*, if a hospital has a question or needs further clarification on a particular outcome, the hospital may request an educational review (82 FR 38402 through 38403). Furthermore, if an educational review is requested for any of the first three quarters of validation yields incorrect CMS validation results for chart-abstracted measures, the corrected quarterly score will be used to compute the final confidence interval (82 FR 38402 through 38403).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20432), we stated that we plan to have similar procedures under the HAC Reduction Program. Therefore, for the HAC Reduction Program beginning with the Q3 2019 data validation, we proposed to have an educational review process, such that hospitals selected for validation would have a 30-day period following the receipt of quarterly validation results to seek educational review. During this 30-day period, hospitals may review, seek

[262] We will devise a two-tailed confidence interval formula using only NHSN HAI measures for the HAC Reduction Program. This will be posted to the QualityNet website.

clarification, and potentially identify a CMS validation error. In addition, like the Hospital IQR Program, we proposed that if an educational review is timely requested for any of the first three quarters and the review yields an incorrect CMS validation result, the corrected quarterly score would be used to compute the final confidence interval. Unlike the Hospital IQR Program educational review process (82 FR 38402), we also proposed that if an educational review is timely requested and an error is identified in the 4th quarter of review, we would use the corrected quarterly score to compute the final confidence interval.

Comment: A commenter supported CMS' proposal to adopt an Educational Review process similar to the current Hospital IQR Program. This commenter also supported the addition of the proposal that if a timely review is requested and an error is identified in the fourth quarter of review, CMS would use the corrected quarterly score to compute the final confidence interval.

Response: We thank the commenter for its support.

Comment: One commenter urged CMS to clearly communicate any administrative policies regarding the validation of NHSN HAI measures and provide education to stakeholders on any changes to existing processes.

Response: We plan to provide education to stakeholders before the implementation of finalized administrative policies to ensure a seamless, uninterrupted transition. We plan to hold education and outreach sessions, as well as post information, consistent with our normal course of communications to provide hospitals with as much information as possible on the new policies.

Comment: A commenter urged CMS to ensure that all measure abstractors complete the NHSN training modules for HAI surveillance in order to be qualified to validate hospital reported data train measure abstractors because it believes this understanding of the application of the NHSN surveillance definitions will prevent unnecessary and time intensive educational reviews.

Response: We thank the commenter for its comment. All abstractors are trained to perform independent abstractions, and CMS provides ongoing training to abstractors to ensure they are competent to conduct abstractions. We will also continue to work with CDC to provide our abstractors with clear and specific NHSN surveillance to improve both hospital reporting accuracy and CMS validation abstraction reliability.

After consideration of the public comments we received, we are finalizing an educational review process, such that hospitals selected for validation would have a 30-day period following the receipt of quarterly validation results to seek educational review. During this 30-day period, hospitals may review, seek clarification, and potentially identify a CMS validation error. If an educational review is timely requested for any of the first three quarters and the review yields an incorrect CMS validation result, the corrected quarterly score would be used to compute the final confidence interval. If an educational review is timely requested and an error is identified in the 4th quarter of review, we would use the corrected quarterly score to compute the final confidence interval. Again, we note we are delaying adoption of the Hospital IQR Program's NHSN HAI measure validation process to begin with Q3 2020 discharges for FY 2023.

(6) Application of Validation Penalty

Currently, under the Hospital IQR Program, we randomly assign half of the hospitals selected for validation to submit CLABSI and CAUTI Validation Templates and the other half of hospitals to submit MRSA and CDI Validation Templates (78 FR 50826 through 50834). CMS selects up to four candidate NHSN HAI cases per hospital from each of the assigned Validation Templates (79 FR 50263 through 50265). CMS also selects up to two candidate Colon and Abdominal Hysterectomy SSI cases from Medicare claims data for patients who had colon surgeries or abdominal hysterectomies that appear suspicious of infection (78 FR 50826 through 50834). The Hospital IQR Program applies a full payment reduction if a hospital fails to meet any part of the validation process (75 FR 50219 through 50220; 81 FR 57180).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20432), for the HAC Reduction Program, if a hospital could not meet the overall validation requirement, we proposed to penalize hospitals that failed validation by assigning the maximum Winsorized z-score only for the set of measures CMS validated. For example, if a hospital was in the half selected to submit CLABSI and CAUTI Validation Templates but failed the validation, we proposed that hospital would receive the maximum Winsorized z-score for CLABSI, CAUTI, and Colon and Abdominal Hysterectomy SSI. Although it would better align with the Hospital IQR Program's current ''all or nothing'' approach (75 FR 50219 through 50220; 81 FR 57180) to penalize hospitals by assigning the maximum Winsorized z-scores for the entire domain, we believe that our chosen approach would be fairer to hospitals and would reduce the likelihood of their automatically ranking in the worst-performing quartile based on validation results. Furthermore, we believe our proposed approach better aligns with the current HAC Reduction Program policy of assigning the maximum Winsorized z-score if hospitals do not submit data to NHSN for a given NHSN HAI measure (81 FR 57013).

Comment: Some commenters appreciated CMS' proposal to adopt what they characterized as a fair validation penalty. Specifically, the commenters believed that the proposed validation penalty is fairer to hospitals, will reduce the likelihood of a penalty due to data validation failure and is consistent with the current HAC reduction program policy of assigning the maximum Winsorized z-score when a hospital fails to submit data for a measure. The commenters stated their appreciation for the change in penalty application to only the measures that fail validation, rather than application of the penalty to all measures.

Response: We thank commenters for their support.

Comment: One commenter expressed concern about penalty application for failing validation and urged that validation penalty be no more than the penalty under Hospital IQR Program. The commenter noted that it is technically possible to fail validation for reporting HAC numbers that are higher than those the hospital actually has, and suggested that failing validation does not necessarily imply being a ''worse performer.'' The commenter also expressed concern over the ''worst performer'' title to those that failed validation instead of performance issues.

Response: We appreciate the commenter's feedback. We continue to believe that hospitals need to submit accurate data for the HAC Reduction Program's integrity. With respect to the ''worst-performer'' title, we will take the commenter's concern under advisement, and consider options on how we identify hospitals that failed validation.

Comment: One commenter expressed concern that hospitals could fail validation due to electronic record issues that may prevent validators from having complete information related to the case, rather than inaccurate case determinations.

Response: We thank the commenter for its comment. We provide all abstractors training to perform independent abstractions, and CMS provides ongoing training to abstractors

to ensure they are competent to conduct abstractions. We continue to work with CDC to provide our abstractors with clear and specific NHSN surveillance to improve both hospital reporting accuracy and CMS validation abstraction reliability. The participating hospital is responsible for sending all the required information necessary for validation. If hospitals are unable to submit data due to CMS system issues, hospitals should contact the QualityNet HelpDesk at: *https://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/Page/PageFooterContent&name=glh.ContactUs.pag*, and the Validation Support Contractor (VSC) at *validation@hcqis.org*.

Comment: A commenter did not believe the penalty associated with a failed validation within the HAC Reduction Program is fair, nor did it believe the facilities would be able to easily replicate the calculation.

Response: We appreciate the commenter's concern; however, in order to ensure that hospitals provide accurate data for the program, we continue to believe a validation penalty of the worst possible Winsorized z-score for the measures that fail validation is fair and appropriate. We believe that facilities will be provided with sufficient information to inform their calculation, as is the current policy under the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing our proposal that if a hospital does not meet the overall validation requirement, we will penalize it by assigning the maximum Winsorized z-score only for the set of measures CMS validated. Again, we note we are delaying adoption of the Hospital IQR Program's NHSN HAI measure validation process to begin with Q3 2020 discharges for FY 2023.

(7) Validation Period

The Hospital IQR Program currently uses a calendar year reporting period for NHSN HAI measures (76 FR 51644). For example, the FY 2020 measure reporting quarters include Q1 2018, Q2 2018, Q3 2018, and Q4 2018. Under the Hospital IQR Program, FY 2020 data validation consists of the following quarters: Q3 2017, Q4 2017, Q1 2018, and Q2 2018, the Hospital IQR Program schedule is available on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?cid=%2012287762888808&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page*. Currently, the HAC Reduction Program utilizes NHSN HAI data from two calendar years to calculate measure results. For example, the FY 2021 measure reporting quarters include Q1 2018 through Q4 2019.

When determining the proposed validation period for the HAC Reduction Program, we considered the performance and validation cycles currently in place under the Hospital IQR Program, and we considered key public reporting dates for the HAC Reduction Program. HAC Reduction Program scores must be calculated in time for hospital specific reports (HSRs) to be issued annually, usually in July, and the 30-day Scoring Calculations Review and Correction period of the HSRs serves as the preview period for *Hospital Compare.* Then, HAC Reduction Program data published on *Hospital Compare* is refreshed annually as soon as feasible following the review period.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20432 through 20433), we stated that after consideration, we proposed that the HAC Reduction Program's performance period would remain 2 calendar years and that the validation period would include the four middle quarters in the HAC Reduction Program performance period (that is, third quarter through second quarter). This approach aligns with current the HAC Reduction Program performance period, it also aligns with current NHSN HAI validation quarters, and because we would continue to collect eight quarters of measure data, we anticipate no impact on the reliability of NHSN HAI results.

Because our validation sample of hospitals is selected annually and because of the time needed to build the required infrastructure, we believe the earliest opportunity to seamlessly begin this work under the HAC Reduction Program is Q3 2019. Therefore, we proposed that the HAC Reduction Program would begin validation of NHSN HAI measures data with July 2019 infection event data. The proposed commencement of validation, along with key validation dates, is shown in the table below.

PROPOSED VALIDATION PERIOD FOR THE HAC REDUCTION PROGRAM

[* Dates are subject to change]

Discharge quarters by fiscal year (FY)	Current NHSN HAI submission deadline *	Current NHSN HAI validation templates *	Estimated CDAC [263] record request	Estimated date records due to CDAC	Estimated validation completion
FY 2022:					
Q1 2019	08/15/2019				
Q2 2019	11/15/2019				
Q3 2019 ^	**02/15/2020**	**02/01/2020**	**02/28/2020**	**03/30/2020**	**06/15/2020**
Q4 2019 ^	**05/15/2020**	**05/01/2020**	**05/30/2020**	**06/29/2020**	**09/15/2020**
Q1 2020 ^	**08/15/2020**	**08/01/2020**	**08/30/2020**	**09/29/2020**	**12/15/2020**
Q2 2020 ^	**11/15/2020**	**11/01/2020**	**11/29/2020**	**12/29/2020**	**03/15/2021**
Q3 2020	02/15/2021				
Q4 2020	05/15/2021				
FY 2023:					
Q1 2020	08/15/2020				
Q2 2020	11/15/2020				
Q3 2020 ^	**02/15/2021**	**02/01/2021**	**02/28/2021**	**03/30/2021**	**06/15/2021**
Q4 2020 ^	**05/15/2021**	**05/01/2021**	**05/30/2021**	**06/29/2021**	**09/15/2021**
Q1 2021 ^	**08/15/2021**	**08/01/2021**	**08/30/2021**	**09/29/2021**	**12/15/2021**
Q2 2021 ^	**11/15/2021**	**11/01/2021**	**11/29/2021**	**12/29/2021**	**03/15/2022**
Q3 2021	02/15/2022				

[263] The CMS Clinical Data Abstraction Center (CDAC) performs the validation. We neglected to define the acronym in the proposed rule, so we define it now.

PROPOSED VALIDATION PERIOD FOR THE HAC REDUCTION PROGRAM—Continued

[* Dates are subject to change]

Discharge quarters by fiscal year (FY)	Current NHSN HAI submission deadline *	Current NHSN HAI validation templates *	Estimated CDAC [263] record request	Estimated date records due to CDAC	Estimated validation completion
Q4 2021	05/15/2022				

Bolded rows with dates in each column, denoted with the ∧ symbol next to the date in the Discharge Quarter by Fiscal Year (FY) column, indicate the validation cycle for the FY.

To maintain symmetry with the current Hospital IQR Program validation schedule as set forth on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1140537256076*, we proposed that for hospitals selected for validation, the NHSN HAI validation templates would be due before the HAC Reduction Program NHSN HAI data submission deadlines. To the greatest extent possible, we proposed to keep the processes the same as they are currently implemented in the Hospital IQR Program. Because these deadlines would function in the same manner as the current policy under the Hospital IQR Program, we expect that most providers are familiar with this process. For more information, we refer readers to the Chart-Abstracted Data Validation Resources information available at: *https://www.qualitynet.org/dcs/ContentServer?cid=1140537256076&pagenameQnetPublic%2FPage%2FnetTier3&c=Page.*

We did not receive any comments on our validation proposals; however, as discussed above, we are delaying adoption of the Hospital IQR Program's NHSN HAI measure validation process into the HAC Reduction Program in order to align with a corresponding delay in removal of these measures from the Hospital IQR Program. We are therefore finalizing our proposal to begin validation with Q3 discharges for FY 2020 for the FY 2023 program year.

The commencement of validation, along with key validation dates, is shown in the table below.

FINALIZED VALIDATION PERIOD FOR THE HAC REDUCTION PROGRAM

[* Dates are subject to change] [264]

Discharge quarters by fiscal year (FY)	Current NHSN HAI submission deadline *	Current NHSN HAI validation templates *	Estimated CDAC [265] record request	Estimated date records due to CDAC	Estimated validation completion
FY 2023:					
Q1 2020	08/15/2020				
Q2 2020	11/15/2020				
Q3 2020 ∧	**02/15/2021**	**02/01/2021**	**02/28/2021**	**03/30/2021**	**06/15/2021**
Q4 2020 ∧	**05/15/2021**	**05/01/2021**	**05/30/2021**	**06/29/2021**	**09/15/2021**
Q1 2021 ∧	**08/15/2021**	**08/01/2021**	**08/30/2021**	**09/29/2021**	**12/15/2021**
Q2 2021 ∧	**11/15/2021**	**11/01/2021**	**11/29/2021**	**12/29/2021**	**03/15/2022**
Q3 2021	02/15/2022				
Q4 2021	05/15/2022				

Bolded rows with dates in each column, denoted with the ∧ symbol next to the date in the Discharge Quarter by Fiscal Year (FY) column, indicate the validation cycle for the FY.

f. Data Accuracy and Completeness Acknowledgement (DACA)

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for DACA requirements previously adopted by the Hospital IQR Program. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20433), we proposed that if the Hospital IQR Program finalizes its proposal to remove NHSN HAI measures from its program, then the HAC Reduction Program would adopt this same process. Hospitals would have to electronically acknowledge the data submitted are accurate and complete to the best of their knowledge. Hospitals would be required to complete and sign the DACA on an annual basis via the QualityNet Secure Portal: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*. The submission period for signing and completing the DACA is April 1 through May 15, with respect to the time period of January 1 through December 31 of the preceding year. The initial HAC Reduction Program proposed annual DACA signing and completing period would be April 1 through May 15, 2020 for calendar year 2019 data.

Comment: One commenter supported CMS' proposal to adopt DACA requirements for hospitals to electronically acknowledge the accuracy and completeness of data to the best of their knowledge on an annual basis via the QualityNet Secure Portal.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing our proposal to require that hospitals electronically acknowledge the data submitted are accurate and complete to the best of their knowledge. Hospitals

[264] As we stated in the proposed rule, the dates of validation are subject to change. In the proposed rule, we proposed to begin validation with Q3 of FY 2019 discharges for FY 2022. However, because the Hospital IQR Program is delaying its removal of NHSN HAI measures by a year, we are delaying the implementation of the HAC Reduction Program's validation process by one year. This table now reflects the updated implementation date of Q3 of FY 2020 discharges for FY 2023.

[265] The CMS Clinical Data Abstraction Center (CDAC) performs the validation. We neglected to define the acronym in the proposed rule, so we define it now.

would be required to complete and sign the DACA on an annual basis via the QualityNet Secure Portal. As noted in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we are delaying removal of the NHSN HAI measures from the Hospital IQR Program until the CY 2020 reporting period/FY 2022 payment determination. For this reason, we are also delaying the first DACA submission under the HAC Reduction Program until April 1 through May 15, 2021 for calendar year 2020 data.

g. Scoring Calculations Review and Correction Period

Although we did not propose any changes to the review and correction procedures for FY 2019 (83 FR 20433 through 20434), we intend to rename the annual 30-day review and correction period to the ''Scoring Calculations Review and Correction Period.'' The purpose of the annual 30-day review and corrections period is to allow hospitals to review the calculation of their HAC Reduction Program scores, and the new name would more clearly convey both the intent and limitation. The naming convention would further distinguish this period from earlier opportunities during which hospitals can review and correct their underlying data.

The HAC Reduction Program will continue to provide annual confidential hospital-specific reports and discharge level information used in the calculation of their Total HAC Scores via the QualityNet Secure Portal. As noted in section IV.J.4.b. of the preamble of the proposed rule regarding quarterly reports, hospitals must also register at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115992011* for a QualityNet Secure Portal account in order to access their annual hospital-specific reports.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50725 through 50728), hospitals have a period of 30 days after the information is posted to the QualityNet Secure Portal to review their HAC Reduction Program scores, submit questions about the calculation of their results, and request corrections for their HAC Reduction Program scores prior to public reporting. Hospitals may use the 30-day Scoring Calculations Review and Correction Period to request corrections to the following information prior to public reporting:

- CMS PSI 90 measure score
- CMS PSI 90 measure result and Winsorized measure result
- Domain 1 score
- CLABSI measure score
- CAUTI measure score
- Colon and Abdominal Hysterectomy SSI measure score
- MRSA Bacteremia measure score
- CDI measure score
- Domain 2 score
- Total HAC Score

As we clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), this 30-day period is not an opportunity for hospitals to submit additional corrections related to the underlying claims data for the CMS PSI 90, or to add new claims to the data extract used to calculate the results. Hospitals have an opportunity to review and correct claims data used in the HAC Reduction Program as described in section IV.J.4.c. of the preamble of the proposed rule, and detailed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727).

As we also clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), this 30-day period is not an opportunity for hospitals to submit additional corrections related to the underlying NHSN HAI data used to calculate the scores, including: reported number of NSHN HAIs; Standardized Infection Ratios (SIRs); or reported central-line days, urinary catheter days, surgical procedures performed, or patient days. Hospitals would have an opportunity to review and correct chart-abstracted NHSN HAI data used in the HAC Reduction Program as described in section IV.J.4.d. of the preamble of the proposed rule.

Comment: A commenter supported CMS' proposed renaming convention for the 30-day review period to the ''Scoring Calculation Review and Correction Period'' to accurately reflect the intent of the process.

Response: We thank the commenter for its support.

Comment: A commenter recommended that CMS clarify the review periods by distinguishing when a hospital is reviewing the underlying data versus the scoring of that data under the HAC Reduction Program. The commenter believed that a clarifying name change is helpful, but requested more information on CMS' quality reporting websites to ensure transparency of the differing review periods in programs.

Response: We thank the commenter for its views. We refer readers to IV.J.4.c. of the preamble of this final rule (Review and Correction of Claims Data Used in the HAC Reduction Program for FY 2019 and Subsequent Years) and IV.J.4.d. of the preamble of this final rule (Review and Correction of Chart-Abstracted NHSN HAI Data used in the HAC Reduction Program for FY 2019 and Subsequent Years) where we discuss the review and corrections process of underlying data for both claims-based and chart-abstracted measures. We will take the commenters concern into account and consider what, if any, changes to CMS' quality reporting websites and education and outreach materials could facilitate greater transparency.

h. Public Reporting of Hospital-Specific Data Beginning FY 2019

(1) Public Reporting of Hospital-Specific Data Beginning FY 2019

Section 1886(p)(6)(A) of the Act requires the Secretary to ''make information available to the public regarding HAC rates of each subsection (d) hospital'' under the HAC Reduction Program. Section 1886(p)(6)(B) of the Act also requires the Secretary to ''ensure that an applicable hospital has the opportunity to review, and submit corrections for, the HAC information to be made public for each hospital.'' Section 1886(p)(6)(C) of the Act requires the Secretary to post the HAC information for each applicable hospital on the *Hospital Compare* website in an easily understood format.

As finalized in FY 2014 IPPS/LTCH PPS final rule (78 FR 50725), we will make the following information public on the *Hospital Compare* website: (1) Hospital scores with respect to each measure; (2) each hospital's domain-specific score; and (3) the hospital's Total HAC Score. If the Hospital IQR Program finalizes its proposal to remove the CMS PSI 90 from the Program, the CMS PSI 90 individual indicator measure results (that is, the child measures) would be reported under the HAC Reduction Program. The CMS PSI 90 measure is reported on the *Hospital Compare* web pages; however, the child measures are reported in the downloadable database on *Hospital Compare.* Similarly, we believe the NHSN HAI measures represent important quality data consumers of healthcare can use to make informed decisions. Therefore, we intend to continue making NHSN HAI data available to the public on a quarterly basis. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38324), our current policy has been to report data under the Hospital IQR Program as soon as it is feasible on CMS websites such as the *Hospital Compare* website, *http://www.medicare.gov/hospitalcompare,* after a 30-day preview period. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20434), we proposed to make data

available in the same form and manner as currently displayed under the Hospital IQR Program.

As we stated in the proposed rule, we intend to maintain as much consistency as possible in how the measures are currently reported on *Hospital Compare,* including how they are displayed and the frequency of reporting.

Comment: Commenters encouraged CMS to commit to publicly reporting the NHSN HAI data on *Hospital Compare* and strongly urged CMS to communicate how it specifically intends to report quality measure data, including NHSN HAI data. One commenter also urged CMS to post data on both the *Hospital Compare* and the *https://data.medicare.gov/* websites.

Response: We thank the commenters for their views. As we stated in the proposed rule, we intend to continue making NHSN HAI data available to the public on a quarterly basis as soon as it is feasible on CMS websites such as the *Hospital Compare* website, *http://www.medicare.gov/hospitalcompare*, after a 30-day preview period. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20434), we proposed to make data available in the same form and manner as currently displayed under the Hospital IQR Program.

Comment: A commenter strongly urged CMS to publicly report both the full CMS PSI 90 composite score and the scores of individual child measures within the composite. In the reporting of the child measures, the commenter encouraged CMS to continue to report the current data fields that presently appear in the CMS *Hospital Compare* downloadable database (for example, denominator, score) because the commenter believed that these fields are helpful in discerning performance in the child measures, and are useful for health care raters that wish to responsibly use the measures in their transparency efforts.

Response: We thank the commenter for the comment. As discussed in section VIII.A.5.b.(2)(a) of the preamble of this final rule, we are finalizing our proposal to remove the CMS PSI 90 measure from the Hospital IQR Program; however, the CMS PSI 90 measure will continue to be reported on the *Hospital Compare* web pages; and the child measures will continue to be reported in the downloadable database on *Hospital Compare.*

(2) Clarification of Location of Publicly-Reported HAC Reduction Program Information

Section 1886(p)(6)(C) of the Act, as codified at 42 CFR 412.172(f), requires that HAC information be posted on the *Hospital Compare* website in an easily understandable format. *Hospital Compare* is the official website for the publication of the required HAC Reduction Program data, and the location where the HAC Reduction Program will continue to post data. We believe the above approach complies with the Act and provides hospitals and the public sufficient access to information.

i. Limitation on Administrative and Judicial Review

Section 1886(p)(7) of the Act, as codified at 42 CFR 412.172(g), provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for any of the following:

- The criteria describing an applicable hospital in paragraph 1886(p)(2)(A) of the Act;
- The specification of hospital acquired conditions under paragraph 1886(p)(3) of the Act;
- The specification of the applicable period under paragraph 1886(p)(4) of the Act;
- The provision of reports to applicable hospitals under paragraph 1886(p)(5) of the Act; and
- The information made available to the public under paragraph 1886(p)(6) of the Act.

For additional information, we refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50729) and FY 2015 IPPS/LTCH PPS final rule (79 FR 50100).

5. Changes to the HAC Reduction Program Scoring Methodology

We regularly examine the HAC Reduction Program's scoring methodology for opportunities for improvement. This year, we examined several alternative scoring options that would allow the scoring methodology to continue to fairly assess all hospitals.

a. Current Methodology

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57022 through 57025), we adopted a Winsorized z-score scoring methodology for FY 2018 in which we rank hospitals by calculating a Total HAC Score based on hospitals' performance on two domains: patient safety (Domain 1) and NHSN HAIs (Domain 2). Domain 1 includes the CMS PSI 90 measure. Domain 2 includes the CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI,[266] MRSA Bacteremia, and CDI measures. Under the current scoring methodology, hospitals' Total HAC Scores are calculated as a weighted average of Domain 1 (15 percent) and Domain 2 (85 percent). Hospitals with a measure score for at least one Domain 2 measure receive a Domain 2 score. Hospitals with 3 or more discharges for at least one component indicator for the CMS PSI 90 receive a Domain 1 score. The first table below illustrates the weight CMS applies to each measure for the roughly 99 percent of non-Maryland hospitals with a Domain 1 score and the second table below illustrates the weight CMS applies to each measure for the one percent of non-Maryland hospitals without a Domain 1 score.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF DOMAIN 2 MEASURES WITH MEASURE SCORES FOR HOSPITALS WITH A DOMAIN 1 SCORE IN FY 2019 (N=3,195)

Number of Domain 2 measures with measure scores	Number (percent) of hospitals in FY 2019 [a b]	Weight applied to:	
		CMS PSI 90	Each Domain 2 measure
0	223 (6.9)	100.0	N/A
1	332 (10.3)	15.0	85.0
2	210 (6.5)	15.0	42.5
3	188 (5.8)	15.0	28.3
4	250 (7.8)	15.0	21.3

[266] Colon and Abdominal Hysterectomy SSI is reported as one score under the HAC Reduction Program.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF DOMAIN 2 MEASURES WITH MEASURE SCORES FOR HOSPITALS WITH A DOMAIN 1 SCORE IN FY 2019 (N=3,195)—Continued

Number of Domain 2 measures with measure scores	Number (percent) of hospitals in FY 2019[a b]	Weight applied to:	
		CMS PSI 90	Each Domain 2 measure
5	1,992 (61.9)	15.0	17.0

[a] The denominator for percentage calculations is all non-Maryland hospitals with a FY 2019 Total HAC Score (N=3,219).
[b] This table is updated from the FY 2019 IPPS/LTCH PPS proposed rule, which used FY 2018 data. To see that table, we refer readers to 83 FR 20434 through 20437.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF DOMAIN 2 MEASURES WITH MEASURE SCORES FOR HOSPITALS WITHOUT A DOMAIN 1 SCORE IN FY 2019 (N=24)

Number of Domain 2 measures with measure scores	Number (percent) of hospitals in FY 2019[a b]	Weight applied to:	
		CMS PSI 90	Each Domain 2 measure
1	8 (0.2)	N/A	100.0
2	1 (0.0)	N/A	50.0
3	0 (0.0)	N/A	33.3
4	3 (0.1)	N/A	25.0
5	12 (0.4)	N/A	20.0

[a] The denominator for percentage calculations is all non-Maryland hospitals with a FY 2019 Total HAC Score (N=3,219).
[b] This table is updated from the FY 2019 IPPS/LTCH PPS proposed rule, which used FY 2018 data. To see that table, we refer readers to FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20434 through 20437).

As shown in the first table above, under the currently methodology, the weight applied to the CMS PSI 90 and each Domain 2 measure is almost the same (15.0 and 17.0 percent, respectively) for hospitals with measure scores for all six program measures. However, for hospitals with between one and four Domain 2 measures, the weight applied to the CMS PSI 90 is lower (and in some cases much lower) than the weight applied to each Domain 2 measure. For hospitals with a measure score for only one or two Domain 2 measures (that is, low-volume hospitals in particular), a disproportionately large weight is applied to each Domain 2 measure. Several stakeholders voiced concerns about the disproportionately large weight applied to the one or two Domain 2 measures for which low-volume hospitals have a measure score. As seen in the tables above; under the currently methodology, the weighting for the Domain 2 measures is dependent on the number of measures with data for those hospitals without a Domain 1 score.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20434 through 20437), we discussed two alternative scoring methodologies for calculating hospitals' Total HAC Scores. Our preferred approach, the Equal Measure Weights policy, involves removing domains and applying an equal weight to each measure for which a hospital has a measure score in Total HAC Score calculations. However, we sought public comment on an additional approach: applying a different weight to each domain depending on the number of measures for which a hospital has a measure score (Variable Domain Weights).

b. Equal Measure Weights

In the proposed rule, we stated that our preferred approach is the Equal Measure Weights Policy. We would remove domains from the HAC Reduction Program and simply assign equal weight to each measure for which a hospital has a measure score. We would calculate each hospital's Total HAC Score as the equally weighted average of the hospital's measure scores. The table below displays the weights applied to each measure under this approach. All other aspects of the HAC Reduction Program scoring methodology would remain the same, including the calculation of measure scores as Winsorized z-scores, the determination of the 75th percentile Total HAC Score, and the determination of the worst-performing quartile.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF MEASURES WITH MEASURE SCORE FOR HOSPITALS WITH AND WITHOUT A CMS PSI 90 SCORE UNDER EQUAL MEASURE WEIGHTS APPROACH

Number of NHSN HAI measures with measure score	Weight applied to:	
	CMS PSI 90	Each NHSN HAI measure
0	100.0	N/A.
1	50.0	50.0.
2	33.3	33.3.
3	25.0	25.0.
4	20.0	20.0.
5	16.7	16.7.
Any number	N/A	100.0 (equally divided among each NHSN HAI measure).

As shown in the table above, by applying an equal weight to each measure for all hospitals, the Equal Measure Weights approach addresses stakeholders' concerns about the disproportionately large weight applied to Domain 2 measures for certain hospitals under the current scoring methodology.

c. Alternative Methodology Considered: Variable Domain Weights

We also analyzed a Variable Domain Weights approach. Under this approach, the weights applied to Domain 1 and Domain 2 depend upon the number of measure scores a hospital has in each domain. The table below displays the weights applied to each domain under this approach.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF DOMAIN 2 MEASURES WITH MEASURE SCORES FOR HOSPITALS WITH AND WITHOUT A DOMAIN 1 SCORE UNDER VARIABLE DOMAIN WEIGHTS APPROACH

Number of Domain 2 measures with measure score	Weight applied to:		
	Domain 1 (CMS PSI 90)	Domain 2	Each Domain 2 measure
0	100.0	N/A	N/A.
1	40.0	60.0	60.0.
2	30.0	70.0	35.0.
3	20.0	80.0	26.7.
4	15.0	85.0	21.3.
5	15.0	85.0	17.0.
Any number	N/A	100.0	Equally divided.

As shown in the table above, under the Variable Domain Weights approach, the difference in the weight applied to the CMS PSI 90 and each Domain 2 measure is smaller than the difference under the current scoring methodology for hospitals that have a Domain 1 score (the first table under the Equal Measure Weights approach discussion, above).

d. Analysis [267]

Our priority is to adopt a policy that improves the scoring methodology and increases fairness for all hospitals. Both proposed approaches address stakeholders' concerns about the disproportionate weight applied to Domain 2 measures for low-volume hospitals. We simulated results under each scoring approach using FY 2019 HAC Reduction Program data. We compared the percentage of hospitals in the worst-performing quartile in FY 2019 to the percentage that would be in the worst-performing quartile under each scoring approach. The table below provides a high-level overview of the impact of these approaches on several key groups of hospitals.

ESTIMATED IMPACT OF SCORING APPROACHES ON PERCENTAGE OF HOSPITALS IN WORST-PERFORMING QUARTILE BY HOSPITAL GROUP [c]

Hospital group [a]	Equal measure weights (%)	Variable domain weights (%)
Teaching hospitals: 100 or more residents (N=248)	3.6	1.6
Safety-net [b] (N=646)	0.9	0.8
Urban hospitals: 400 or more beds (N=358)	2.5	0.8
Hospitals with fewer than 100 beds (N=1,208)	−1.7	−1.0
Hospitals with a measure score for:		
Zero Domain 2 measures (N=223)	0.4	0.0
One Domain 2 measure (N=340)	−4.1	−2.9
Two Domain 2 measures (N=211)	−3.8	−3.3
Three Domain 2 measures (N=188)	−0.5	0.5
Four Domain 2 measures (N=253)	0.0	0.4
Five Domain 2 measures (N=2,004)	1.1	0.7

[a] The number of hospitals in the given hospital group for FY 2019 is specified in parenthesis in this column (for example, N=248).
[b] Hospitals are considered safety-net hospitals if they are in the top quintile for DSH percent.
[c] This table is updated from the FY 2019 IPPS/LTCH PPS proposed rule, which used FY 2018 data.

As shown in the table above, the Equal Measure Weights approach generally has a larger impact than the Variable Domain Weights approach. Under the Equal Measure Weights approach, as compared to the current methodology using FY 2019 HAC Reduction Program data, the percentage of hospitals in the worst-performing quartile decreases by 1.7 percent for small hospitals (that is, fewer than 100 beds), 4.1 percent for hospitals with one Domain 2 measure, 3.8 percent for hospitals with two Domain 2 measures, while it increases by 2.5 percent for large urban hospitals (that is, 400 or more beds) and 3.6 percent for large teaching hospitals (that is, 100 or more residents). The Variable Domain Weights approach decreases the percentage of hospitals in the worst-performing quartile by 1.0 percent for small hospitals, 2.9 percent for hospitals with one Domain 2 measure, and 3.3 for

[267] This analysis is updated from the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20434 through 20437), which used FY 2018 data.

hospitals with two Domain 2 measures, while it increases the percentage of hospitals in the worst-performing quartile by 0.8 percent for large urban hospitals and 1.6 percent for large teaching hospitals.

We prefer the Equal Measure Weights approach because it reduces the percentage of low-volume hospitals in the worst-performing quartile in the simplest manner to hospitals, while not greatly increasing the potential costs on other hospital groups. In addition, should we add measures or remove measures from the program in the future, we would not need to modify the weighting scheme under the Equal Measure Weights approach, unlike the current scoring methodology or the Variable Domain Weights approach.

Finally, the Equal Measure Weights policy aligns with the intent of the original program design to apply a similar weight to each measure. That is, we applied a weight of 35 percent to Domain 1 and 65 percent to Domain 2 in FY 2015, so that the weight applied to each measure would be roughly the same for hospitals with measure scores for all measures. When we added Colon and Abdominal Hysterectomy SSI to Domain 2 in FY 2016 and CDI and MRSA Bacteremia in FY 2017, we increased the weight of Domain 2 to 75 percent and 85 percent, respectively, so that the weight applied to each measure would be nearly the same for hospitals with measure scores for all measures. However, the static domain weights we applied for these program years led to a substantially lower weight being applied to the CMS PSI 90 compared with Domain 2 measures for hospitals with only one or two Domain 2 measures. After assessing the results of our analysis and these additional considerations, we proposed to adopt the Equal Measure Weights Policy starting in FY 2020.

We also recognize that under this proposal the NHSN HAI portfolio of up to five measures would continue to be weighted much more highly than the CMS PSI 90 for the vast majority of hospitals with more than one NHSN HAI data meeting minimum precision criteria (MPC) of 1.0. For example, hospitals reporting five NHSN HAI measures meeting the MPC of 1.0 and CMS PSI 90 would be weighted as 83.33 percent using the equal weighting proposal for the set of NHSN HAI measures and 16.67 percent for the CMS PSI 90. Hospitals reporting fewer NHSN HAIs meeting the MPC of 1.0 would receive lower total HAI weighting to account for the reduced number of NHSN HAI measures.

This proposal is intended to address the impact of disproportionate weighting at the measure level for the subset of hospitals with relatively few NHSN HAI measures. Under the current weighting methodology, hospitals reporting on a single NHSN HAI measure receive 85 percent measure level weight for that one measure.

Comment: Many commenters supported the Equal Measure Weights approach. Some commenters supported this approach because they believed it will improve the fairness of the HAC Reduction Program's penalty assessments on smaller and low-volume hospitals whose HAI domain scores could often rest on only one or two measures. Some commenters supported this approach because they believed it will ensure that patient safety and adverse event avoidance (CMS PSI 90) remains a fixture of the HAC Reduction Program. Other commenters supported this approach because they believed that its adoption would simplify the calculation of performance results.

Response: We thank the commenters for their support for our preferred approach. We agree that the Equal Measure Weights policy aligns with the intent of the original program design to apply a similar weight to each measure and will help address the concern about the substantially high weight being applied to one or two HNSN HAI measures when a hospital does not have data for the other HNSN HAI measures. We also believe the Equal Weights approach simplifies the methodology and will result in small and low-volume hospitals being scored more fairly.

Comment: Some commenters supported and favored the Equal Measure Weights approach, but also supported the Variable Domain Weights approach over the current methodology. These commenters believed that either proposal would result in a more equitable and useful scoring methodology for all hospitals.

Response: We thank the commenters for their support of either proposed approach. We agree that either approach could improve the current methodology, but the Equal Measure Weights approach remains our preferred approach.

Comment: One commenter supported the Equal Measure Weights approach for the scoring methodology, but requested that CMS run hospital level preview reports before implementation.

Response: We thank commenter for this suggestion. We will review the feasibility of this suggestion with our contractors and provide an update through our normal outreach and communication methods. We also note that as part of public reporting, hospitals will receive an HSR during the HAC Reduction Program's Scoring Calculations Review and Correction Period, usually in July, which is in advance of public reporting in January. This HSR would include the results using the new weighting approach and allow hospitals to review these results prior to public reporting or application of payment adjustments.

Comment: Some commenters supported the Equal Measure Weights approach but encouraged CMS to reexamine the Equal Measure Weights approach and Variable Domain Weights approach whenever it considers adding a new measure to ensure that the finalized approach does not unfairly penalize one type of hospital.

Response: We thank the comment for this suggestion. We strive for continuous improvement in the HAC Reduction Program and will continue to monitor the unintended consequences of our policies.

Comment: Some commenters supported the Variable Domain Weights approach over the Equal Measure Weights approach because they believed that the Variable Domain Weights approach could reduce the emphasis on the CMS PSI 90 measure.

Response: We thank the commenters for their support of the Variable Domain Weights approach. We note that we continue to believe the CMS PSI–90 measure is a valuable measure for the HAC Reduction Program, and part of our reasoning in proposing new scoring methodologies is to facilitate scoring more evenly across measures.

Comment: A few commenters recommended retaining the current scoring methodology because they believe that using the new methodologies would negatively impact large teaching and urban hospitals. A few commenters also believed that the Variable Domain Weights approach was the same as the current methodology.

Response: We thank the commenters for their feedback. We proposed the Equal Measure Weights approach to create a more equitable approach for all hospitals and closer align payment to performance as directed under our statutory requirements.

Comment: Some commenters opposed both the Equal Measure Weights approach and the Variable Domain Weights approach, while others simply expressed concerns, because the commenters believed that both approaches, as well as CMS' attempt to reduce the effect of the program on low-volume hospitals, could result in increased penalties on other hospital groups, including teaching hospitals,

large hospitals, and hospitals caring for larger numbers of disadvantaged patients.

Response: We thank the commenters for their comments. We will continue to review unintended consequences of our policies. As with any proposal, some hospitals may benefit more than others. We believe that the Equal Measure Weights approach is more equitable for most hospitals as compared to the current methodology to implement our statutory requirement to link payment to eligible hospitals based on their Hospital Acquired Condition performance.

Comment: Some commenters urged CMS to further examine the unintended consequences of its proposed changes to the HAC Reduction Program methodology to mitigate any negative impact on essential hospitals.

Response: We thank the commenters for their feedback. We will continue to review unintended consequences of our policies.

Comment: A few commenters opposed both of the proposed methodologies because the commenters believed that small rural tribal hospitals will be penalized even with the proposed changes. The commenters explained that when volumes are low, shifting the weighting to measures where there are reported incidents serves only to artificially weight and enhance them, rather than giving the hospital its due credit for having zero incidents in other identified measures, either within the domains or among the two domains. The commenters suggested that CMS' use of ''expected'' events is contrary to the objectives of the program for small and rural hospitals, and suggested that if a low volume hospital has no events in previous years, the expected rate becomes very low. The commenters noted that one incident will then result in a very detrimental result for the hospital.

Response: We strive for continuous improvement in the HAC Reduction Program and will continue to monitor ways to improve the program. Though the impact to small tribal hospitals are minimal, this policy will decrease the number of small rural hospitals found in the worst-performing quartile. We are also working with the CDC to identify additional changes to measure specifications included in the program that could enhance program participation for smaller hospitals.

Comment: Some commenters urged CMS to consider additional changes to the HAC Program beyond the measure domain weightings. Some commenters recommended that CMS work with the CDC to examine whether the number of expected infections hospitals must receive a score on the HAI measures could be lowered without compromising the measures' reliability and accuracy. Commenters believed that part of the reason that many small hospitals do not have scores on the HAI measures is because their volumes are not sufficient to meet the threshold of one expected infection. By lowering the threshold, the commenters said, CMS may be able to score smaller hospitals on a wider variety of HAI measures. Commenters also urged CMS to work with stakeholders on analysis and make the impact of changing the threshold available for public review and comment.

Response: Earlier this year, the HAC Reduction Program performed an analysis of the approach encouraged by these commenters. Our preliminary findings did not demonstrate the anticipated impact, and tended to exacerbate the scoring issues associated with low-volume and small hospitals. As such, we continue to believe that the current number of expected infections is ideal to maintain appropriate reliability and accuracy. CMS will continue to work with CDC on approaches to address the commenters concerns. We seek to optimize the participation of low volume facilities while maintaining reliability and validity.

Comment: One commenter expressed concern about CMS' proposals to remove measures from the Hospital IQR Program and adopt them in the HAC Reduction Program. The commenter asserted that, because HAC Reduction Program does not provide incentives for hospitals to submit quality measure data, removing measures from Hospital IQR Program and adopting them in HAC Reduction Program may imperil our quality data collection efforts, as hospitals would not have any incentive to submit the data needed to assess hospitals under HAC Reduction Program.

Response: We would like to clarify that the HAC Reduction Program is established by statute and its measure set is not limited to those measures adopted under the Hospital IQR Program. While we understand the commenter's concern, we note that hospitals that fail to report quality measure data for HAC Reduction Program purposes will be assessed the worst possible score for those measures, and we continue to believe that incentive to be sufficient to ensure that all eligible hospitals submit all required data to the HAC Reduction Program.

Comment: Some commenters offered alternative scoring methodologies. Some recommended that CMS consider alternatives either focusing on improving the measures or comparing hospitals based upon the number of measures scores they have. The commenters suggested that a measure improvement approach might, for example, consider changes to the measures themselves that would result in smaller hospitals being more likely to have measure scores on the NHSN measures in Domain 2 (such as reducing the number of qualifying infection events to less than 1). The commenters suggested that a more systematic approach would be to modify the program's scoring such that it is comparing cohorts of hospitals based upon the measures for which they have scores (rather than comparing performance across varying measure score completeness).

Response: We thank the commenters for their comments. We have considered several scoring options where cohorts of hospitals were compared based on the measures and domains for which they have scores. These options were: (1) Extremely complicated resulting in a lack of transparency, parsimony and program score results; or (2) yielded minimal impact in improving the inclusion of small hospitals. We will continue to explore methods for improving the program and will look further into these comments raised.

Comment: Some commenters recommended that CMS ensure that the methodology and quality measures in the HAC Reduction Program are tailored to measure hospitals' improvements on HACs accurately and do not disproportionately penalize certain types of hospitals.

Response: We interpret the commenter's comment to suggest that the HAC Reduction Program could account for hospitals' improvement on HACs. However, the HAC Reduction Program's statutory authority does not allow us to provide incentive payments for improvement.

After consideration of the public comments we received, we are finalizing our policy to adopt an Equal Measure Weights scoring methodology beginning in FY 2020.

6. Applicable Period for FY 2021

Consistent with the definition specified at § 412.170, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20437), we proposed to adopt the applicable period for the FY 2021 HAC Reduction Program for the CMS PSI 90 as the 24-month period from July 1, 2017 through June 30, 2019, and the applicable period for NHSN HAI measures as the 24-month period from

January 1, 2018 through December 31, 2019.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38271), we finalized a return to a 24-month data collection period for the calculation of HAC Reduction Program measure results. As we stated then, we believe that using 24 months of data for the CMS PSI 90 and the NHSN HAI measures balances the Program's needs against the burden imposed on hospitals' data-collection processes, and allows for sufficient time to process the data for each measure and calculate the measure results.

Comment: Commenters supported the proposed applicable period for FY 2021.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing, consistent with 42 CFR 412.170, the applicable period for the FY 2021 HAC Reduction Program for the CMS PSI 90 as the 24-month period from July 1, 2017 through June 30, 2019, and the applicable period for NHSN HAI measures as the 24-month period from January 1, 2018 through December 31, 2019.

7. Request for Comments on Additional Measures for Potential Future Adoption

As we did in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19986 through 19990), and as part of our ongoing efforts to evaluate and strengthen the HAC Reduction Program, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20437), we sought stakeholder feedback on the adoption of additional Program measures.

We welcomed public comment and suggestions for additional HAC Reduction Program measures, specifically on whether electronic clinical quality measures (eCQMs) would benefit the program at some point in the future. We first raised the potential future consideration of electronically specified measures in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50104), and stated that we would continue to review the viability of including electronic measures. We are now specifically interested in stakeholder comments regarding the potential for the Program's future adoption of eCQMs. These measures use data from electronic health records (EHRs) and/or health information technology systems to measure health care quality. We believe eCQMs will allow for the improved measurement of processes, observations, treatments and outcomes. Measuring and reporting eCQMs provide information on the safety, effectiveness, and timeliness of care. We are also interested in adopting eCQMs because we support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying attention to improving clinicians' and beneficiaries' experience when interacting with CMS programs. We believe eCQMs offer many benefits to clinicians and quality reporting and are an improvement over traditional quality measures because they leverage the EHR to generate chart-abstracted data, which is less resource intensive and likely to produce fewer human errors than traditional chart-abstraction.

We believe that our continued efforts to reduce HACs are vital to improving patients' quality of care and reducing complications and mortality, while simultaneously decreasing costs. The reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur.

Comment: Commenters strongly recommended that all new measures, including eCQMs, be NQF-endorsed, approved by the MAP, scientifically valid, reliable, and feasible, and that such measures be reviewed to determine whether they are appropriate for review in the NQF SDS trial period. Commenters also believed new measures should be evaluated within the Meaningful Measures Initiative framework and appropriate corresponding measure removals should be considered to balance a measure's addition. A commenter opposed additional claims-based measures because claims data does not demonstrate if the standard of care was met and are not actionable improve care delivery and outcomes. Other commenters believed that although claims-based reporting is far from a perfect assessment of care quality, elimination of these measures could create a significant risk to patient safety. Many commenters believed that the HAC Reduction Program should not directly adopt new measures, including eCQMs, into the program without providing stakeholders to gain opportunity to familiarize themselves with a measure before it is used to determine their Medicare payments.

Most commenters believed that hospitals should have the measure publicly reported for at least a year without penalty. Some commenters suggested that this should be accomplished by including measures in the Hospital IQR Program prior to adopting them to the HAC Reduction Program, or by reported on them *Hospital Compare* for a year, or by creating a reporting only category within the HAC Reduction Program. These commenters urged CMS to give hospitals time to become accustomed to reporting and measuring these items before implementation.

Response: We thank the commenters for their feedback.

Comment: One commenter suggested the HAC Reduction Program consider telemedicine, patient reported data and wearables. Another commenter recommended that CMS use its data to identify at risk-patients before they are in a disease state.

Response: We thank the commenter for their suggestions. As a statutory requirement, the HAC Reduction Program can only include measures that assess conditions that are hospital-acquired (that is, not present on admission) while a patient in the inpatient hospital setting.

Comment: A few commenters recommended that CMS consider adding a measure to account for surgical site infections associated with hip and knee replacement surgeries for inpatient and outpatient procedures using NHSN measures. Another commenter recommended adding a measure to address the inappropriate overuse of antibiotics and infection prevention practices.

Response: We thank the commenters for their feedback.

Comment: A number of commenters supported eCQMs for the reporting of HAC Reduction Program measures and stated that such measures would be beneficial. One commenter expressed optimism that electronically reported data elements could provide more accurate, informative, and timely information about clinical care for patients.

Response: We thank the commenters for their comments in support of the potential for eCQMs in the HAC Reduction Program.

Comment: Commenters encouraged CMS to consider adopting NQF-endorsed measures and to ensure that they have reliable risk-adjustment. One commenter believed eCQMs can be risk adjusted to account for socioeconomic status and health history for appropriate national comparisons of care.

Response: We thank the commenters for their comments.

Comment: A commenter urged that, prior to adopting any eCQMs for the HAC Reduction Program: Those eCQMs must be thoroughly tested for validity,

reliability, and feasibility and determined to produce comparable and consistent results; the data elements should be accurately and efficiently gathered in the healthcare provider workflow, using data elements already collected as part of the care process and stored in EHRs or other interoperable clinical and financial technology; and that the eCQMs should provide an accurate reflection of care delivered, and be actionable to drive meaningful improvements in care delivery.

Response: We thank the commenter for its feedback. Any measure proposed for the HAC Reduction Program would be assessed to ensure that it is a reliable, valid, and appropriate measure for the Program. In addition, any measure proposed would be subject to CMS' pre-rulemaking and rulemaking process before being adopted in the HAC Reduction Program, providing multiple opportunities for stakeholder comment and input.

Comment: Some commenters believed that eCQMs could reduce reporting burden; although some cautioned about the potential for inherent incongruities between claims codes and the quality of care provided to the patient when using eCQMs instead of claims quality measurement. The commenters recommended that any additions be done thoughtfully and with regard to alignment, timeliness of implementation, and the amount of burden that will be incurred.

Response: We thank the commenters for their comments and will take them into consideration should CMS decide to pursue an eCQM for the HAC Reduction Program.

Comment: Commenters opposed the addition of measures simply for the sake of having eCQMs and noted that such an approach would not be helpful.

Response: We thank the commenters for their comments about the potential future use of eCQMs in the HAC Reduction Program.

Comment: Commenters encouraged CMS to consider alignment, timing, and the amount of burden associated with a given eCQM. Commenters believed that eCQM implementation needs to allow time for this development work, and that CMS set realistic timeframes.

Response: We thank the commenters for their comments and will take them into consideration should CMS decide to pursue an eCQM for the HAC Reduction Program.

Comment: Some commenters believed the HAC Reduction Program's measures should clearly support improving the patient experience of care (including quality, outcomes, and satisfaction). Other commenters recommended focusing on preventable common medical errors for which the HAC Reduction Program has few measures, such as medication errors. Some commenters supported the development of outcomes-driven clinical quality measures that can be extracted from electronic clinical data

Response: We thank the commenters for their suggestions. Measures for the HAC Reduction Program, by statutory authority, must address conditions that are hospital-acquired and were not present-on-admission. As such, measures assessing patient experience of care, satisfaction, and other similar types of measures would not be appropriate for the HAC Reduction Program.

Comment: A number of commenters expressed caution about adopting eCQMs into the HAC Reduction Program because they believed there are still required improvements for eCQMs. Some commenters were concerned with that different vendors may not have equivalent eCQMs from system to system, and believed that because of this variability, it would be unfair to base hospital reimbursement on measures where performance may simply be a function of which electronic health record vendor a facility is using.

Response: We thank the commenters for their comments and will take them into consideration should CMS decide to pursue an eCQM for the HAC Reduction Program.

Comment: A commenter believes that eCQMs should not be considered for inclusion in HAC Reduction Program because eCQMs are costly and labor intensive to report and CMS has sent conflicting signals with respect to eCQMs. The commenter noted that CMS is proposing to retire nearly half of the current eCQM metrics and requests clear direction in order to minimize reporting expenses.

Response: We thank the commenter for their comments about the future use of eCQMs in the HAC Reduction Program.

Comment: Commenters noted that seeking EHR input early in the measure development process can help set realistic expectations for feasibility of EHR data collection, timeline and cost. Commenters recommended that CMS: Collaborate with accreditation organizations (for example, The Joint Commission), private payers, and States to develop consensus; support a core measure set that closely aligns to the CMS eCQM menu set; standardize set of vendor-agnostic tools and notes to auto feed quality data elements.

Response: We thank the commenters for their comments about eCQMs and will take these suggestions under advisement as we continue to work on eCQMs.

Comment: Some commenters recommended that eCQMs should be selected based on data elements that are already used in electronic health records. A commenter expressed concern that it is difficult to capture an infection upon admission as a discrete data element in an electronic health record. Other commenters expressed concern about current eCQMs' degree of accuracy particularly with surgical procedures and risk-adjustment factors. A commenter expressed the need for quality abstractors to work closely with coders to ensure that the measure specifications and coding support the quality measure's specifications.

Response: We thank the commenters for their comments and will take them into consideration.

Comment: A commenter recommended having a thorough validation process of any eCQMs. Others encouraged CMS to postpone adding eCQMs to payment programs until the first period of eCQM validation is complete under the Hospital IQR Program. Another commenter requested that CMS focus on addressing current concerns with eCQM reporting rather than on developing additional eCQMs for inclusion in hospital reporting programs for the future. Other commenters recommended that CMS focus on the inclusion of a small number of measures in the eCQM program that are meaningful and not overly burdensome will provide hospitals with additional time and bandwidth to address the considerable challenges of electronic data reporting.

Response: We thank the commenters for their comments about eCQMs and we will take them into consideration.

Comment: Several commenters encouraged the advancement of standards for Certified EHR Technology (CEHRT) to better support measure development. Commenters also encouraged interoperability and the establishment of electronic health record data standards to ensure measures can be assessed comparably across systems.

Response: We thank the commenters for their comments about CEHRT to support measure development. We will take these into consideration.

Comment: Commenters recommended that CMS incentivize, perhaps through scoring bonuses, the development and testing of new eCQMs.

Response: We thank the commenters for their views and will take them into consideration as we continue to explore

additional measures for potential future adoption.

K. Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272), establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days. The provisions of section 1886(h) of the Act are implemented in regulations at 42 CFR 413.75 through 413.83.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulation regarding the calculation of this additional payment is located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. Therefore, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit (that is, a cap) on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals

Section 1886(h)(4)(H)(ii) of the Act authorizes the Secretary to prescribe rules that allow hospitals that form affiliated groups to elect to apply direct GME caps on an aggregate basis, and such authority applies for purposes of aggregating IME caps under section 1886(d)(5)(B)(viii) of the Act. Under such authority, the Secretary promulgated rules to allow hospitals that are members of the same Medicare GME affiliated group to elect to apply their direct GME and IME FTE caps on an aggregate basis. As specified in §§ 412.105(f)(1)(vi) and 413.79(f) of the regulations, hospitals that are part of the same Medicare GME affiliated group are permitted to apply their IME and direct GME FTE caps on an aggregate basis, and to temporarily adjust each hospital's caps to reflect the rotation of residents among affiliated hospitals during an academic year. Sections 413.75(b) and 413.79(f) specify the rules for Medicare GME affiliated groups. Generally, two or more hospitals may form a Medicare GME affiliated group if the hospitals have a shared rotational arrangement and are either located in the same urban or rural area or in contiguous urban or rural areas, are under common ownership, or are jointly listed as program sponsors or major participating institutions in the same program. Sections 413.75(b) and 413.79(f) also address emergency Medicare GME affiliation agreements, which can apply in the event of a section 1135 waiver and if certain conditions are met.

For a new urban teaching hospital that received an adjustment to its FTE cap under § 412.105(f)(1)(vii) or § 413.79(e)(1), or both, § 413.79(e)(1)(iv) provides that the new urban hospital may enter into a Medicare GME affiliation agreement only if the resulting adjustment is an increase to its direct GME and IME FTE caps (for purposes of this discussion, the term ''urban'' is defined as that term is described at § 412.64(b) of the regulations). We adopted this policy in the FY 2006 IPPS final rule (70 FR 47452 through 47454). Prior to that final rule, new urban teaching hospitals were not permitted to participate in a Medicare GME affiliation agreement (63 FR 26333). In modifying our rules to allow new urban teaching hospitals to participate in Medicare GME affiliation agreements, we noted our concerns about such affiliation agreements (70 FR 47452). Specifically, we were concerned that hospitals with existing medical residency training programs could otherwise, with the cooperation of new teaching hospitals, circumvent the statutory FTE caps by establishing new medical residency programs in the new teaching hospitals solely for the purpose of affiliating with the new teaching hospitals to receive an upward adjustment to their FTE caps under an affiliation agreement. This would effectively allow existing teaching hospitals to achieve an increase in their FTE resident caps beyond the number allowed by their statutory caps (70 FR 47452). Accordingly, we adopted the restriction under § 413.79(e)(1)(iv). We refer readers to the FY 2006 IPPS final rule for a discussion of the regulatory history of this provision (70 FR 47452 through 47454).

As we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20438), we have received questions about whether two (or more) new urban teaching hospitals can form a Medicare GME affiliated group; that is, whether an affiliated group consisting solely of new urban teaching hospitals is permissible, considering that, under § 413.79(e)(1)(iv), a new urban teaching hospital may only enter into a Medicare GME affiliation agreement if the resulting adjustments to its direct GME and IME FTE caps are increases to those caps. The type of Medicare GME affiliated group allowed under the current regulation at § 413.79(e)(1)(iv) involves an existing teaching hospital(s) (a hospital with caps based on training occurring in 1996) and a new teaching hospital(s) (a hospital with caps established after 1996), and therefore, we do not believe a Medicare GME affiliation agreement consisting solely of new urban teaching hospitals is

permissible under § 413.79(e)(1)(iv). However, as we stated in the proposed rule, we believe it is important to provide flexibility with regard to Medicare GME affiliation agreements in light of the statutorily mandated caps on the number of FTE residents a hospital may count for direct GME and IME payment purposes. As we noted in the FY 2006 IPPS final rule, while the rules we established in § 413.79(e)(1)(iv) were meant to prevent gaming on the part of existing teaching hospitals, we did not wish to preclude affiliations that clearly are designed to facilitate additional training at a new teaching hospital. We believe allowing two (or more) new urban teaching hospitals to form a Medicare GME affiliated group will enable these hospitals to provide residents training at their facilities with both the required and more varied training experiences necessary to complete their residency training programs. Furthermore, we believe a change will facilitate increased training within local, smaller-sized communities because generally new urban teaching hospitals are smaller-sized, community-based hospitals compared with existing urban teaching hospitals, which are generally large academic medical centers. Accordingly, under our authority in section 1886(h)(4)(H)(ii) of the Act, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20439), we proposed to revise the regulation to specify that new urban teaching hospitals (that is, hospitals that qualify for an adjustment under § 412.105(f)(1)(vii) or § 413.79(e)(1), or both) may form a Medicare GME affiliated group and therefore be eligible to receive both decreases and increases to their FTE caps.

In the proposed rule, we emphasized that the existing restriction under § 413.79(e)(1)(iv) would still apply to Medicare GME affiliated groups composed of existing and new urban teaching hospitals, given our concerns about gaming. We stated that we do not share the same level of concern in regards to Medicare GME affiliated groups consisting solely of new urban teaching hospitals because we believe these teaching hospitals are similarly situated in terms of size and scope of residency training programs and, therefore, less likely to participate in a Medicare GME affiliated group where the outcome of that agreement would only provide advantages to one of the participating hospitals. However, we still believe it is important to ensure that Medicare GME affiliation agreements entered into between new urban teaching hospitals are consistent with the intent of the Medicare GME affiliation agreement provision; that is, to promote the cross-training of residents at the participating hospitals and not to provide for an unfair advantage of one participating hospital at the expense of another hospital.

Therefore, we proposed to revise § 413.79(e)(1)(iv) by designating the existing provision of paragraph (iv) as paragraph (A) and adding paragraph (B) to specify that an urban hospital that qualifies for an adjustment to its FTE cap under this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE cap only if the decrease results from a Medicare GME affiliated group consisting solely of two or more urban hospitals that qualify to receive adjustments to their FTE caps under paragraph (e)(1). Because Medicare GME affiliation agreements can only be entered into at the start of an academic year (that is, July 1), we proposed that this change would be effective beginning with affiliation agreements entered into for the July 1, 2019 through June 30, 2020 residency training year. We noted that, if the proposed change is adopted in the final rule, it would apply to both Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements.

Comment: Commenters supported the proposed change to the regulations to allow new urban teaching hospitals to form a Medicare GME affiliated group(s) and therefore be eligible to receive decreases to their FTE caps. The commenters stated that the proposal would provide flexibility under the statutorily mandated cap and would support the cross-training of residents. One commenter expressed appreciation for the proposal and specifically referenced the need for residency positions in Florida by stating that Florida is ranked near the bottom of the nation (42nd) by the Association of American Medical Colleges (AAMC) in the number of medical residency positions per 100,000 people (18.8 residents per 100,000 versus 26.2 nationally) and currently has a shortage of more than 800 residency positions available in relation to the number of graduate medical students. Other commenters stated the proposal would provide residents with required and more diverse training experiences, allow residents to train where previously they were unable due to the current restrictions, and fill residencies where needed, which in turn will provide for a better workforce pipeline. Another commenter stated that allowing teaching hospitals to combine resources responds to two needs, growing and training the physician workforce and improving patient access, which are both key factors in improving health care and access to health care. One commenter supported the proposed change and requested CMS continue to support to GME programs, specifically to allow urban teaching hospitals to partner with rural hospitals to incentivize those relationships to be mutually beneficial to both hospitals and improve access to care in rural areas.

Response: We appreciate the commenters' support of the proposed policy. As discussed later in this preamble, we are finalizing our proposal with modification. In response to the comment regarding partnerships between urban and rural teaching hospitals, we refer readers to the most recent discussion of rural tracks included in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57027 through 57031).

Comment: Commenters requested that CMS clarify the term ''new teaching hospital'' as it relates to the proposed provision. The commenters stated that CMS defines the term ''new teaching hospital'' as referring to hospitals that started training residents after 1996, more than 20 years ago. However, the commenters added, to the medical community, ''new teaching hospital'' is a hospital still in its cap-building period. The commenters requested that CMS confirm the proposed provision is meant to apply to hospitals that have already established an FTE cap(s).

Response: In the proposed rule (83 FR 20439), we referred to new urban teaching hospitals as hospitals that qualify for an adjustment under § 412.105(f)(1)(vii) or § 413.79(e)(1), or both. These regulations describe how caps are calculated for a hospital that had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996 and begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995. (Specifically, a new medical residency training program is defined in regulation at § 413.79(l) as a medical residency program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.) We also refer readers to the FY 2010 IPPS/LTCH PPS final rule where we discuss the definition of new medical residency training program (74 FR 43908 through 43917). Therefore, the commenter is correct that a new teaching hospital would include a hospital that started training residents

more than 20 years ago because the term ''new teaching hospital'' includes both a hospital that already completed its cap-building period and received its own permanent FTE caps (based on training residents in a new program(s) that received initial accreditation or began on or *after* January 1, 1995), or a hospital that some point in the future will for the first time train residents in a new program and complete its cap-building period and receive its own permanent FTE caps.

In response to the request that CMS confirm that the proposed provision was meant to apply to hospitals that have already established FTE caps, we note that the proposal, which we are finalizing, to allow a new urban teaching hospital to be part of a Medicare GME affiliated group composed solely of new urban teaching hospitals requires that a least one of the new urban teaching hospitals participating in the Medicare GME affiliated group has established FTE caps. (As explained further below, our proposal does not require that all participating hospitals have established FTE caps.) If a Medicare GME affiliated group were to consist solely of new urban teaching hospitals that do not have established FTE caps, there would be no cap amounts to transfer under the agreement. In addition, we note that when a new teaching hospital is within the cap-building period for a new program(s), the hospital's caps are not yet established and it is paid for IME and direct GME based on its actual count of FTE residents in the new program (§ 413.79(e)(1)(ii)). Because these FTEs are not capped, they cannot be decreased under a Medicare GME affiliation agreement.

However, the proposal was not meant to exclude new teaching hospitals that do not yet have FTE caps established from participating in a Medicare GME affiliated group. Rather, such hospitals have always been able to participate in a Medicare GME affiliated group as long as these hospitals are the entities receiving increases to their FTE caps of zero under the affiliation agreement(s). For example, under our proposal, a new urban teaching hospital that does *not* yet have FTE caps could receive an increase to its FTE caps of zero through a Medicare GME affiliation agreement wherein it is training residents in an existing program coming from a new urban teaching hospital that has permanent FTE caps. In such a scenario, the new urban teaching hospital with permanent FTE caps would be decreasing its FTE caps such that the other new urban teaching hospital, which does not have FTE caps of its own, would have temporary FTE caps above zero and could receive IME and direct GME payment for the residents rotating in from the existing program.

Comment: One commenter opposed CMS' interpretation that Medicare GME affiliation agreements consisting solely of new urban teaching hospitals are not permissible under § 413.79(e)(1)(iv). The commenter stated that when growing the physician workforce is a priority in improving health care, CMS should be looking at facilitating and incentivizing this goal. The commenter stated that it had long supported efforts to increase the 1996 caps and urged CMS and Congress to lift the caps on GME for hospitals in order to update and modernize the training and recruitment of physicians. In lieu of increased funding for GME, the commenter urged CMS to look at ways to increase GME caps under existing regulations.

Response: We disagree with the commenter that affiliation agreements consisting solely of new urban teaching hospitals are permissible under § 413.79(e)(1)(iv). These regulations state the following: ''(e)ffective for Medicare GME affiliation agreements entered into on or after October 1, 2005, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.'' The language means that a new urban teaching hospital can only be part of a Medicare GME affiliated group if it receives an increase to its FTE cap; that is, receives cap slots from another hospital. In order to allow for the transfer of FTE cap slots under a Medicare GME affiliation agreement, there would need to be a hospital that receives a decrease to its caps; that is, lends cap slots to another hospital. Therefore, under current regulations, Medicare GME affiliation agreements cannot consist solely of new urban teaching hospitals.

In response to the request that CMS look for ways to increase FTE caps under current regulations, we note that the current regulations do provide some means of establishing and increasing FTE resident caps. New urban and rural teaching hospitals that do not have caps established can receive permanent FTE caps when they train residents in a new program after a 5-year cap-building period (§§ 413.79(e) and 412.105(f)(1)(vii)). Furthermore, both new and existing rural teaching hospitals that train residents in a new program receive an increase to their permanent FTE caps each time they train residents in a new program (§ 413.79(e)(3)). Urban teaching hospitals that participate in a rural track program can receive an add-on to their permanent FTE caps for the time the residents spend training at the urban teaching hospital as part of the rural track program (§§ 412.105(f)(x) and 413.79(k)) (we refer readers to the August 22, 2016 **Federal Register** (81 FR 57027) for a discussion of rural tracks). Lifting hospitals' 1996 caps would require legislation.

Comment: Two commenters supported the proposed change to allow Medicare GME affiliated groups to consist solely of new urban teaching hospitals. However, these commenters also requested that CMS provide additional flexibilities, and they proposed several policy alternatives for CMS to consider.

One commenter stated the practicality of two new teaching hospitals in close vicinity to have shared rotational arrangements is minimal. The commenter understood and appreciated CMS' concern that some teaching hospitals with existing medical residency training programs may try and circumvent the statutory FTE caps by establishing new residency training programs at new teaching hospitals solely for the purposes of affiliation. However, the commenter stated that, under these restrictions, CMS limits the ability to cross-train future physicians, especially in multihospital settings in rural areas. The commenter stated many ''new'' teaching hospitals started training programs after the 1996 caps were established, and these hospitals have since become associated with larger teaching hospitals and medical schools. The commenter suggested that after a specified time-period in which the new teaching hospital first began training residents, CMS allow a new teaching hospital to lend cap slots to existing teaching hospitals that are part of related organizations. The commenter suggested a 10-year waiting period, which is consistent with the length of time a hospital must remain reclassified as rural in order to retain any increases to its IME cap associated with being rural, as described in the regulations at § 412.105(f)(1)(xv).

Response: We appreciate the commenter's suggestion to provide additional flexibility for new urban teaching hospitals under the Medicare GME affiliation agreement regulations. However, we disagree with the commenter's proposal that after a 10-year period, CMS should allow a new urban teaching hospital to lend cap slots to an existing teaching hospital that is

part of a related organization. It may be administratively difficult for CMS and its contractors to ensure that the new teaching hospital is participating in an agreement with an existing teaching hospital(s) that is part of a related organization. Ensuring that the term ''related organizations'' is applied consistently would require additional rulemaking.

Comment: One commenter believed CMS' overall concern regarding Medicare GME affiliation agreements as expressed in the FY 2019 IPPS/LTCH PPS proposed rule is misplaced, and that there is no need for CMS to protect ''smaller-sized, community-based hospitals'' from existing teaching hospitals. The commenter stated a Medicare GME affiliation agreement is a voluntary contractual arrangement between two organizations with two distinct Medicare provider numbers and Medicare provider agreements. The commenter noted it has worked with many of its member teaching hospitals—large and small, public and private, urban and suburban—on Medicare GME affiliation agreements and has not encountered a situation where any one of these hospitals was not entering into the agreement of its own free will, ensuring that its own interests are met through the affiliation agreement.

Response: We continue to believe it is important to ensure that the intent of Medicare GME affiliation agreements is met; that is, Medicare GME affiliation agreements are in place to promote the cross-training of residents at the participating hospitals and not to provide for an unfair advantage of one participating hospital at the expense of another hospital. However, we appreciate hearing that the commenter has not encountered situations where a Medicare GME affiliation agreement has only benefited one or some of the participating hospitals, particularly because a Medicare GME affiliation agreement is a voluntary contractual arrangement.

Comment: One commenter stated that, as part of CMS' new teaching hospital rulemaking and policy clarification (74 FR 43908), CMS has specified that, among other requirements, a new teaching hospital must establish new programs with new residents in order to build direct GME and IME FTE caps. The commenter stated that, under these requirements, CMS has essentially prohibited an existing teaching hospital from entering in a Medicare GME affiliation agreement with a new teaching hospital in order to circumvent its statutory FTE caps. The commenter questioned why the new program requirements for new teaching hospitals combined with a time-based restriction on Medicare GME affiliation agreements would not be sufficient to achieve CMS' policy goals. The commenter noted that, in 2006 and in the FY 2019 IPPS/LTCH PPS proposed rule, CMS has granted/is granting some small flexibility to new teaching hospitals, some of which have had caps for over a decade. Therefore, the commenter believed that CMS does not seem concerned about these new teaching hospitals (that have had FTE caps for over a decade) circumventing their statutory caps. The commenter questioned why, if CMS is willing to grant flexibility to allow new teaching hospitals to lend slots to other new teaching hospitals that have had FTE caps for well over a decade, CMS cannot grant the same flexibility to new teaching hospitals to lend FTE cap slots to hospitals with 1996 caps that are similarly situated in the community.

Response: If we understand the commenter correctly, the commenter is stating that in order to receive FTE caps a new teaching hospital must train residents in a new program (which is comprised of new residents, new teaching staff, and a new program director), and that because the involvement of an existing teaching hospital would call into question the ''newness'' of that program, an existing teaching hospital would be prevented from using a new teaching hospital's FTE caps for its own purposes. We do not believe this argument is applicable to both our proposed policy and the policy finalized in this final rule. That is, as explained above, a new teaching hospital that is within its cap-building period for a new program(s) cannot use those slots as part of a Medicare GME affiliation agreement during that cap-building period anyway (regardless of an increase or decrease) because those slots are not yet permanent cap slots. Rather, our proposed and final policies instead focus on expanding the flexibility of new teaching hospitals entering into Medicare GME affiliation agreements *after* its FTE caps are permanently set.

Comment: One commenter stated CMS did not provide data to support its claims that existing urban teaching hospitals are generally large academic medical centers and that new urban teaching hospitals differ in size from existing urban teaching hospitals. The commenter reported that it had analyzed data included in the Hospital Cost Report Information System (HCRIS) using FY 2016 cost reports to try to verify the validity of CMS' claims. The commenter stated that because there is no standard definition of academic medical center (the term generally refers to a large hospital closely affiliated with a medical school), for purposes of the analysis, the commenter defined an academic medical center as a teaching hospital with at least 500 beds. Based on the commenter's analysis, only 22.7 percent of hospitals training residents in 1996 had 500 or more available beds. The commenter stated that, in total, 72.8 percent of existing teaching hospitals that reported training residents in 1996 had between 100 and 500 available beds, and therefore would not be considered a ''large academic medical center.'' Therefore, the commenter disagreed with CMS' assertion that existing teaching hospitals are generally large academic medical centers. The commenter stated that, based on its analysis, 22 percent of existing teaching hospitals had between 100 and 200 available beds, and another 22 percent of existing teaching hospitals had between 200 and 300 available beds. The commenter noted that, of the hospitals that received caps after 1996, 81.9 percent of these hospitals also had between 100 and 500 beds. Therefore, the commenter stated that, based on its analysis, the percentage of existing teaching hospitals and new teaching hospitals of the same size is within 10 points. The commenter noted that even though very small urban hospitals (fewer than 100 beds) were disproportionately nonteaching hospitals in 1996 (and 40 percent remain nonteaching), the commenter's analysis indicates the vast majority of existing teaching hospitals and new teaching hospitals are not substantially different in size from each other. Therefore, the commenter disagreed with CMS' rationale that a distinction between existing teaching hospitals and new teaching hospitals is necessary and encouraged CMS to reconsider its policy regarding treating new teaching hospitals differently from existing teaching hospitals for purposes of Medicare GME affiliation agreements.

Response: We have not independently verified the commenter's analysis or performed a detailed cost report analysis for purposes of this proposal. However, even if many new teaching hospitals are approximately the same size as many existing teaching hospitals, we still believe a distinction can be made between existing teaching hospitals and those new teaching hospitals that have just started training residents, with the former having greater expertise in the logistics of running residency training programs than the latter. However, we are receptive to the commenter's concerns, and therefore,

we are modifying our proposed policy, as explained further below, to provide greater flexibility for new urban teaching hospitals to affiliate with existing teaching hospitals.

Comment: One commenter stated that because ''new'' teaching hospitals could have started training residents as early as 1997, it does not seem appropriate to characterize a hospital that has been training residents for close to 20 years as ''new'' and use that as a basis to draw a distinction between that hospital and other hospitals in 2018. The commenter stated that, for this reason, it along with national colleagues and the provider community have encouraged CMS to provide flexibility to new teaching hospitals after some reasonable period of time (for example, 5 years after the establishment of a cap, or 10 years after first training residents). The commenter stated that, at that point in time, it is difficult to reasonably still characterize the hospital as a ''new'' teaching hospital and hold the hospital to a different standard compared to—in CMS' terminology—an ''existing'' teaching hospital.

The commenter also suggested a policy alternative that would be associated with putting a limit on the proportion of FTE cap slots a new teaching hospital could lend to an existing teaching hospital. The commenter suggested that CMS could simply limit the number of shared FTE cap slots to some reasonable percentage, thereby ensuring that the new teaching hospital's cap generally ''stays'' with it. The commenter noted that, for example, CMS could specify that a new teaching hospital could enter into a Medicare GME affiliation agreement with an existing teaching hospital such that it may experience a decrease in its FTE cap but for no more than more than 20 percent of the new teaching hospital's FTE cap slots. The commenter stated there is nothing explicit in the statute to guide the selection of a particular percentage. However, the commenter believed that such a policy determination would be well within CMS' rulemaking authority.

The commenter discussed teaching hospitals located in the same health system. The commenter noted that that CMS' extremely limited policy restrictions, even with the addition of the flexibility included within the FY 2019 IPPS/LTCH PPS proposed rule, seem extremely outdated in an era where hospitals are entering into system arrangements to create centers of excellence and to locate services where they best serve their communities. The commenter stated that for CMS to hold one teaching hospital within an integrated delivery system to one set of Medicare GME affiliation agreement requirements and another teaching hospital within that same health system to a different set of requirements (seemingly to protect one from the other) is inconsistent with the intent of joint membership in the system. The commenter stated that CMS' current policy is contrary to the very notion of ''systemness'' and clinical/academic integration, which many health care leaders and policymakers are trying to promote as a means of improving quality of care for patients and improved training experiences for residents. Therefore, the commenter suggested that, in addition to the policy change included as part of the FY 2019 IPPS/LTCH PPS proposed rule, CMS, at a minimum, permit new urban teaching hospitals to enter into Medicare GME affiliation agreements with any existing teaching hospital under the same corporate parent whereby the existing urban teaching hospital could experience an increase to its FTE cap.

Response: We do not agree with the commenter's suggestion to allow a new urban teaching hospital to enter into a Medicare GME affiliation agreement with any existing teaching hospital under the same corporate parent wherein the new urban teaching hospital would experience a decrease to its FTE cap. We believe that understanding the hospitals' corporate structure for purposes of determining which hospitals can affiliate could prove to be administratively burdensome, and that corporate structures may change over time, which could call into question the validity of Medicare GME affiliation agreement structured under such an approach.

In response to the commenter's suggestion to permit a new urban teaching hospital to participate in a Medicare GME affiliation agreement and receive a decrease to its FTE cap for a certain proportion of FTE cap slots, we believe it would be challenging to determine an appropriate percentage of FTE cap slots from a new urban teaching hospital that should be permitted to be transferred to an existing teaching hospital. Furthermore, an appropriate percentage may differ among new urban teaching hospitals based on their individual training needs, adding to the administrative complexity.

However, we do believe that a time-limited approach may provide new urban teaching hospitals the opportunity to receive decreases to their caps while at the same time addressing our concern that existing teaching hospitals not use new teaching hospitals to circumvent their FTE caps. Specifically, we believe that requiring a new urban teaching hospital to wait a certain period of time prior to lending its cap slots to an existing teaching hospital through a Medicare GME affiliation agreement (that is, the new urban teaching hospital would receive a decrease to its FTE caps as part of the affiliation agreement) would demonstrate that the new teaching hospital is, in fact, establishing and expanding its own new residency training programs rather than serving as a means for an existing teaching hospital to receive additional FTE caps. We further believe that a time-limited approach would be a more equitable way of providing new urban teaching hospitals with the opportunity to decrease their FTE caps instead of using a percentage of slots or determining whether a new urban teaching hospital falls under the same corporate structure as an existing teaching hospital. As previously stated, hospitals participating in a Medicare GME affiliation agreement may have different training needs such that a single percentage would not be advantageous to all new urban teaching hospitals. In addition, not all new urban teaching hospitals may have existing teaching hospitals within the same corporate structure that are in a position to receive FTE cap slots as part of a Medicare GME affiliation agreement.

As noted earlier, one commenter made the suggestion of a time-limited period of 5 years after the establishment of a cap, or 10 years after first training residents. Based on the comments received, we believe that the potential misuse of Medicare GME affiliation agreements can be mitigated after a certain period of time. We agree that a 5-year waiting period after the establishment of an FTE cap is a suitable waiting period for purposes of allowing a new urban teaching hospital to participate in a Medicare GME affiliation agreement with an existing teaching hospital and receive a decrease to its FTE cap as a result of that affiliation agreement. We are comfortable with a 5-year waiting period because it is consistent with our already established policies regarding the use of FTE cap slots received under sections 5503 and 5506 of the Affordable Care Act. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72194), we stated that a hospital that received FTE cap slots under section 5503 may use those FTE cap slots for Medicare GME affiliation agreements after 5 years, which coincides with the end of the period of

other restrictions applicable to the slots awarded under section 5503. In that same final rule with comment period, we stated that a hospital is able to use the slots it received under section 5506 for a Medicare GME affiliation agreement 5 years after the date the slots are made permanent at the respective hospital (75 FR 72221). That is, under both provisions of the Affordable Care Act, hospitals that received cap slots were/are encouraged to use their additional FTE cap slots to establish or expand existing residency training programs prior to using those cap slots as part of a Medicare GME affiliation agreement. Accordingly, we are finalizing our proposed policy with modifications so that new urban teaching hospitals will have additional flexibilities under the Medicare GME affiliation agreement regulations after a 5-year waiting period, effective for Medicare GME affiliation agreements entered into on or after July 1, 2019.

We are finalizing a policy that, effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, a new urban teaching hospital (that is, a hospital that established permanent FTE caps after 1996) may enter into a Medicare GME affiliated group and receive a decrease to its FTE caps if the decrease results from a Medicare GME affiliated group consisting solely of two or more new urban teaching hospitals. In addition, we are finalizing a policy that, effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, a new urban teaching hospital(s) may enter into a Medicare GME affiliated group with an existing teaching hospital(s) (that is, a hospital(s) with 1996 FTE caps) and receive a decrease to its FTE caps, as long as the new urban teaching's hospitals caps have been in effect for 5 or more years. That is, once a new urban teaching hospital's caps are effective, after a cap-building period, the new urban teaching hospital can participate in a Medicare GME affiliation agreement with an existing teaching hospital and receive a decrease to its FTE caps after an additional 5-year waiting period.

Because Medicare GME affiliation agreements are effective consistent with the residency training year (July 1 through June 30), under the policy finalized in this rule, the new urban teaching hospital will be able to participate in an affiliation agreement with an existing teaching hospital and receive a decrease to its FTE caps effective with the July 1 date (the residency training year) that begins at least 5 years after the new urban teaching hospital's caps are effective. In the August 22, 2014 **Federal Register** (79 FR 50110), we finalized a policy that a new teaching hospital's FTE caps are effective beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started. Therefore, in applying both the policy finalized in the August 22, 2014 **Federal Register** and the 5-year waiting period for new urban teaching hospitals finalized in this rule, a new urban teaching hospital can lend FTE cap slots to an existing teaching hospital under a Medicare GME affiliation agreement, effective with the July 1 date (the residency training year) that is at least 5 years after the start of the hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program. Consistent with this policy, we are amending the regulations at § 413.79(e)(1)(iv) as follows:

- Effective for Medicare GME affiliation agreements entered into on or after October 1, 2005, except as provided in § 413.79(e)(1)(iv)(B)(*2*), an urban hospital that qualifies for an adjustment to its FTE cap under § 413.79(e)(1) is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.
- Effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, an urban hospital that received an adjustment to its FTE cap under § 413.79(e)(1) is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE cap, provided the Medicare GME affiliated group meets one of the following conditions:

□ The Medicare GME affiliated group consists solely of two or more urban hospitals that qualify for adjustments to their FTE caps under § 413.79(e)(1).

□ The Medicare GME affiliated group includes an urban hospital(s) that received FTE cap(s) under § 413.79(c)(2)(i) and/or § 412.105(f)(1)(iv)(A). This Medicare GME affiliated group must be established effective with a July 1 date (the residency training year) that is at least 5 years after the start of the cost reporting period that coincides with or follows the start of the sixth program year of the first new program for which the hospital's FTE cap was adjusted in accordance with § 413.79(e)(1) or § 412.105(f)(1)(v)(C) or (D), or both.

We note that we have made a conforming change to § 413.79(e)(1)(iv)(A) to clarify that new teaching hospitals can continue to participate in Medicare GME affiliated groups with existing teaching hospitals wherein the new teaching hospitals receive increases to their FTE caps. In addition, we are clarifying that the terms ''qualifies'' and ''qualify'' used at § 413.79(e)(1)(iv)(A) and § 413.79(e)(1)(iv)(B)(*1*) are meant to include new teaching hospitals that have already established permanent FTE caps and new teaching hospitals that in the future will establish permanent FTE caps.

The 5-year waiting period and the policy described at § 413.79(e)(1)(iv)(B)(*2*) may best be explained through the examples below.

Example 1: Assume Hospital A's (a new urban teaching hospital that did not train residents in 1996) cost reporting period is from July 1 to June 30. Hospital A started training residents in its first new program effective July 1, 2014. Hospital A's 5-year cap-building period lasts through June 30, 2019 and its caps are effective July 1, 2019. Hospital A would be able to participate in a Medicare GME affiliation agreement with an existing teaching hospital and receive a decrease to its FTE caps beginning with the July 1 date (the residency training year) that is at least 5 years after July 1, 2019 (the start of the cost reporting period in which the permanent FTE caps are effective). Therefore, Hospital A would be able to receive a decrease to its FTE caps effective July 1, 2024.

Example 2: Assume Hospital B (a new urban teaching hospital that did not train residents in 1996) has a cost reporting period that is from January 1 to December 31. Hospital B also started training residents in its first new program effective July 1, 2014. Hospital B's 5-year cap building period lasts through June 30, 2019 and its cap is effective January 1, 2020. Hospital B would be able to participate in a Medicare GME affiliation agreement with an existing teaching hospital and receive a decrease to its FTE caps beginning with the July 1 date (the residency training year) that is at least 5 years after January 1, 2020 (the start of the cost reporting period in which the permanent FTE caps are effective). Therefore, Hospital B would be able to receive a decrease to its FTE caps effective July 1, 2025.

Example 3: Assume Hospital C (a new urban teaching hospital that did not train residents in 1996) has a cost reporting period that is from October 1 to September 30. Hospital C, like Hospitals A and B, started training residents in its first new program

effective July 1, 2014. Hospital C's 5-year cap building period lasts through June 30, 2019 and its caps are effective October 1, 2019. Hospital C would be able to participate in a Medicare GME affiliation agreement with an existing teaching hospital and receive a decrease to its FTE caps beginning with the July 1 date (the residency training year) that is at least 5 years after October 1, 2019 (the start of the cost reporting period in which the permanent FTE caps are effective). Therefore, Hospital C would be able to receive a decrease to its FTE caps effective July 1, 2025.

Because the policy finalized in this final rule is consistent with the start of the residency training year, that is, July 1, new urban teaching hospitals with fiscal years other than July 1 through June 30 may have to wait some additional time before being able to receive a decrease to their FTE resident caps through a Medicare GME affiliation agreement with an existing teaching hospital. However, the delay for these new urban teaching hospitals is a one-time delay, consistent with the timing of implementation of FTE caps, and we believe any negative aspect of this delay is far outweighed by the additional flexibility provided to these new urban teaching hospitals for purposes of Medicare GME affiliation agreements.

Unlike the examples provided above for Hospitals A, B, and C, the commenters mentioned ''new'' urban teaching hospitals that established their FTE caps after 1996, but have had those caps in place already for close to 20 years. These new urban teaching hospitals have already completed the 5-year waiting period and can receive a decrease to their FTE caps through Medicare GME affiliation agreements with existing teaching hospitals effective July 1, 2019. For example, assume Hospital D (a new urban teaching hospital that was not training residents in 1996) established its caps effective July 1, 2000. Hospital D can receive a decrease to its FTE caps through a Medicare GME affiliation agreement with an existing teaching hospital effective July 1, 2019.

In summary, we are finalizing our proposed policy with modifications. Effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, a new urban teaching hospital may enter into a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE caps if the decrease results from a Medicare GME affiliated group consisting solely of two or more new urban teaching hospitals. In addition, effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, a new urban teaching hospital may participate in a Medicare GME affiliated group with an existing teaching hospital and receive an adjustment that is a decrease to the urban hospital's FTE caps, provided the Medicare GME affiliation agreement is effective with a July 1 date (the residency training year) that is at least 5 years after the start of the new urban teaching hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program. Other requirements for Medicare GME affiliated groups and agreements at §§ 413.75(b) and 413.79(f) remain unchanged. The policies included in this final rule apply to both Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements.

3. Out of Scope Public Comments Received

We received public comments regarding GME issues that were outside of the scope of the proposals included in the FY 2019 IPPS/LTCH PPS proposed rule. These comments requested that—

- CMS not establish FTE caps and PRAs for hospitals that have trained a de minimis number of FTE residents.
- CMS extend the cap-building window for teaching hospitals in rural, underserved, underresourced communities and/or areas currently lacking medical training infrastructure.
- CMS permit hospitals with new or established GME programs in areas of need to apply for additional residency slots through a ''Cap Flexibility'' demonstration project; prioritizing those supplying psychiatric residency training to regions with a maldistribution of physicians that provide mental health care and treatment.
- CMS use ''Cap Flexibility'' to allow new GME teaching hospitals in areas of need to have up to an additional 5 years beyond the current 5-year window to add residents to their training programs.
- Indian Health Service and Tribal Hospitals be made eligible to receive Medicare funding for residency training programs.
- CMS review the ''frozen cap'' for the Psychiatric Teaching Status Adjustment Cap for rural providers and CMS re-review the current care needs at the national level across inpatient psychiatric facilities and adjust regulations accordingly.
- CMS release its findings regarding awardee hospitals' use of their section 5503 slots and their compliance with the terms and conditions of section 5503.

Because we consider these public comments to be outside of the scope of the proposed rule, we are not addressing them in this final rule.

4. Notice of Closure of Teaching Hospital and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ''Affordable Care Act''), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is, March 23, 2008). In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72212), we established regulations (42 CFR 413.79(o)) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010.

b. Notice of Closure of Memorial Hospital of Rhode Island, Located in Pawtucket, RI, and the Application Process—Round 13

CMS has learned of the closure of Memorial Hospital of Rhode Island, located in Pawtucket, RI (CCN 410001). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 13th round (''Round 13'') of the application and selection process. The table below contains the identifying information and IME and direct GME FTE resident caps for the closed

teaching hospital, which is part of the Round 13 application process under section 5506 of the Affordable Care Act.

CCN	Provider name	City and state	CBSA code	Terminating date	IME FTE resident cap (including +/− MMA Sec. 422[1] and ACA Sec. 5503[2] adjustments)	Direct GME FTE resident cap (including +/− MMA Sec. 422[1] and ACA Sec. 5503[2] adjustments)
410001	Memorial Hospital of Rhode Island.	Pawtucket, RI	39300	January 31, 2018.	67.75 + 5.91 sec. 422 increase = 73.66[3].	75.56 − 0.47 sec. 422 reduction − 2.47 sec. 5503 reduction = 72.62.[4]

[1] Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
[2] Section 5503 of the Affordable Care Act of 2010, Public Law 111–148 and Public Law 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.
[3] Memorial Hospital of Rhode Island's 1996 IME FTE resident cap is 67.75. Under section 422 of the MMA, the hospital received an increase of 5.91 to its IME FTE resident cap: 67.75 + 5.91 = 73.66.
[4] Memorial Hospital of Rhode Island's 1996 direct GME FTE resident cap is 75.56. Under section 422 of the MMA, the hospital received a reduction of 0.47 to its direct GME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 2.47 to its direct GME FTE resident cap: 75.56 − 0.47 − 2.47 = 72.62.

c. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR53436). Therefore, hospitals that wish to apply for and receive slots from the FTE resident caps of closed Memorial Hospital of Rhode Island, located in Pawtucket, RI, must submit applications (Section 5506 Application Form posted on Direct Graduate Medical Education (DGME) website as noted at the end of this section) directly to the CMS Central Office no later than October 31, 2018. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the October 31, 2018 deadline date. It is *not* sufficient for applications to be postmarked by this date.

After an applying hospital sends a hard copy of a section 5506 slot application to the CMS Central Office mailing address, the hospital is strongly encouraged to notify the CMS Central Office of the mailed application by sending an email to: *ACA5506application@cms.hhs.gov*. In the email, the hospital should state: ''On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under Round 13 due to the closure of Memorial Hospital of Rhode Island. If you have any questions, please contact me at [insert phone number] or [insert your email address].'' An applying hospital should *not* attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy application that is being mailed to the CMS Central Office.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.html* to download a copy of the section 5506 application form (Section 5506 Application Form) that hospitals must use to apply for slots under section 5506 of the Affordable Care Act. Hospitals should also access this same website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

L. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed below). Section 15003 also requires that, no later than 120 days after enactment of Public Law 114–255, the Secretary must issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period, so long as the maximum number of 30 hospitals stipulated by the Affordable Care Act is not exceeded. In this final rule, we are providing a summary of the previous legislative provisions and their implementation; a description of the provisions of section 15003 of Public Law 114–255; our final policies for implementation; the finalized budget neutrality methodology for the extension period authorized by section 15003 of Public Law 114–255, including a discussion of the budget neutrality methodology used in previous final rules for periods prior to the extension period; and an update on the reconciliation of actual and estimated costs of the demonstration for previous years (2011, 2012, and 2013).

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or

rehabilitation unit) as reported in its most recent cost report;

- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost reporting periods beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the demonstration program and converted to CAH status. This left 9 hospitals participating at that time. In 2008, we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These 4 additional hospitals began under the demonstration payment methodology with the hospitals' first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals withdrew from the demonstration program during CYs 2009 and 2010. In CY 2011, one hospital among this original set of participating hospitals withdrew. These actions left 7 of the hospitals that were selected to participate in either 2004 or 2008 participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, changing the Rural Community Hospital Demonstration program in several ways. First, the Secretary was required to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during the 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation.

In addition, the Affordable Care Act required, during the 5-year extension period, that the Secretary expand the number of States with low population densities determined by the Secretary to 20. Further, the Secretary was required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period. The Affordable Care Act also allowed not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period.

We published a solicitation for applications for additional participants in the Rural Community Hospital Demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). The 20 States with the lowest population density that were eligible for the demonstration program were: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). Sixteen new hospitals began participation in the demonstration with the first cost reporting period beginning on or after April 1, 2011.

In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital of the set selected in 2011 withdrew from the demonstration, which left 22 hospitals participating in the demonstration, effective July 1, 2013, all of which continued their participation through December 2014. Starting from that date and extending through the end of FY 2015, the 7 hospitals that were selected in either 2004 or 2008 ended their scheduled 5-year periods of performance authorized by the Affordable Care Act on a rolling basis. Likewise, the participation period for the 14 hospitals that entered the demonstration, following the mandate of the Affordable Care Act and that were still participating, ended their scheduled periods of performance on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. (One hospital among this group closed in October 2015.)

3. Provisions of the 21st Century Cures Act (Pub. L. 114–255) and Finalized Policies for Implementation

a. Statutory Provisions

As stated earlier, section 15003 of Public Law 114–255 further amended section 410A of Public Law 108–173 to require the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Thus, the Secretary is required to conduct the demonstration for an additional 5-year period. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation. Furthermore, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals that are not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In addition, section 15003 of Public Law 114–255 amended section 410A of Public Law 108–173 to add paragraph (g)(6)(A) which requires that the Secretary issue a solicitation for applications no later than 120 days after enactment of paragraph (g)(6), to select additional rural community hospitals located in any State to participate in the demonstration program for the second 5 years of the 10-year extension period, without exceeding the maximum number of hospitals (that is, 30) permitted under section 410A(g)(3) of Public Law 108–173 (as amended by the Affordable Care Act). Section 410A(g)(6)(B) of Public Law 108–173 provides that, in determining which hospitals submitting an application pursuant to this solicitation are to be selected for participation in the demonstration, the Secretary must give priority to rural community hospitals

located in one of the 20 States with the lowest population densities, as determined using the 2015 Statistical Abstract of the United States. The Secretary may also consider closures of hospitals located in rural areas in the State in which an applicant hospital is located during the 5-year period immediately preceding the date of enactment of the 21st Century Cures Act (December 13, 2016), as well as the population density of the State in which the rural community hospital is located.

b. Solicitation for Additional Participants

As required under section 15003 of Public Law 114–255, we issued a solicitation for additional hospitals to participate in the demonstration. We released this solicitation on April 17, 2017. As described in the FY 2018 IPPS/LTCH PPS proposed rule, the solicitation identified the 20 States with the lowest population density according to the population estimates from the Census Bureau for 2013, from the *ProQuest Statistical Abstract of the United States, 2015*. These 20 States are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Vermont, and Wyoming. Applications were due May 17, 2017. Applications were assessed in accordance with the information requested in the solicitation; that is, the problem description, plan for financial viability, goals for the demonstration, contributions to quality of care, and collaboration with other providers and organizations. In accordance with the authorizing statute, closure of hospitals within the State of the applicant hospital and population density were considered in assessing applications.

c. Terms of Participation for the Extension Period Authorized by Public Law 114–255

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19994), we stated that our goal was to finalize the selection of participants for the extension period authorized by Public Law 114–255 by June 2017, in time to include in the FY 2018 IPPS/LTCH PPS final rule an estimate of the costs of the demonstration during FY 2018 and the resulting budget neutrality offset amount, for these newly participating hospitals, as well as for those hospitals among the previously participating hospitals that decided to participate in the extension period. (The specific method for ensuring budget neutrality under section 410A of Pub. L. 108–173 was described in the FY 2018 IPPS proposed rule, consistent with general policies adopted in previous years.) We indicated that upon announcing the selection of new participants, we would confirm the start dates for the periods of performance for these newly selected hospitals and for previously participating hospitals. We stated, on the other hand, that if final selection were not to occur by June 2017, we would not be able to include an estimate of the costs of the demonstration or an estimate of the budget neutrality offset amount for FY 2018 for these additional hospitals in the FY 2018 IPPS/LTCH PPS final rule.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period and the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the period of performance under the first 5-year extension period ended. However, by the time of the FY 2018 IPPS/LTCH PPS final rule, we had not been able to verify which among the previously participating hospitals would be continuing participation, and thus were not able to estimate the costs of the demonstration for that year's final rule. We stated in the final rule that we would instead include the estimated costs of the demonstration for all participating hospitals for FY 2018, along with those for FY 2019, in the budget neutrality offset amount for the FY 2019 proposed and final rules.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by the Affordable Care Act elected to continue in the second 5-year extension period for the full second 5-year extension period. Of the four hospitals that did not elect to continue participating, three hospitals converted to CAH status during the time period of the second 5-year extension period. Thus, the 5-year period of performance for each of these hospitals started on dates beginning May 1, 2015 and extending through January 1, 2017. On November 20, 2017, we announced that, as a result of the solicitation issued earlier in the year, 13 additional hospitals were selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (Hereafter, these two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) We announced, as well, that each of these newly participating hospitals would begin its 5-year period of participation effective the start of the first cost reporting period on or after October 1, 2017.

We described these provisions in the FY 2019 IPPS/LTCH PPS proposed rule. Since the publication of the proposed rule, one of the hospitals selected in 2017 has withdrawn from the demonstration, prior to beginning participation in the demonstration on July 1, 2018. Thus, 29 hospitals are participating during FY 2018.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, made it extremely unlikely that this demonstration program could be held to budget neutrality under the methodology normally used to calculate it—that is, cost-based payments to participating small rural hospitals were likely to

increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. In addition, a rural community hospital's participation in this demonstration program would be unlikely to yield benefits to the participants if budget neutrality were to be implemented by reducing other payments for these same hospitals. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. Methodology Used in Previous Final Rules for Periods Prior to the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we have determined the amount by which the actual costs of the demonstration for an earlier, given year, differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we have incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. (We note that we have calculated this difference for FYs 2005 through 2010 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.)

c. Budget Neutrality Methodology for the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

(1) General Approach

We finalized our budget neutrality methodology for periods of participation under the second 5 years of the 10-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous years, we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20444) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year. As we described in the FY 2018 final rule and FY 2019 proposed rule, we are incorporating several distinct components into the budget neutrality offset amount for FY 2019:

- For each previously participating hospital that has decided to participate in the second 5 years of the 10-year extension period, the cost-based payment methodology under the demonstration began on the date immediately following the end date of its period of performance for the first 5-year extension period. In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology has been applied to the date following the end date of its period of performance for the first extension period to the date of conversion. As we finalized in the FY 2018 IPPS/LTCH PPS final rule, we are applying a specific methodology for ensuring that the budget neutrality requirement under section 410A of Public Law 108–173 is met. To reflect the costs of the demonstration for the previously participating hospitals, for their cost reporting periods starting in FYs 2015, 2016, and 2017, we will use available finalized cost reports that detail the actual costs of the demonstration for each of these fiscal years. We will then incorporate these amounts in the budget neutrality offset amount to be included in a future IPPS final rule. We expect to do this in either FY 2020 or FY 2021, based on the availability of finalized reports.
- In addition, we will include a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. For FY 2019, in this final rule, we are including the estimated costs of the demonstration for FYs 2018 and 2019 in accordance with the methodology finalized in the FY 2018 IPPS/LTCH PPS final rule.
- Similar to previous years, in order to meet the budget neutrality requirement in section 410A(c)(2) of Public Law 108–173 with respect to the second 5-year extension period, we will continue to implement the policy according to when finalized cost reports become available for each of the second 5 years of the 10-year extension period for the newly participating hospitals and for cost reporting periods starting in or after FY 2018 that occur during the second 5-year extension period for the previously participating hospitals. We will determine the difference between the actual costs of the demonstration as determined from these finalized cost reports and the estimated cost indicated in the corresponding fiscal year IPPS final rule, and include that difference either as a positive or negative adjustment in the upcoming year's final rule.

As described earlier, we have calculated this difference for FYs 2005 through 2010 between the actual costs of the demonstration, as determined

from finalized cost reports and estimated costs of the demonstration set forth in the applicable IPPS final rules for these years, and then incorporated that amount into the budget neutrality offset amount for an upcoming fiscal year. As we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20444), in this FY 2019 IPPS/LTCH PPS final rule, we are including this difference based on finalized cost reports for FYs 2011, 2012, and 2013 in the budget neutrality offset adjustment to be applied to the national IPPS rates for FY 2019. In future IPPS rules, we will continue this reconciliation, calculating the difference between actual and estimated costs for the remaining years of the first extension period (that is, FYs 2014 through 2016), and, as described above, the further years of the demonstration under the second extension period, applying this difference to the budget neutrality offset adjustments identified in future years' final rules.

(2) Methodology for the Budget Neutrality Adjustment for the Previously Participating Hospitals for FYs 2015 Through 2017

As we finalized in the FY 2018 IPPS/LTCH PPS final rule (and again described in the FY 2019 IPPS/LTCH PPS proposed rule), for each previously participating hospital, the cost-based payment methodology under the demonstration will be applied to the date immediately following the end date of its period of performance for the first 5-year extension period. We are applying the same methodology as previously finalized to account for the costs of the demonstration and ensure that the budget neutrality requirement under section 410A of Public Law 108–173 is met for the previously participating hospitals for cost reporting periods starting in FYs 2015, 2016, and 2017. We believe it is appropriate to determine such a specific methodology applicable to these cost reporting periods because they are a component of the payment methodology for the demonstration under the second extension period, authorized by section 15003 of Public Law 114–255, yet encompass the provision of services and incurred costs occurring prior to the start of FY 2018, when the terms of continuation for these hospitals under this second extension period were finalized.

To reflect the costs of the demonstration for the previously participating hospitals for their cost reporting periods under the second extension period starting before FY 2018 (that is, cost reporting periods starting in FYs 2015, 2016, and 2017), we will determine the actual costs of the demonstration for each of these fiscal years when finalized cost reports become available. Thus, for a hospital with an end date of June 30, 2015 for the first participation period, we will determine from finalized cost reports the specific amount contributing to the total costs of the demonstration for the 3 cost reporting years from July 1, 2015 through June 30, 2018; for a hospital with an end date of June 30, 2016, we will determine from finalized cost reports the amount contributing to costs of the demonstration for the 2 cost reporting periods from July 1, 2016 through June 30, 2018.

We note that, for these hospitals, this last cost report period may include services occurring since the enactment of Public Law 114–255 and also during FY 2018. However, we believe that applying a uniform method for determining costs across a cost report year would be more reasonable from the standpoint of operational feasibility and consistent application of cost determination principles. Under this approach, we will incorporate these amounts for the previously participating hospitals for cost reporting periods starting in FYs 2015, 2016, and 2017 into a single amount to be included in the calculation of the budget neutrality offset amount to the national IPPS rates in a future final rule after such finalized cost reports become available. As noted above, we expect to do this in FY 2020 or FY 2021.

(3) Methodology for Estimating Demonstration Costs for FY 2018

As discussed earlier and as we described in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20444), as a component of the overall budget neutrality methodology, we are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. As explained above, for FY 2019, we will be including the estimated costs of the demonstration for FYs 2018 and 2019.

As described in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38286) and FY 2019 IPPS/LTCH PPS proposed rule, we are incorporating a specific calculation to account for the fact that the cost reporting periods for the participating hospitals applicable to the estimate of the costs of the demonstration for FY 2018 would start at different points of time during FY 2018. That is, we are prorating estimated reasonable cost amounts and amounts that would be paid without the demonstration for FY 2018 according to the fraction of the number of months within the hospital's cost reporting period starting in FY 2018 that fall within the total number of months in the fiscal year. For example, if a hospital started its cost reporting period on January 1, 2018, we are multiplying the estimated cost and payment amounts, derived as described below, by a factor of 0.75. (In this discussion of how the overall calculations are conducted, this factor is referred to as ''the hospital-specific prorating factor.'') The methodology for calculating the amount applicable to FY 2018 to be incorporated into the budget neutrality offset amount for FY 2019 was described in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38286) and proceeds according to the following steps:

Step 1: For each of the 29 participating hospitals, we identify the reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. (For each of these hospitals, these ''as submitted'' cost reports are those with cost report period end dates in CY 2016.) We believe these most recent available cost reports to be an accurate predictor of the costs of the demonstration in FY 2018 because they give us a recent picture of the participating hospitals' costs.

For each hospital, we multiply each of these amounts by the FY 2017 and 2018 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. The result for each participating hospital would be the general estimated reasonable cost amount for covered inpatient hospital services for FY 2018.

Consistent with our methods in previous years for formulating this estimate, we apply the IPPS market basket percentage increases for FYs 2017 through 2018 to the applicable estimated reasonable cost amounts (described above) in order to model the estimated FY 2018 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2018 under applicable Medicare

payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. We then multiply each of these hospital-specific amounts (for covered inpatient hospital services including swing-bed services), by the FYs 2017 and 2018 (in accordance with the discussion above) IPPS applicable percentage increases. This methodology differs from Step 1, in which we are applying the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

We note that, in the FY 2019 IPPS/LTCH PPS proposed rule, we had applied a 3-percent volume adjustment to the estimates resulting from each of Steps 1 and 2. This increase was consistent with previous policy, and intended to reflect the possibility that hospitals' inpatient caseloads might increase. However, we stated in the proposed rule that we would evaluate the appropriateness of this increase in light of empirical trends specific to the participating hospitals. For each of the 17 previously participating hospitals, we compared the number of Medicare inpatient discharge reported on their cost reports for cost reporting years ending in 2012 and in 2016, and found an overall decline between these years of approximately 14 percent. For the 12 newly selected hospitals, we examined statistics on inpatient discharges for 2014 and 2016 reported on their applications, and found an increase between these years of approximately 1.7 percent. Considering that the overall trend reflects declining Medicare inpatient discharges, we have determined that the additional 3-percent adjustment is no longer justified and, therefore, are omitting it from these estimated amounts in this final rule.

Step 3: We subtract the amounts derived in Step 2 from the amount derived in Step 1. According to our methodology, each of these resulting amounts indicates the difference for the hospital (for covered inpatient hospital services, including swing beds), which would be the general estimated amount of the costs of the demonstration for FY 2018.

Step 4: For each hospital, we multiply the amount derived in Step 3 by the hospital-specific prorating factor. The resulting amount represents for each hospital the cost of the demonstration applicable to the cost reporting period beginning in FY 2018, on the basis of which the specific component of the budget neutrality offset amount applicable to FY 2018 is derived.

Step 5: We then sum these hospital-specific amounts derived in Step 4 across all 29 hospitals participating in the demonstration in FY 2018. This resulting sum represents the estimated costs of the demonstration applicable to FY 2018 to be incorporated in the budget neutrality offset amount for rulemaking in FY 2019.

In the FY 2019 IPPS/LTCH PPS proposed rule, the resulting amount applicable to FY 2018 was $33,254,247. We stated that this estimated amount was based on specific assumptions regarding the data sources used, and that if updated data became available prior to the FY 2019 IPPS/LTCH PPS final rule, we would use them as appropriate to estimate the costs for the demonstration program applicable to FY 2018 in accordance with our methodology for determining the budget neutrality estimate.

For this final rule, the estimated amount for the costs of the demonstration applicable to FY 2018 differs from that in the proposed rule because of the following factors, which we have identified: (1) Removing the hospital that has withdrawn; and (2) omitting the 3-percent volume adjustment. Based on these updated data, for this final rule, the resulting amount applicable to FY 2018 is $31,070,880, which we have included in the budget neutrality offset adjustment for FY 2019.

(4) Methodology for Estimating Demonstration Costs for FY 2019

As described in the FY 2019 IPPS/LTCH PPS proposed rule, we are applying two differences specific to the methodology described for FY 2018 to estimate the costs of the demonstration for FY 2019. We are using the same set of ''as submitted'' cost reports in determining preliminary cost and payment amounts for covered inpatient hospital services. However, in updating these amounts to reflect increases in cost and payment, our methodology for determining the component of the budget neutrality offset amount applicable to FY 2019 entails applying the market basket percentage increase and applicable percentage increase for FY 2019, in addition to these update factors for FYs 2017 and 2018. The finalized amounts for FY 2019 for these respective update factors are found in section IV.B. of the preamble to this final rule. Also, because we are expecting all of the participating hospitals to participate for the entire 12-month period encompassing FY 2019, there will be no application of any prorating factor in determining the estimated costs of the demonstration for FY 2019. (In addition, for the reasons described earlier, we are omitting the 3-percent volume adjustment in determining this estimate.)

For the FY 2019 IPPS/LTCH PPS proposed rule, the resulting amount for FY 2019 was $78,409,842. Similar to above, we stated that if updated data became available prior to the final rule, we would use them to the extent appropriate to estimate the costs for the demonstration program in FY 2019 in accordance with our finalized methodology. Thus, the estimated amount of the costs of the demonstration for FY 2019 included in this FY 2019 IPPS/LTCH PPS final rule differs from that in the proposed rule because of several factors: (1) We are using the finalized market basket percentage and applicable percentage increase for FY 2019; (2) we are omitting cost report data on the one hospital that withdrew from the demonstration program; and (3) similar to our earlier discussion, we are omitting the 3-percent volume adjustment for FY 2019. Based on updated data, for this FY 2019 final rule, the resulting amount for FY 2019 is $70,929,313, which we are including in the budget neutrality offset adjustment for FY 2019.

(5) Reconciling Actual and Estimated Costs for the Years of the Extension Period

Similar to previous years, as finalized in the FY 2018 IPPS/LTCH PPS final rule, we plan to operationalize the second specific component to the budget neutrality requirement. That is, when finalized cost reports become available for each of the second 5 years of the 10-year extension period for the newly participating hospitals and for cost reporting periods starting in or after FY 2018 that occur during the second 5-year extension period for the previously participating hospitals, we will calculate the difference between the actual costs of the demonstration as determined from these finalized cost reports and the estimated cost indicated in the corresponding fiscal year IPPS final rule, and include that difference either as a positive or negative

adjustment in the upcoming year's final rule.

Therefore, in keeping with the methodologies used in previous final rules, we will continue to use a methodology for calculating the budget neutrality offset amount for the second 5 years of the 10-year extension period consisting of two components: (1) The estimated demonstration costs in the upcoming fiscal year (as described earlier); and (2) the amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once finalized cost reports become available for that year) differed from the budget neutrality offset amount finalized in the corresponding year's IPPS final rule.

d. Reconciling Actual and Estimated Costs of the Demonstration for Previous Years (2011, 2012, and 2013)

As described earlier, we have calculated the difference for FYs 2005 through 2010 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57037), we finalized a proposal to reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration was scheduled to end December 31, 2016. In that final rule, we stated that we believed it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. We stated that such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration would represent an administratively streamlined method, allowing for the determination of any appropriate adjustment to the IPPS rates and obviating the need for multiple, fiscal year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we stated that we expected any such analysis would be conducted in FY 2020.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38287), with the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, we modified the plan outlined in the FY 2017 IPPS/LTCH PPS final rule, and instead returned to the general procedure in previous final rules; that is, as finalized cost reports become available, we would determine the amount by which the actual costs of the demonstration for an earlier, given year differ from the estimated costs for the demonstration set forth in the IPPS final rule for the corresponding fiscal year, and then incorporate that amount into the budget neutrality offset amount for an upcoming fiscal year. We finalized a policy that if the actual costs of the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference would be added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the final rule. Likewise, we finalized a policy that if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference would be subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for an upcoming fiscal year. However, given that this adjustment for specific years could be positive or negative, we would combine this reconciliation for multiple prior years into one adjustment to be applied to the budget neutrality offset amount for a single fiscal year, thus reducing the possibility of both positive and negative adjustments to be applied in consecutive years, and enhancing administrative feasibility. Specifically, when finalized cost reports for FYs 2011, 2012, and 2013 are available, we stated that we would include this difference for these years in the budget neutrality offset adjustment to be applied to the national IPPS rates in a future final rule. We stated that we expected that this would occur in FY 2019. We also stated that when finalized cost reports for FYs 2014 through 2016 are available, we would include the difference between the actual costs as reflected on these cost reports and the amounts included in the budget neutrality offset amounts for these fiscal years in a future final rule. We stated that we plan to provide an update in a future final rule regarding the year that we would expect that this analysis would occur.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule, we identified the differences between the total cost of the demonstration as indicated on finalized FY 2011 and 2012 cost reports and the estimates for the costs of the demonstration for the corresponding year in each of these years' final rules, and we proposed to adjust the current year's budget neutrality offset amount by the combined difference. We stated that if any information relevant to the determination of these amounts (for example, a cost report reopening) would necessitate a revision of these amounts, we would make the appropriate change and include the determination in the FY 2019 IPPS/LTCH PPS final rule. We stated, furthermore, that if the needed costs reports are available in time for the FY 2019 IPPS/LTCH PPS final rule, we also would identify the difference between the total cost of the demonstration based on finalized FY 2013 cost reports and the estimates for the costs of the demonstration for that year, and incorporate that amount into the budget neutrality offset amount for FY 2019.

As described in the FY 2019 IPPS/LTCH PPS proposed rule, finalized cost reports are available for the 16 hospitals that completed a cost reporting period beginning in FY 2011 according to the demonstration cost-based payment methodology. We note that the estimate of the costs of the demonstration for FY 2011 that was incorporated into the budget neutrality offset amount was formulated prior to the selection of hospitals under the expansion of the demonstration authorized by the Affordable Care Act. Accordingly, we based the estimate of the costs of the demonstration for FY 2011 on projected costs for 30 hospitals, the maximum number allowed by the authorizing statute in the Affordable Care Act. The actual costs of the demonstration for FY 2011 (that is, the amount from finalized cost reports for the 16 hospitals that were paid under the demonstration payment methodology for cost reporting periods with start dates during FY 2011), fell short of the estimated amount that was finalized in the FY 2011 IPPS/LTCH PPS final rule for FY 2011 by $29,971,829. We have identified no factors that require a change to this number for this FY 2019 final rule.

In addition, as also described in the FY 2019 IPPS/LTCH PPS proposed rule, finalized cost reports for the 23 demonstration hospitals that began a cost reporting period in FY 2012 are also now available. The actual costs of the demonstration as determined from these finalized cost reports fell short of the estimated amount that was finalized in the FY 2012 IPPS final rule by $8,500,373. Similarly, we have identified no factors that require a change to this number for this year's final rule.

For this final rule, finalized cost reports for the 22 hospitals that

completed a cost reporting period under the demonstration payment methodology beginning in FY 2013 are available. The actual costs of the demonstration as determined from these finalized cost reports fell short of the estimated amount that was finalized in the FY 2013 IPPS final rule by $5,398,382.

We note that the amounts identified for the actual cost of the demonstration for each of FYs 2011, 2012, and 2013 (determined from finalized cost reports) is less than the amount that was identified in the final rule for the respective year. Therefore, in keeping with previous policy finalized in situations when the costs of the demonstration fell short of the amount estimated in the corresponding year's final rule, we are including this component as a negative adjustment to the budget neutrality offset amount for the current fiscal year.

e. Total Final Budget Neutrality Offset Amount for FY 2019

For this FY 2019 IPPS/LTCH PPS final rule, we are incorporating the following components into the calculation of the total budget neutrality offset for FY 2019:

Step 1: The amount determined under section IV.L.4.c.(3) of the preamble of this final rule, representing the difference applicable to FY 2018 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration to participating hospitals for covered inpatient hospital services and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. The determination of this amount includes prorating to reflect for each participating hospital the fraction of the number of months for the cost report year starting in FY 2018 falling into the overall 12 months of the fiscal year. This estimated amount is $31,070,880.

Step 2: The amount, determined under section IV.L.4.c.(4) of the preamble of this final rule representing the corresponding difference of these estimated amounts for FY 2019. No prorating is applied in the determination of this amount. This estimated amount is $70,929,313.

Step 3: The amount determined under section IV.L.4.d. of the preamble of this final rule according to which the actual costs of the demonstration for FY 2011 for the 16 hospitals that completed a cost reporting period beginning in FY 2011 differ from the estimated amount that was incorporated into the budget neutrality offset amount for FY 2011 in the FY 2011 IPPS/LTCH PPS final rule. Analysis of this set of cost reports shows that the actual costs of the demonstration fell short of the estimated amount finalized in the FY 2011 IPPS/LTCH PPS final rule by $29,971,829.

Step 4: The amount determined under section IV.L.4.d. of the preamble of this final rule, according to which the actual costs for the demonstration for FY 2012 for the 23 hospitals that completed a cost reporting period beginning in FY 2012 differ from the estimated amount in the FY 2012 final rule. Analysis of this set of cost reports shows that the actual costs of the demonstration for FY 2012 fell short of the estimated amount finalized in the FY 2012 IPPS/LTCH PPS final rule by $8,500,373.

Step 5: The amount, also determined under section IV.L.4.d. of the preamble of this final rule, according to which the actual costs of the demonstration for FY 2013 for the 22 hospitals that completed a cost reporting period beginning in FY 2013 differ from the estimated amount in the FY 2013 final rule. Analysis of this set of cost reports shows that the actual costs of the demonstration for FY 2013 fell short of the estimated amount finalized in the FY 2013 IPPS/LTCH PPS final rule by $5,398,382.

In keeping with previously finalized policy, we are applying these differences, according to which the actual costs of the demonstration for each of FYs 2011, 2012, and 2013 fell short of the estimated amount determined in the final rule for each of these fiscal years, by reducing the budget neutrality offset amount to the national IPPS rates for FY 2019 by these amounts.

Thus, the total budget neutrality offset amount that we are applying to the national IPPS rates for FY 2019 is: The amount determined under Step 1 ($31,070,880) plus the amount determined under Step 2 ($70,929,313) minus the amount determined under Step 3 ($29,971,829) minus the amount determined under Step 4 ($8,500,373) minus the amount determined under Step 5 ($5,398,382). This total is $58,129,609.

In addition, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule, we will incorporate the actual costs of the demonstration for the previously participating hospitals for cost reporting periods starting in FYs 2015, 2016, and 2017 into a single amount to be included in the calculation of the budget neutrality offset amount to the national IPPS rates in a future final rule after such finalized cost reports become available. We expect to do this in FY 2020 or FY 2021.

In response to the FY 2019 IPPS/LTCH PPS proposed rule, we received one public comment in support of continuing the demonstration. We appreciate the commenter's support.

M. Revision of Hospital Inpatient Admission Orders Documentation Requirements Under Medicare Part A

1. Background

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68426 through 68433), we solicited public comments for potential policy changes to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between hospital admission decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50942), we adopted a set of policies widely referred to as the ''2 midnight'' payment policy. Among the finalized changes, we codified through regulations at 42 CFR 412.3 the longstanding policy that a beneficiary becomes a hospital inpatient if formally admitted pursuant to the order of a physician (or other qualified practitioner as provided in the regulations) in accordance with the hospital conditions of participation (CoPs). In addition, we required that a written inpatient admission order be present in the medical record as a specific condition of Medicare Part A payment. In response to public comments that the requirement of a written admission order as a condition of payment is duplicative and burdensome on hospitals, we responded that the physician order reflects affirmation by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary, and the ''order serves the unique purpose of initiating the inpatient admission and documenting the physician's (or other qualified practitioner as provided in the regulations) intent to admit the patient, which impacts its required timing.'' Therefore, we finalized the policy requiring a written inpatient order for all hospital admissions as a specific condition of payment. We acknowledged that in the extremely rare circumstance the order to admit is missing or defective, yet the intent, decision, and recommendation of the ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record, medical review

contractors are provided with discretion to determine that this information constructively satisfies the requirement that a written hospital inpatient admission order be present in the medical record.

2. Revisions Regarding Admission Order Documentation Requirements

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20447 and 20448), despite the discretion granted to medical reviewers to determine that admission order information derived from the medical record constructively satisfies the requirement that a written hospital inpatient admission order is present in the medical record, as we have gained experience with the policy, it has come to our attention that some medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders. Common technical discrepancies consist of missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge. We have become aware that, particularly during the case review process, these discrepancies have occasionally been the primary reason for denying Medicare payment of an individual claim. In looking to reduce unnecessary administrative burden on physicians and providers and having gained experience with the policy since it was implemented, we have concluded that if the hospital is operating in accordance with the hospital CoPs, medical reviews should primarily focus on whether the inpatient admission was medically reasonable and necessary rather than occasional inadvertent signature documentation issues unrelated to the medical necessity of the inpatient stay. It was not our intent when we finalized the admission order documentation requirements that they should by themselves lead to the denial of payment for medically reasonable and necessary inpatient stays, even if such denials occur infrequently.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20447 and 20448), we proposed to revise the admission order documentation requirements by removing the requirement that written inpatient admission orders are a specific requirement for Medicare Part A payment. Specifically, we proposed to revise the inpatient admission order policy to no longer require a written inpatient admission order to be present in the medical record as a specific condition of Medicare Part A payment. Hospitals and physicians are still required to document relevant orders in the medical record to substantiate medical necessity requirements. If other available documentation, such as the physician certification statement when required, progress notes, or the medical record as a whole, supports that all the coverage criteria (including medical necessity) are met, and the hospital is operating in accordance with the hospital conditions of participation (CoPs), we stated that we believe it is no longer necessary to also require specific documentation requirements of inpatient admission orders as a condition of Medicare Part A payment. We stated that the proposal would not change the requirement that an individual is considered an inpatient if formally admitted as an inpatient under an order for inpatient admission. While this continues to be a requirement, as indicated earlier, technical discrepancies with the documentation of inpatient admission orders have led to the denial of otherwise medically necessary inpatient admission. To reduce this unnecessary administrative burden on physicians and providers, we proposed to no longer require that the specific documentation requirements of inpatient admission orders be present in the medical record as a condition of Medicare Part A payment.

Accordingly, we proposed to revise the regulations at 42 CFR 412.3(a) to remove the language stating that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A. We note that we did not propose any changes with respect to the ''2 midnight'' payment policy.

Comment: Numerous commenters supported CMS' proposal. One commenter conveyed that there are instances where medical records clearly indicate inpatient intent but the associated claim is denied only because the inpatient admission order was missing a signature. Another commenter agreed with CMS' proposal because the requirement for an inpatient admission order to be present in the medical record is duplicative in nature. One commenter explained that alleviating this requirement will result in significant burden reduction for physicians and providers.

Response: We appreciate the commenters' support.

Comment: Some commenters were concerned that the proposal may render the inpatient admission order completely insignificant and not required for any purpose. In addition, and in further context, the commenters referenced previous CMS subregulatory guidance from January 2014 which explained that if a practitioner disagreed with the decision to admit a patient to inpatient status, the practitioner could simply refrain from authenticating the inpatient admission order and the patient would remain in outpatient status. The commenters were concerned that if CMS no longer requires a written inpatient admission order to be present in the medical record as a specific condition of Medicare Part A payment, CMS would not be able to distinguish between orders that were simply defective and orders that were intentionally not signed.

Other commenters believed that the proposal would make the payment process even more difficult, especially in instances where patients were not registered by the hospital admissions staff, did not receive the required notice of their inpatient status, and there was no valid admission order related to their visit. The commenters were concerned that these particular cases would prevent patients from being knowledgeable of their appeal rights and financial liability.

Some commenters believed that, without an inpatient admission order, Medicare coverage of SNF services would be at risk due to issues such as lack of clarity in the medical record or a MAC's misinterpretation of physician intent, and stated that denial of such needed services would negatively impact patients' health.

Response: Our proposal does not change the requirement that, for purposes of Part A payment, an individual becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission. The physician order remains a significant requirement because it reflects a determination by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary, and initiates the process for inpatient admission.

Regarding the concerns of some commenters regarding orders that were intentionally not signed because the practitioner responsible for signing disagreed with the decision to admit, it should never have been the case that the only evidence in the medical record regarding this uncommon situation was the absence of the physician's or other qualified practitioner's signature. The medical record as a whole should reflect whether there was a decision by a physician or other qualified practitioner to admit the beneficiary as an inpatient or not. This fact is precisely why, under our current guidance, we acknowledged

that in the extremely rare circumstance where the order to admit is missing or defective, yet the intent, decision, and recommendation of the ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record, medical review contractors have discretion to determine that this information constructively satisfies the requirement that a written hospital inpatient admission order be present in the medical record. We disagree with these commenters that reliance only on the absence of the signature in these uncommon situations reflected good medical documentation practice.

Regarding the commenters who were concerned that our proposal would remove the requirement for an order altogether, affecting patient appeal rights, or increase financial liability, as stated earlier, the physician order remains a requirement for purposes of reflecting a determination by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary, initiating the inpatient admission. Additionally, regardless of this proposal and other physician order requirements described earlier, the hospital CoPs include the requirement that all Medicare inpatients must receive written information about their hospital discharge appeal rights.

Comment: Commenters inquired about situations where a patient in outpatient status under observation spent two medically necessary midnights and was subsequently discharged. The commenters stated that, in these situations, providers are allowed to obtain an admission order at any time prior to formal discharge. The commenters inquired whether providers can review this stay after discharge, determine the 2-midnight benchmark was met, and submit a claim for inpatient admission.

Response: Again, the proposal would not change the requirement that, for purposes of Part A payment, an individual becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission. As noted previously, the physician order reflects the determination by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary, and initiates the inpatient admission. With respect to the question about reviewing an outpatient stay after discharge and submitting an inpatient claim for that stay, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50942) in our response to comments where we stated that ''The physician order cannot be effective retroactively. Inpatient status only applies prospectively, starting from the time the patient is formally admitted pursuant to a physician order for inpatient admission, in accordance with our current policy.''

Comment: Some commenters asked whether condition code 44 was still required to change a patient's status from inpatient to outpatient. Other commenters asked whether condition code 44 could still be used by hospitals without the presence of an inpatient admission order.

Response: We consider these comments regarding the use of condition code 44 to be outside the scope of the proposed rule because we did not make a proposal regarding changing patient status from inpatient to outpatient. Therefore, we are not responding to these comments in this final rule.

Comment: Some commenters wanted to know how the proposed policy changes the process for moving a patient from observation status to inpatient status and the timing of inpatient billing related to this process. Some commenters stated that the proposed policy change appears to suggest that the completion of admission orders would now be optional and other available documentation could be used to create retroactive orders.

Response: As stated earlier, the proposal does not change the requirement that, for purposes of Part A payment, an individual becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission. In addition, this proposal does not change the fact that hospitals are required to operate in accordance with appropriate CoPs.

Regarding the comment about retroactive orders, it has been and continues to be longstanding Medicare policy to not permit retroactive orders. The order must be furnished at or before the time of the inpatient admission. The order can be written in advance of the formal admission (for example, for a prescheduled surgery), but the inpatient admission does not occur until hospital services are provided to the beneficiary.

Comment: Commenters also discussed how the proposed policy may affect procedures on the inpatient only list. Specifically, the commenters wanted to know how this policy proposal applies to patients who receive procedures on the inpatient only list when the patient is an outpatient. In instances when a patient's status changes to inpatient prior to an inpatient order being placed, the commenters questioned whether hospitals would be able to determine the inpatient only procedure was performed and submit a bill for Medicare Part A payment.

Response: The proposed revision does not include revisions to the policy for processing payment for inpatient only list procedures. As noted previously, our proposal does not change the requirement that, for purposes of Part A payment, an individual becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission. The physician order remains a significant requirement because it reflects a determination by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary, and initiates the process for inpatient admission. We did not understand the comment regarding a patient's status changing prior to an order being placed. Therefore, we are unable to specifically respond to that comment.

Comment: Commenters inquired if the proposal would change the requirements regarding which practitioners are allowed to furnish inpatient admission orders.

Response: The proposed revision relating to hospital inpatient admission order documentation requirements under Medicare Part A does not include revisions to the requirements regarding which practitioners are allowed furnish inpatient admission orders.

Comment: A number of commenters had specific questions regarding technical discrepancies. Specifically, the commenters wanted to know if CMS will be publishing a list of acceptable and unacceptable technical discrepancies considered by medical review contractors for the purposes of approving or denying Medicare Part A payment for inpatient admissions. In addition, the commenters wanted to know if CMS will require a specific error rate for compliance with inpatient physician orders, such as for provider technical errors that may be deemed excessive or unacceptable. The commenters also inquired whether providers will be required to document in the medical record whether technical discrepancies occurred in order for Medicare Part A payment to be considered. For example, the commenters wanted to know if an inpatient order for a medically necessary inpatient admission is not signed prior to the patient's discharge, will the facility need to document why the technical discrepancy occurred.

Response: We have not considered developing a list of acceptable or unacceptable technical discrepancies nor have we considered requiring a technical discrepancy error rate.

In regards to the comment regarding whether this proposed policy would require documentation of how a technical discrepancy occurred, we refer readers to the following subregulatory guidance from the Medicare Benefits Policy Manual (MBPM), Chapter 1, Section 10.2.: ''The order to admit may be missing or defective (that is, illegible, or incomplete, for example 'inpatient' is not specified), yet the intent, decision, and recommendation of the ordering practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record. In these situations, contractors have been provided with discretion to determine that this information provides acceptable evidence to support the hospital inpatient admission. However, there can be no uncertainty regarding the intent, decision, and recommendation by the ordering practitioner to admit the beneficiary as an inpatient, and no reasonable possibility that the care could have been adequately provided in an outpatient setting.'' This guidance will remain in effect after this rule is finalized.

Comment: Some commenters recommended that CMS change the audit requirements for contractors so that claims are not denied solely on technical issues found in the inpatient admission order. The commenters also suggested that CMS amend its Medicare Manual to clarify if an inpatient admission order is deemed defective.

Response: We thank the commenters for their recommendations and suggestions. In carrying out their work, medical review contractors are required to follow CMS regulations and policy guidance. If necessary, we may revise our manuals and/or issue additional subregulatory guidance as appropriate with respect to the finalized regulation.

Comment: Some commenters submitted information to demonstrate that CMS had indeed at one point intended to require orders and deny payment based on the absence of orders. As such, the commenters indicated that CMS' FY 2019 proposed policy would institute a change in language that may confuse hospitals due to lack of clarity. The commenters stated that any change should be accompanied with further changes to relevant CoPs and codified through provider education mechanisms.

The commenters stated that because of perceived uncertainty and lack of clarity in comparing previous CMS guidance and rulemaking language to the language in the policy proposal, providers are going to need assistance in how to proceed in determining how to document inpatient admission orders and ensure proper processing of Medicare Part A payment. The commenters requested that the proposed policy be incorporated into hospital's post-discharge review in addition to the audits performed by Medicare contractors.

In addition, commenters believed that the 2-midnight rule amended the Medicare CoPs to require an inpatient admission order. The commenters explained that if CMS proceeds with its proposal, the Agency would have to revise the CoPs to clarify that an order is no longer a condition for Medicare Part A payment.

Response: In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50942), we adopted a set of policies widely referred to as the ''2-midnight'' payment policy, as well as codified the requirement that a physician order for inpatient admission was a specific condition for Part A payment. In that rulemaking, we acknowledged that, in the extremely rare circumstance that the order to admit is missing or defective, yet the intent, decision, and recommendation of the ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record, medical review contractors are provided with discretion to determine that this information constructively satisfies the requirement that a written hospital inpatient admission order be present in the medical record.

However, as we have gained experience with the policy, it has come to our attention that, despite the discretion granted to medical reviewers to determine that admission order information derived from the medical record constructively satisfies the requirement that a written hospital inpatient admission order is present in the medical record, some medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders. Particularly during the case review process, these discrepancies have occasionally been the primary reason for denying Medicare payment of an individual claim. We note that when we finalized the admission order documentation requirements in past rulemaking and guidance, it was not our intent that admission order documentation requirements should, by themselves, lead to the denial of payment for medically reasonable and necessary inpatient stay, even if such denials occur infrequently. It is our intention that this revised policy will properly adjust the focus of the medical review process towards determining whether an inpatient stay was medically reasonable and necessary and intended by the admitting physician rather than towards occasional inadvertent signature or documentation issues unrelated to the medical necessity of the inpatient stay or the intent of the physician.

Regarding whether CMS would also need to make revisions to the CoPs in order to support this finalized revised regulation, we note that CMS did not make any amendments to the CoPs when we adopted the 2-midnight payment policy or our current inpatient admission order policy; therefore, there is no need to revise the CoPs as a result of the regulatory change we are now finalizing.

Comment: Commenters also asked if the proposal includes any changes to physician certification policy or regulations and whether physician certification will still be required to support payment for an inpatient Medicare Part A claim. Commenters believed CMS' preamble language that ''(i)f other available documentation, such as the physician certification statement when required, progress notes, or the medical record as a whole . . .'' implied that physician certification statements were not always required.

Response: The proposed revision of hospital inpatient admission orders documentation requirements under Medicare Part A did not include any changes to physician certification requirements. Not all types of covered services provided to Medicare beneficiaries require physician certification. Physician certification of inpatient services is required for cases that are 20 inpatient days or more (long-stay cases), for outlier cases of hospitals other than inpatient psychiatric facilities, and for cases of CAHs. We refer readers also to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66997), and 42 CFR part 412, subpart F, 42 CFR 424.13, and 42 CFR 424.15.

Comment: Commenters wanted to know if the proposed revision of hospital inpatient admission orders documentation requirements under Medicare Part A has an effective date or whether the guidance will be retroactive.

Response: The proposed revision of hospital inpatient admission orders documentation requirements under Medicare Part A will be effective for dates of admission occurring on or after October 1, 2018. Previous guidance in our manual regarding constructive satisfaction of hospital inpatient admission order requirements still applies to dates of admission before

October 1, 2018, and will continue to apply after the effective date of this final rule.

Comment: Commenters were concerned that the proposal to revise 42 CFR 412.3(a) to remove the language stating that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A, will not reduce the administrative burden to providers. The commenters expressed that inpatient admissions will still be denied based solely on timeliness or completion of the attending physician's order and that other Medicare regulations will be referenced as the source of denial.

Response: We will continue to stay engaged with medical review contractors, as we have historically, so that there is awareness and understanding of this revision. As indicated earlier, if necessary, we may revise our manuals and/or issue additional subregulatory guidance as needed.

Comment: Commenters also suggested alternative options to address CMS' concerns regarding hospital inpatient admission order documentation requirements under Medicare Part A, including policy proposals that would substantively change the 2-midnight rule.

Response: We did not propose changes to the 2-midnight rule with this proposal to revise hospital inpatient admission orders documentation requirements. However, we will continue to monitor this policy and may propose additional changes in future rulemaking, or issue further clarifications in subregulatory guidance, as necessary.

Comment: Some commenters believed that removing the hospital inpatient admission order documentation requirement will have negative effects on both the cost and quality of care by losing the assurance that a qualified physician has close involvement in the decision to admit the patient, that they are involved early in the patients care, and that admitting physicians are free from postdischarge financial pressures from the hospital.

Response: We refer readers to our impact discussion regarding this proposal in Appendix A—Economic Analyses, Section I.H.10. of the preamble of this final rule where we state, ''our actuaries estimate that any increase in Medicare payments due to the change will be negligible, given the anticipated low volume of claims that will be payable under this policy that would not have been paid under the current policy.'' Furthermore and as stated earlier, this policy proposal would not change the requirement that a beneficiary becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission (nor that the documentation must still otherwise meet medical necessity and coverage criteria); only that the documentation requirement for inpatient orders to be present in the medical record will no longer be a specific condition of Part A payment.

Comment: Some commenters expressed concern that the proposal to revise the inpatient admission order policy presents a problem for the capture of specific data elements necessary for compliance with electronic clinical quality measures.

Response: As indicated earlier, this proposal would not change the requirement that an individual is considered an inpatient if formally admitted as an inpatient under an order for inpatient admission. The physician order reflects affirmation by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary, and serves the purpose of initiating the inpatient admission and documenting the physician's (or other qualified practitioner's, as provided in the regulations) intent to admit the patient. Accordingly, inpatient admission order documentation information should continue to be available in electronic health records.

Comment: Commenters pointed out that this policy proposal only applies to the inpatient prospective payment system and that to encourage consistency across payment systems and reduce documentation burden, CMS should make the same change to documentation requirements at other sites where there will be an inpatient admission, such as in psychiatry and rehabilitation. The commenters acknowledged that this will require rulemaking and encourages CMS to make these changes as soon as possible.

Response: We appreciate the recommendations made by the commenters and will take these comments into consideration in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to revise the inpatient admission order policy to no longer require a written inpatient admission order to be present in the medical record as a specific condition of Medicare Part A payment. Specifically, we are finalizing our proposal to revise the regulation at 42 CFR 412.3(a) to remove the language stating that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.

V. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that

qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Annual Update for FY 2019

The final annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2019 is discussed in section III. of the Addendum to this FY 2019 IPPS/LTCH PPS final rule.

In section II.D. of the preamble of this FY 2019 IPPS/LTCH PPS final rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we proposed and are finalizing for FY 2019, in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not making a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

VI. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2019

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FYs 2014 and 2015 IPPS/LTCH PPS final rules (78 FR 50747 through 50748 and 79 FR 50156 through 50157, respectively), we adopted a policy of using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2014 and subsequent fiscal years for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. However, in the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent years. Accordingly, for FY 2019, the rate-of-increase percentage to be applied to the target amount for these hospitals is the FY 2019 percentage increase in the 2014-based IPPS operating market basket.

For the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20449), based on IGI's 2017 fourth quarter forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2019 would be 2.8 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, we stated in the proposed rule that the FY 2019 rate-of-increase percentage that would be applied to the FY 2018 target amounts in order to calculate the FY 2019 target amounts for children's hospitals, cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be 2.8 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we indicated in the proposed rule that if more recent data became available for the final rule, we would use them to calculate the final IPPS operating market basket update for FY 2019. For this FY 2019 IPPS/LTCH PPS final rule, based on IGI's 2018 second quarter forecast (which is the most recent data available), we calculated the 2014-based IPPS operating market basket update for FY 2019 to be 2.9 percent. Therefore, the FY 2019 rate-of-increase percentage that is applied to the FY 2018 target amounts in order to calculate the FY 2019 target amounts for children's hospitals, cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.9 percent, in accordance with the applicable regulations at 42 CFR 413.40.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under section 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2019, in accordance with § 412.22(i) and § 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2019, the update to the target amount for long-term care neoplastic disease hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2019, which would be equal to the percentage increase in the hospital market basket index, which, in the proposed rule, was estimated to be the percentage increase in the 2014-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, for the FY 2019 proposed rule, the update to an extended neoplastic disease care hospital's target amount for FY 2019 was 2.8 percent, which was based on IGI's 2017 fourth quarter forecast. Furthermore, we proposed that if more recent data became available for the final rule, we would use that updated data to calculate the IPPS operating market basket update for FY 2019. For this final rule, based on IGI's second quarter 2018 forecast (which is the most recent data available), the update to an extended neoplastic disease care hospital's target amount for FY 2019 is 2.9 percent.

We did not receive any public comments in response to these proposals. Therefore, we are finalizing them as proposed.

B. Changes to Regulations Governing Satellite Facilities

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294), we finalized a change to our hospital-within-hospital (HwH) regulations at 42 CFR 412.22(e) to only require, as of October 1, 2017, that IPPS-excluded HwHs that are co-located with IPPS hospitals comply with the separateness and control requirements in those regulations. We adopted this change because we believe that the policy concerns that underlay the previous HwH regulations (that is, inappropriate patient shifting and hospitals acting as illegal de facto units) are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other, in large part due to changes that have been made to the way most types of IPPS-excluded hospitals are paid under Medicare. In response to our proposal on this issue, we received some public comments requesting that CMS make analogous changes to the rules governing satellite facilities, and we responded in the FY 2018 IPPS/LTCH PPS final rule that we would take that request under consideration for future rulemaking.

Under 42 CFR 412.22(h), a satellite facility is defined as part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

There are significant similarities between the definition of a satellite facility and the definition of an HwH as those definitions relate to their co-location with host hospitals. Our policies on satellite facilities have also been premised on many of the same concerns that formed the basis for our HwH policies. That is, the separateness and control policies for satellite facilities at 42 CFR 412.22(h) were aimed at mitigating our concern that the co-location of a satellite facility and a host hospital raised a potential for inappropriate patient shifting that we believed could be guided more by attempts to maximize Medicare reimbursements than by patient welfare (71 FR 48107). However, just as changes to the way most types of IPPS-excluded hospitals are paid under Medicare have sufficiently moderated this concern in situations where IPPS-excluded hospitals are co-located with each other, we believe that these payment changes also sufficiently moderate these concerns in situations where IPPS-excluded satellite facilities are co-located with IPPS-excluded host hospitals. Furthermore, we believe that there is no compelling policy rationale for treating satellite facilities and HwHs differently on the issue of separateness and control because there is no meaningful distinction between these types of facilities that would justify a satellite facility having to comply with separateness and control requirements in a situation in which an HwH would not be required to comply (we note that the separateness and control requirements for satellite facilities are not the same as those for HwHs; however, they are similar). Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20450 and 20451), we proposed to revise our regulations at

§ 412.22(h)(2)(iii)(A) to only require IPPS-excluded satellite facilities that are co-located with IPPS hospitals to comply with the separateness and control requirements. Specifically, we proposed to add a new paragraph (*4*) to § 412.22(h)(2)(iii)(A) to specify that, effective on or after October 1, 2018, a satellite facility that is part of an IPPS-excluded hospital that provides inpatient services in a building also used by an IPPS-excluded hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS-excluded hospital, is not required to meet the criteria in § 412.22(h)(2)(iii)(A)(*1*) through (*3*) in order to be excluded from the IPPS. We stated that proposed new § 412.22(h)(2)(iii)(A)(*4*) would also specify that a satellite facility that is part of an IPPS-excluded hospital which is located in a building also used by an IPPS hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS hospital, is still required to meet the criteria in § 412.22 (h)(2)(iii)(A)(*1*) through (*3*) in order to be excluded from the IPPS.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20451), we also proposed that, for cost reporting periods beginning on or after October 1, 2019, an IPPS-excluded hospital would no longer be precluded from having an excluded psychiatric and/or rehabilitation unit. Consistent with our proposed changes to the regulations governing satellite facilities discussed earlier, we also proposed to add new paragraph (iv) to § 412.25(e)(2) to specify that an IPPS-excluded satellite facility of an IPPS-excluded unit of an IPPS-excluded hospital would not have to comply with the separateness and control requirements so long as the satellite of the excluded unit is not co-located with an IPPS hospital, and to make conforming revisions to § 412.25(e)(2)(iii)(A) to subject that provision to paragraph (iv), which we are finalizing without modification after consideration of public comments, as discussed in section VI.C. of the preamble of this final rule.

In the FY 2019 IPPS/LTCH PPS proposed rule, we stated that it is important to point out that payment rules, such as the HwH or satellite facility rules, never waive or supersede the requirement that all hospitals must comply with the hospital conditions of participation (CoPs). All hospitals, regardless of payment status, must always demonstrate separate and independent compliance with the hospital CoPs, even when an entire hospital or a part of a hospital is located in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. We further noted that the proposal would not affect IPPS-excluded satellite facilities that are co-located with IPPS hospitals that are currently grandfathered under § 412.22(h)(2)(iii)(A)(*2*). Those satellite facilities would continue to maintain their IPPS-excluded status without complying with the separateness and control requirements so long as all applicable requirements at § 412.22(h) are met.

Comment: Several commenters supported CMS' proposals. Some commenters requested that CMS expand the scope of the proposal and exempt IPPS-excluded satellite facilities that are not co-located with IPPS hospitals from all separateness and control requirements in § 412.22(h)(2), not just those requirements at § 412.22(h)(2)(iii)(A)(*1*) through (*3*).

Response: We appreciate the commenters' support of our proposals. We have reviewed the remaining requirements in § 412.22(h)(2) and do not believe that it is appropriate to expand our proposals to excuse compliance with those requirements for IPPS-excluded satellite facilities that are not co-located with IPPS hospitals. For example, the commenter requested that satellite facilities be exempted from the requirement that they comply with the applicable payment rules which form the basis of their exclusion from the IPPS. We believe that such an exclusion fundamentally undermines the Medicare program and would advantage satellite facilities beyond any other hospital type. In addition, we believe that such an expanded proposal would advantage satellite facilities over HwHs (meaning that satellite facilities would be exempt from separateness and control requirements in situations in which an HwH would not be), and this directly contradicts our goal of bringing satellite facilities and HwH regulations into alignment.

We note that, in response to the proposed rule, several commenters addressed issues relating to HwHs and satellite facilities that were outside the scope of the proposals in the proposed rule related to the CoPs and our existing regulations concerning HwHs. We are not addressing those comments in this final rule. However, we may take them into consideration for future rulemaking.

After consideration of the public comments received, we are finalizing our proposals without modification. Specifically, we are adding a new paragraph (*4*) to § 412.22(h)(2)(iii)(A) to specify that, effective on or after October 1, 2018, a satellite facility that is part of an IPPS-excluded hospital that provides inpatient services in a building also used by an IPPS-excluded hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS-excluded hospital, is not required to meet the criteria in § 412.22(h)(2)(iii)(A)(*1*) through (*3*) in order to be excluded from the IPPS. New § 412.22(h)(2)(iii)(A)(*4*) specifies that a satellite facility that is part of an IPPS-excluded hospital which is located in a building also used by an IPPS hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS hospital, is still required to meet the criteria in § 412.22 (h)(2)(iii)(A)(*1*) through (*3*) in order to be excluded from the IPPS.

C. Changes to Regulations Governing Excluded Units of Hospitals

Under existing regulations at 42 CFR 412.25, an excluded psychiatric or rehabilitation unit cannot be part of an institution that is excluded in its entirety from the IPPS. These regulations were codified in the FY 1994 IPPS final rule (58 FR 46318). However, as we explained in that rule, while this prohibition was not explicitly stated in the regulations until that time, the prohibition had been our longstanding policy. This policy was adopted at that time because it would have been redundant to allow an IPPS-excluded hospital to have an IPPS-excluded unit because both the hospital and the unit would have been paid under the same Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) payment system methodology, described in section VI.A. of this final rule. In addition, we were concerned about the possibility of IPPS-excluded hospitals artificially inflating their target amounts by operating IPPS-excluded units (58 FR 46318).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294), we finalized a change to the HwH regulations to only require, as of October 1, 2017, that IPPS-excluded HwHs that are co-located with IPPS hospitals comply with the separateness and control requirements in those regulations. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20451), we proposed to make similar changes to the regulations governing satellite facilities, which would allow these facilities, including satellite facilities of hospital units, to maintain their IPPS-excluded status without complying with the separateness and control requirements so long as they are not co-located with an IPPS hospital. In conjunction with

the HwH regulation changes and the proposed satellite facilities regulation changes, and as part of our continued efforts to reduce regulatory burden and achieve program simplification, we stated that we believe it is appropriate to propose changes to our regulations for the establishment of IPPS-excluded units in IPPS-excluded hospitals. Given the introduction of prospective payment systems for both inpatient rehabilitation facilities and units (collectively IRFs) and psychiatric hospitals and units (collectively IPFs), we indicated that we no longer believe it is redundant for an IPPS-excluded hospital to have an IPPS-excluded unit, nor is it possible for IPPS-excluded hospitals to use units to artificially inflate their target amounts, because Medicare payment for discharges from the units would not be based on reasonable cost. For example, under our proposal, an LTCH operating a psychiatric unit would receive payment under the IPF PPS for discharges from the psychiatric unit and payment under the LTCH PPS for discharges not from the psychiatric unit. Payment for discharges from the psychiatric unit would be made under the IPF PPS rather than the LTCH PPS because Medicare pays for services provided by an excluded hospital unit under a separate payment system from the hospital in which the unit is a part. For the purposes of payment, services furnished by a unit are considered to be inpatient hospital services provided by the unit and not inpatient hospital services provided by the hospital operating the unit.

In the FY 2019 IPPS/LTCH PPS proposed rule, we proposed to revise § 412.25(a)(1)(ii) to specify that the requirement that an excluded psychiatric or rehabilitation unit cannot be part of an IPPS-excluded hospital is only effective through cost reporting periods beginning on or before September 30, 2019. Under the proposal, effective with cost reporting periods beginning on or after October 1, 2019, an IPPS-excluded hospital would be permitted to have an excluded psychiatric and/or rehabilitation unit. In addition, we proposed to revise § 412.25(d) to specify that an IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital (for example, an IRF may not have an IRF unit). We stated that we believe that this proposed change would be consistent with the current preclusion in § 412.25(d) that prevents one hospital from having more than one of the same type of IPPS-excluded unit. However, we noted that if these proposed changes to the payment rules are finalized, an IPPS-excluded hospital operating an IPPS-excluded unit must continue to be in compliance with other Medicare regulations and CoPs applicable to the hospital or unit. An IPPS-excluded unit within a hospital is part of the hospital. Noncompliance with any of the hospital CoPs at 42 CFR 482.1 through 482.58 at any part of a certified hospital is noncompliance for the entire Medicare-certified hospital. Therefore, noncompliance with the hospital CoPs in an IPPS excluded unit is CoP noncompliance for the entire certified hospital. For example, the CoPs that govern IPFs would apply to an IPF that operates an excluded rehabilitation unit, and those CoPs require that certain psychiatric treatment protocols apply to every IPF patient (including those in the rehabilitation unit).

We proposed that cost reporting periods beginning on or after October 1, 2019 would be the effective date of these changes to allow sufficient time for both CMS and IPPS-excluded hospitals to make the necessary administrative and operational changes to fully implement the proposed changes. We stated that we believed this proposed effective date would, to the best of our ability, ensure that these units can begin to operate without unnecessary administrative issues and delays.

Comment: Several commenters supported CMS' proposals to allow IPPS-excluded hospitals to operate IPPS-excluded units and to make the proposed change effective for cost reporting periods beginning on or after October 1, 2019. However, some of these commenters requested that CMS not delay the effective date until FY 2020 as proposed.

Response: We appreciate the commenters' support. While we appreciate that providers may wish to begin operating units as soon as possible, we believe that making the change effective for cost reporting periods beginning in FY 2019 is operationally not feasible, given the administrative and operational changes that must be made in order to fully implement this policy while minimizing unintended consequences of these changes. Therefore, we are not changing the effective date of this policy change to make it earlier than FY 2020 as requested by the commenters.

Comment: Some commenters objected to CMS' proposal to allow IPPS-excluded hospitals to operate IPPS-excluded units. Specifically, these commenters objected to the fact that, if the proposal is finalized, an LTCH would be allowed to operate an IRF unit but an IRF would not be allowed to operate a ''long-term care unit'' and contended that this result is unfair. Some of these commenters also expressed concern about the effect of these proposals on patient care and believed that the proposed change is inconsistent with the hospital CoPs, which do not allow co-located hospitals to jointly meet the CoPs. Other commenters argued that CMS did not sufficiently explain the proposal in the proposed rule or CMS should have made other regulatory text changes, such as allowing long-term care units. Some commenters requested that CMS withdraw the proposal and provide more outreach activities or implement small-scale models prior to making a regulatory change.

Response: We believe the commenters may have misunderstood the crux of our proposal. Our proposal was not merely ''to allow LTCHs to operate rehabilitation units.'' Rather, under our proposal, all types of IPPS-excluded hospitals (including both LTCHs and IRFs) would be able to operate all types of IPPS-excluded units (rehabilitation and psychiatric) so long as such a unit would not be in a hospital of the same type. While one of the possible outcome of this proposal would be an LTCH operating an IRF unit, the reason an IRF could not operate a distinct part long-term care unit (which would be paid under the LTCH PPS) is because the Act does not allow for long-term care units (as we have stated on numerous occasions and some commenters acknowledged). However, we point out that, under our proposal, an IRF would be allowed to operate a psychiatric unit and a psychiatric hospital would also be allowed to operate a rehabilitation unit, as long as applicable CoPs are met.

While we appreciate the concern expressed by some commenters relating to the care accessible to Medicare beneficiaries, we disagree that such concerns are valid or germane to our proposed revisions. As discussed in more detail earlier, the reason why we prohibited IPPS-excluded hospitals from operating IPPS-excluded units was because we were concerned that the IPPS-excluded hospital could artificially manipulate its TEFRA ceiling. As we also discussed in more detail earlier, that concern is no longer valid, given reforms in payment systems for IPPS-excluded hospitals. Therefore, we believe it is appropriate to retire a policy that no longer serves its purpose. In addition, while the commenters stated their concern, they did not provide data or information to indicate that the proposed change would adversely affect patients nor did they

indicate what data or information should be used in any analysis. We also note that our proposal would not impact the ability of an LTCH to offer rehabilitation services (which they currently can offer and are paid under the LTCH PPS) and that, under our proposal, IPPS hospitals can continue to operate IRF units. Similarly, in response to the commenters' request for additional outreach activities or small-scale models, it is unclear from the comments what purpose these outreach activities or small-scale models would serve (aside from delaying the implementation of the policy). Based on the number and variety of comments in response to our proposals, we believe our proposals and rationale for our proposals as presented in the proposed rule provided sufficient information for stakeholders to opine on the issue. In particular, it is not clear to us what the commenters found insufficient, and we reiterate the previously referenced discussion from the proposed rule in which we discuss that the underlying concern for the prohibition on IPPS-excluded hospitals from operating IPPS-excluded units was based on payment concerns that are no longer valid, given the reforms to payment systems between when CMS adopted the policy and now. For these reasons, we are not withdrawing our proposal as the commenters requested.

With respect to the comment that the proposed changes are inconsistent with the hospital CoPs, as we stated earlier, our proposal to allow IPPS-excluded hospitals to operate IPPS-excluded units is a payment rule, which cannot supersede the hospital CoPs. We believe that our proposal is consistent with the CoPs as well as with the finalized changes to the separateness and control rules for HwHs and satellite facilities discussed in section VI.B. of the preamble of this final rule.

We note that, in response to the proposed rule, some commenters requested other changes in light of our proposals—for example, changing the hospital CoPs to allow additional integration between co-located hospitals—that were outside the scope of the provisions in the proposed rule. While we are not addressing those comments in this final rule, we will take these suggestions into consideration for possible future rulemaking.

Comment: Some commenters requested clarification regarding whether patients in units would be included in the calculation of an LTCH's average length of stay at § 412.23(e)(3). Some of these commenters believed that it was implied in our proposal that they would not be included.

Response: We are clarifying that the days that patients stay in psychiatric and rehabilitation units would be excluded from the calculation of an LTCH's average length of stay. Specifically, as LTCH patients with a principal diagnosis relating to a psychiatric or rehabilitation diagnosis must be paid under the site neutral rate, and as those LTCH patients site neutral days are not counted toward a facility's average length of stay calculation, we believe that excluding psychiatric and rehabilitation unit days from the calculation of the LTCH's average length of stay is the most appropriate policy. Furthermore, under policies discussed and finalized earlier, patients in IPPS-excluded units in an LTCH will not be paid under the LTCH PPS. In other instances in which an LTCH patient is not paid at an LTCH rate, such as patients under a Medicare Advantage plan, those patients are excluded from the average length of stay calculation. Therefore, we believe that treating unit patients similar to Medicare Advantage plan patients would ensure consistency in the program. As such, in this final rule, we are revising § 412.23(e)(3) by adding a new paragraph (vii) that specifies that, for cost reporting periods beginning on or after October 1, 2019, the Medicare inpatient days from patients treated in an IPPS-excluded unit will not be included in the Medicare average length of stay calculation.

Comment: Some commenters requested that CMS make a conforming change to § 412.25(a)(1)(iii) of the regulations in order to implement the proposals.

Response: Upon review of our proposals, we agree with the commenters that we should make a conforming change to the basis for exclusion requirements for IPPS-excluded units in § 412.25(a)(1)(iii), without which an IPPS-excluded unit would not be able to be co-located with an IPPS-excluded hospital, despite finalizing our proposal. Therefore, in finalizing changes to the regulations for IPPS-excluded units, we also are making a conforming change to § 412.25(a)(1)(iii) to avoid an inadvertent contradiction. Specifically, we are replacing the phrase ''beds that are not excluded from the inpatient prospective payment system'' currently in the regulations with the phrase ''beds that are paid under the applicable payment system under which the hospital is paid.''

We received several public comments that addressed issues related to services provided in excluded units that were outside the scope of the provisions of the proposed rule. We are not addressing those comments in this final rule but may take them under consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing our changes to § 412.25(a)(1)(ii) as proposed without modification, making a conforming change to § 412.25(a)(1)(iii) by replacing the phrase ''beds that are not excluded from the inpatient prospective payment system'' with the phrase ''beds that are paid under the applicable payment system under which the hospital is paid'', as described earlier in our response to comments, revising § 412.25(d) to specify that an IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital, and revising § 412.23(e)(3) to specify that discharges from IPPS-excluded units will not be included in the calculation of an LTCH's average length of stay.

D. Report on Adjustment (Exception) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we

are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2017.

The table below includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2017. As indicated above, the adjustments made during FY 2017 only pertain to cost reporting periods ending in years prior to FY 2017. Total adjustment payments made to excluded hospitals during FY 2017 are $8,811,316. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of hospital	Number	Excess cost over ceiling	Adjustment payments
Children's Hospitals	1	$600,616	$336,553
Cancer Hospitals	1	13,057,016	8,025,996
Religious Nonmedical Health Care Institution (RNHCI)	1	411,854	184,816
Psychiatric Unit	2	6,126,163	263,951
Total	.....	.....	8,811,316

E. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

As discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20451 through 20453), section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorizes a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration is titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and is commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute states the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulates several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limits participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 requires the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 requires that the demonstration be budget neutral. Specifically, this provision states that in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 states that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, CMS released a request for applications (RFA) for the FCHIP demonstration. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and, in addition, to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the MHRFP. The RFA identified four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, ambulance services, and home health services, and an increase in the number of swing beds available to furnish skilled nursing facility/nursing facility services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Ten CAHs were selected for participation in the demonstration, which started on August 1, 2016. These CAHs are located in Montana, Nevada, and North Dakota, and they are participating in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065) and FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296). Eight CAHs are participating in the telehealth intervention, three CAHs are participating in the skilled nursing facility/nursing facility bed intervention, and two CAHs are participating in the ambulance services intervention. Each CAH is allowed to participate in more than one of the interventions. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention included in the RFA.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065) and FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), we finalized a policy to address the budget neutrality requirement for the demonstration. As explained in the FY 2018 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is,

the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration and uncertainty associated with projected Medicare utilization and costs, we adopted a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we will comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. As we estimated for the FY 2019 IPPS/LTCH PPS proposed rule, for this FY 2019 IPPS/LTCH PPS final rule, we estimate that the total impact of the payment recoupment will be no greater than 0.03 percent of CAHs' total Medicare payments within one fiscal year (that is, Medicare Part A and Part B). The final budget neutrality estimates for the FCHIP demonstration will be based on the demonstration period, which is August 1, 2016 through July 31, 2019.

The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. As stated in the FY 2018 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020. The 3-year period for recoupment will allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs' operations. Therefore, because any reduction to CAH payments in order to recoup excess costs under the demonstration will not begin until CY 2020, this policy will have no impact for any national payment system for FY 2019.

We did not receive any public comments on our discussion of the FCHIP demonstration in the FY 2019 IPPS/LTCH PPS proposed rule.

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2019

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act (''subclause II'' LTCHs) also provided an alternative definition of LTCHs. However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals''), to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-

specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this final rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS:

- Section 15004(a), which changed the moratorium on increasing the number of beds in existing LTCHs and LTCH satellite facilities. However, we note that this moratorium expired effective October 1, 2017.
- Section 15004(b), which specifies that, beginning in FY 2018, the estimated aggregate amount of HCO payments in a given year is equal to 99.6875 percent of the 8 percent estimated aggregate payments for standard Federal payment rate cases (that is, 7.975 percent) while requiring that we adjust the standard Federal payment rate each year to ensure budget neutrality for HCO payments as if estimated aggregate HCO payments made for standard Federal payment rate discharges remained at 8 percent as done through our previous regulatory requirement. (We note these provisions do not apply with respect to the computation of the applicable site neutral payment rate under section 1886(m)(6) of the Act.)
- Section 15006, which amended sections 114(c)(1)(A) and (c)(2) of the MMSEA, which provided a statutory extension on the moratoria on the full implementation of the 25-percent threshold policy on LTCH PPS discharges for LTCHs governed under § 412.534, § 412.536, and § 412.538 based on the LTCH's cost reporting period beginning dates. In addition to the statutory moratorium, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38318 through 38320), we also implemented a 1-year regulatory delay on the full implementation of the 25-percent threshold policy under § 412.538.
- Section 15007, which extends the exclusion of Medicare Advantage plans' and site neutral payment rate discharges from the calculation of the average length of stay for all LTCHs, for discharges occurring in any cost reporting period beginning on or after October 1, 2015.
- Section 15008, which changed the classification of certain hospitals. Specifically, section 15008 of Public Law 114–255 provided for the change in Medicare classification for ''subclause (II)'' LTCHs by redesignating such hospitals from section 1886(d)(1)(B)(iv)(II) of the Act to section 1886(d)(1)(B)(vi) of the Act, which is described earlier.
- Section 15009, which provides for a temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals for discharges occurring in cost reporting periods beginning during FY 2018 and 2019 for LTCHs that meet specified statutory criteria to be excepted from the site neutral payment rate.
- Section 15010, which created a new temporary exception to the site neutral payment rate for certain severe wound discharges from certain LTCHs during such LTCHs' cost reporting periods beginning during FY 2018.

As we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20465), we are making conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018, Public Law 115–123, which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C of the preamble of this final rule for a discussion of our final policy.

We received several public comments that addressed issues that were outside the scope of the FY 2019 proposed rule. Therefore we are not responding to them in this final rule. We may take these public comments under consideration in future rulemaking.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148 (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (§ 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH is currently also permitted to charge the beneficiary for services delivered on those uncovered days (§ 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed on beneficiaries whose discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, payment for discharges occurring in cost reporting periods beginning in FY 2016 or 2017) are considered to be site neutral payment rate payments.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2019

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 757 MS–DRG groupings. For FY 2019, there are 761 MS–DRG groupings based on the changes, as discussed in section II.F. of the preamble of this FY 2019 IPPS/LTCH PPS final rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In this section of the final rule, we provide a general summary of our existing methodology for determining the FY 2019 MS–LTC–DRG relative weights under the LTCH PPS.

As we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20455), in general, for FY 2019, we are continuing to use our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.B.3. of the preamble of this final rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, as we proposed, the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate had been in effect at the time of discharge when claims data from time periods before the dual rate LTCH PPS payment structure applies are used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data

from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, our MS–LTC–DRG relative weight calculations do not use data from cases paid at the site neutral payment rate under § 412.522(c)(1) or data from cases that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of that discharge. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.B.3.c. of the preamble of this final rule). In addition, in this FY 2019 IPPS/LTCH PPS final rule, for FY 2019, as we proposed, we are continuing to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.B.3.c. of the preamble of this final rule.

Furthermore, for FY 2019, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, as we proposed, we are continuing to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we grouped all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we accounted for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we made adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.B.3.g. of the preamble of this final rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Currently, for claims submitted using version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in Subparts I through S of Part 162. Among other requirements, on or after January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.F.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to

a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2019

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this FY 2019 IPPS/LTCH PPS final rule, as we proposed, we updated the MS–LTC–DRG classifications effective October 1, 2018, through September 30, 2019 (FY 2019), consistent with the changes to specific MS–DRG classifications presented in section II.F. of the preamble of this final rule. Accordingly, the MS–LTC–DRGs for FY 2019 presented in this final rule are the same as the MS–DRGs that are being used under the IPPS for FY 2019. In addition, because the MS–LTC–DRGs for FY 2019 are the same as the MS–DRGs for FY 2019, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 36 as discussed in section II.F. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, also are applicable under the LTCH PPS for FY 2019.

3. Development of the FY 2019 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the MS–LTC–DRG Relative Weights for FY 2019

In this FY 2019 IPPS/LTCH PPS final rule, as we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20456), we are continuing to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2019, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our application of our existing methodology for determining the MS–LTC–DRG relative weights for FY 2019, and we

discuss the effects of our policies concerning the data used to determine the FY 2019 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

In previous fiscal years, Table 13A—Composition of Low-Volume Quintiles for MS–LTC–DRGs (which was listed in section VI. of the Addendum to the proposed and final rules and available via the internet on the CMS website) listed the composition of the low-volume quintiles for MS–LTC–DRGs for the respective year, and Table 13B—No-Volume MS–LTC–DRG Crosswalk (also listed in section VI. of the Addendum to the proposed rule final rules and available via the internet on the CMS website) listed the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs). The information contained in Tables 13A and 13B is used in the development Table 11—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges, which contains the proposed and final MS–LTC–DRGs and their respective proposed and final relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases) for the respective fiscal year (and also is listed in section VI. of the Addendum to the proposed and final rules and is available via the internet on the CMS website). Because the information contained in Tables 13A and 13B does not contain payment rates or factors for the applicable payment year, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20457), we proposed to generally provide the data previously published in Tables 13A and 13B for each annual proposed and final rule as one of our supplemental IPPS/LTCH PPS related data files that are made available for public use via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. To streamline the information made available to the public that is used in the annual development of Table 11, we stated we believe that this proposed change in the presentation of the information contained in Tables 13A and 13B will make it easier for the public to navigate and find the relevant data and information used for the development of proposed and final payment rates or factors for the applicable payment year while continuing to furnish the same information the tables provided in previous fiscal years.

We did not receive any public comments on these proposals. Therefore, we are finalizing, without modification, the proposals and the continued use of the existing policies, as proposed.

c. Data

For the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20457), consistent with our proposals regarding the calculation of the proposed MS–LTC–DRG relative weights for FY 2019, we obtained total charges from FY 2017 Medicare LTCH claims data from the December 2017 update of the FY 2017 MedPAR file, which was the best available data at that time, and we proposed to use Version 36 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we proposed that if more recent data become available, we would use those data and the finalized Version 36 of the GROUPER in establishing the FY 2019 MS–LTC–DRG relative weights in the final rule. For this final rule, based on updated from FY 2017 Medicare LTCH claims data from the March 2018 update of the FY 2017 MedPAR file, which is the best available data at the time of development of this final rule, and we used Version 36 of the GROUPER to classify LTCH cases. To calculate the FY 2019 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, as we proposed, we continued to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2018 update of the FY 2017 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2017 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945 and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2017 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. We note that, for purposes of developing the FY 2019 MS–LTC–DRG relative weights using our current methodology, we did not make any exceptions regarding the identification of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain severe wound care discharges from certain LTCHs or for certain spinal cord specialty hospitals provided by sections 15009 and 15010 of Public Law 114–255, respectively, had our implementation of that law and the dual rate LTCH PPS payment structure been in effect at the time of the discharge. At this time, it is uncertain how many LTCHs and how many cases in the claims data we used for this final rule meet the criteria to be excluded from the site neutral payment rate under those exceptions (or would have met the criteria for exclusion had the dual rate LTCH PPS payment structure been in effect at the time of the discharge). Therefore, for the remainder of this section, when we refer to LTCH claims only from cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had the applicable statutes been in effect at the time of the discharge), such data do not include any discharges that would have been paid based on the LTCH PPS standard Federal payment rate under the provisions of sections 15009 and 15010 of Public Law 114–255, had the exception been in effect at the time of the discharge.

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part

C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the proposed MS–LTC–DRG relative weights for FY 2019.

In summary, in general, we identified the claims data used in the development of the FY 2019 MS–LTC–DRG relative weights in this final rule, as we proposed, by trimming claims data that were paid the site neutral payment rate (or would have been paid the site neutral payment rate had the dual payment rate structure been in effect, except for discharges which would have been excluded from the site neutral payment under the temporary exception for certain severe wound care discharges from certain LTCHs and under the temporary exception for certain spinal cord specialty hospitals), as well as the claims data of 9 all-inclusive rate providers reported in the March 2018 update of the FY 2017 MedPAR file and any Medicare Advantage claims data. (We note that, there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2018 update of the FY 2017 MedPAR file. However, had there been we would trim the claims data from those LTCHs as well, in accordance with our established policy.) As we proposed, we used the remaining data (that is, the applicable LTCH data) to calculate the relative weights for FY 2019.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2019 IPPS/LTCH PPS final rule, as we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20458), we continued to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2019. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2019, as we proposed, we continued to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. (Step 3) of the preamble of this final rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio was multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of the final rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). For FY 2019, as we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20459), we are continuing to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2019 MS–LTC–DRG relative weights.

In determining the FY 2019 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, as we proposed, we made adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VII.B.3.g. of the preamble of this final rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, as we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20459), we are continuing to employ the quintile methodology for low-

volume MS–LTC–DRGs, such that we group the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)). In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, as we proposed, we made adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.B.3.g. (Step 6) of the preamble of this final rule.

In this final rule, based on the best available data (that is, the March 2018 update of the FY 2017 MedPAR files), we identified 271 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles, each containing at least 54 MS–LTC–DRGs (271/5 = 54 with a remainder of 1). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, as we proposed, we employed our historical methodology for determining which of the low-volume quintiles would contain the additional low-volume MS–LTC–DRG. Specifically for this final rule, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first 55 (1st through 55th) of low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 54 MS–LTC–DRGs with the highest average charge cases were assigned into Quintile 5. Because the average charge of the 55th low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 54th low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 56th low-volume MS–LTC–DRG (assigned to Quintile 2), we assigned it to Quintile 1 (such that Quintile 1 contains 55 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This resulted in 4 of the 5 low-volume quintiles containing 54 MS–LTC–DRGs (Quintiles 2, 3, 4, and 5) and 1 low-volume quintile containing 55 MS–LTC–DRGs (Quintile 1). As discussed earlier, for this final rule, as we proposed, we are providing the list of the composition of the low-volume quintiles for MS–LTC–DRGs for FY 2019 (previously displayed in Table 13A, which was in previous fiscal years listed in section VI. of the Addendum to the respective proposed and final rules and available via the internet on the CMS website) in a supplemental data file for public use posted via the internet on the CMS website for this final rule at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

In order to determine the FY 2019 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, as we proposed, we used the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in section VII.B.3.g. of the preamble of this final rule. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the FY 2019 MS–LTC–DRG Relative Weights

In this final rule, as we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20460), we are continuing to use our current methodology to determine the FY 2019 MS–LTC–DRG relative weights.

In summary, to determine the FY 2019 MS–LTC–DRG relative weights, as we proposed, we grouped applicable LTCH cases to the appropriate MS–LTC–DRG, while taking into account the low-volume quintiles (as described above) and cross-walked no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate MS–LTC–DRG (or low-volume quintile), as we proposed, we calculated the FY 2019 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). Next, as we proposed, we adjusted the number of applicable LTCH cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (Step 3 below). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1 below) and statistical outliers (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges (Step 3 below), as we proposed, we calculated ''relative adjusted weights'' for each MS–LTC–DRG (or low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our calculation of the FY 2019 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2019 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the FY 2019 MS–LTC–DRG relative weights, as we proposed, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our calculation of the FY 2019 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we continued to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers were removed prior to calculating the relative

weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the proposed relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the FY 2019 MS–LTC–DRG relative weights, consistent with our historical approach, as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This had the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produced the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2019 MS–LTC–DRG relative weights would lower the FY 2019 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, as we proposed, we continued to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the FY 2019 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, as we proposed, we calculated the FY 2019 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio was then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2019 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from Step 3 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) were then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a FY 2019 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the March 2018 update of the FY 2017 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

As we proposed, we cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' MS–LTC–DRG was assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this final rule).

Of the 761 MS–LTC–DRGs for FY 2019, we identified 346 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases (the number identified includes the 8 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed below). As we proposed, we assigned relative weights to each of the 346 no-volume MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to 1 of the remaining 415 (761 − 346 = 415) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2017 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as the MS–LTC–DRGs to which we cross-walked 1 of the 346 ''no volume'' MS–LTC–DRGs.) Then, as we generally proposed, we assigned the 346 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the March 2018 update of the FY 2017 MedPAR file, and to which it is similar

clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543)). We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2018, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

We then assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2019. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology described in Steps 1 through 4 above) was assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2019. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments as described in Step 6 were required in order to maintain monotonically increasing relative weights.)

As discussed earlier, for this final rule, as we proposed, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2019 (previously displayed in Table 13B, which was in previous fiscal years listed in section VI. of the Addendum to the respective proposed and final rules and available via the internet on the CMS website) in a supplemental data file for public use posted via the internet on the CMS website for this final rule at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the relative weights for the FY 2019 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume MS–LTC–DRGs crosswalk information for FY 2019 (which, as previously stated, we are providing in a supplemental data file posted via the internet on the CMS website for this final rule).

Example: There were no trimmed applicable LTCH cases in the FY 2017 MedPAR file that we used for this final rule for MS–LTC–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 070 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.8822 for FY 2019 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice, we used the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in this final rule.

For FY 2019, consistent with our historical relative weight methodology, as we proposed, we established a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Pancreas Transplant (MS–LTC–DRG 010); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, as we proposed, we established a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

As discussed in section VII.C. of the preamble of this final rule, section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) extended the transitional blended payment rate for site neutral payment rate cases for an additional 2 years (that is, discharges occurring in cost reporting periods beginning in FYs 2018 and 2019 will continue to be paid under the blended payment rate). Therefore, in this final rule, consistent with our practice in FYs 2016 through 2018, as we proposed, we established a relative weight for FY 2019 equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–

LTC–DRG 946 (Rehabilitation without CC/MCC). As we discussed when we implemented the dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs do not meet the criteria for exclusion from the site neutral payment rate. As such, under the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, there are no applicable LTCH cases to use in calculating a relative weight for the ''psychiatric and rehabilitation'' MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs would always be paid at the site neutral payment rate, and, therefore, those MS–LTC–DRGs would never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that would be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, which was extended to include FYs 2018 and 2019 under Public Law 115–123. (We refer readers to section VII.C. of the preamble of this final rule for a detailed discussion of the extension of the transitional blended payment method provisions under Pub. L. 115–123 and our policies for FY 2019.) Under the transitional payment method for site neutral payment rate cases, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2018, and on or before September 30, 2019, site neutral payment rate cases are paid a blended payment rate, calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate. Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the transitional blended payment for site neutral payment rate cases grouped to one of the ''psychiatric or rehabilitation'' MS–LTC–DRGs in FY 2019, we assigned a relative weight to these MS–LTC–DRGs for FY 2019 that is the same as the FY 2018 relative weight (which is also the same as the FYs 2016 and 2017 relative weight). We believe that using the respective FY 2015 relative weight for each of the ''psychiatric or rehabilitation'' MS–LTC–DRGs results in appropriate payments for LTCH cases that are paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar MS–LTC–DRGs for which we were able to determine relative weights based on applicable LTCH cases in the March 2018 update of the FY 2017 MedPAR file data using the steps described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 ''psychiatric and rehabilitation'' MS–LTC–DRGs to be used for the sole purposes of determining half of the transitional blended payment for site neutral payment rate cases during the transition period (80 FR 49631 through 49632) or payment for discharges from spinal cord specialty hospitals under § 412.522(b)(4).

In summary, for FY 2019, we established a relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs listed previously (that is, MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946). Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website, reflects this policy.

Step 6—Adjust the FY 2019 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2019 MS–LTC–DRG relative weights, consistent with our historical methodology, as we proposed, we continued to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2019 MS–LTC–DRG relative weights in this final rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website.

Step 7—Calculate the FY 2019 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–

LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, as we proposed, we updated the MS–LTC–DRG classifications and relative weights for FY 2019 based on the most recent available LTCH data for applicable LTCH cases, and continued to apply a budget neutrality adjustment in determining the FY 2019 MS–LTC–DRG relative weights.

In this FY 2019 IPPS/LTCH PPS final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we continued to use our established two-step budget neutrality methodology.

To calculate the normalization factor for FY 2019, we grouped applicable LTCH cases using the FY 2019 Version 36 GROUPER, and the recalibrated FY 2019 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2018 GROUPER Version 35 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2018 by the average CMI for FY 2019. That ratio is the normalization factor. Because the calculation of the normalization factor involves the relative weights for the MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume MS–LTC–DRGs are included in the calculation (and the MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the budget neutrality adjustment factor, we simulated estimated total FY 2019 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2019 normalized relative weights and GROUPER Version 36; simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2018 MS–LTC–DRG relative weights and the FY 2018 GROUPER Version 35; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2018 by the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2019. The resulting ratio is the budget neutrality adjustment factor. The calculation of the budget neutrality factor involves the relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume MS–LTC–DRGs or to MS–LTC–DRGs with no applicable LTCH cases, and generally does not include payments for cases grouped to a MS–LTC–DRG with no applicable LTCH cases. (Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less, which are removed from the relative weight calculation in step (2) that are grouped to a MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the budget neutrality factor calculation).

In this final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we continued to use our established two-step budget neutrality methodology. Therefore, in this final rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2019, as we proposed, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2019 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Used the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2017 MedPAR file) and grouped them using the FY 2019 GROUPER (that is, Version 36 for FY 2019) and the recalibrated FY 2019 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) grouped the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2018 GROUPER (Version 35) and FY 2018 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) computed the ratio of these average case-mix indexes by dividing the average CMI for FY 2018 (determined in Step 1.b.) by the average case-mix index for FY 2019 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2019, each recalibrated MS–LTC–DRG relative weight was multiplied by the normalization factor of 1.275254 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we calculated a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2019 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. mentioned previously) after reclassification and recalibration to estimated aggregate payments for FY 2019 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. mentioned previously).

That is, for this final rule, for FY 2019, under the second step of the budget neutrality methodology, as we proposed, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) Simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2019 and GROUPER Version 35 (as described above); (2.b.) simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2018 GROUPER (Version 35) and the FY 2018 MS–LTC–DRG relative weights in Table 11 of the FY 2018 IPPS/LTCH PPS final rule available on the internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculated the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2019 MS–LTC–DRG relative weights, each normalized relative weight was then multiplied by a budget neutrality factor of 0.9931052 (the value determined in Step 2.c.) in

the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the FY 2019 MS–LTC–DRG relative weights in this final rule, consistent with our existing methodology, as we proposed, we applied a normalization factor of 1.275254 and a budget neutrality factor of 0.9931052. Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2019.

C. Modifications to the Application of the Site Neutral Payment Rate (§ 412.522)

Section 1206 of Pathway for SGR Reform Act (Pub. L. 113–67) mandated the new dual rate payment system under the LTCH PPS beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. In addition, the statute established a transitional blended payment method for cases that would be paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. For those discharges, the applicable site neutral payment rate is the transitional blended payment rate specified in section 1886(m)(6)(B)(iii) of the Act. Section 1886(m)(6)(B)(iii) of the Act specifies that the transitional blended payment rate is comprised of 50 percent of the site neutral payment rate for the discharge under section 1886(m)(6)(B)(ii) of the Act and 50 percent of the LTCH PPS standard Federal payment rate that would have applied to the discharge if paragraph (6) of section 1886(m) of the Act had not been enacted.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49610 through 49612), we specified under § 412.522(c)(3), for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015, and on or before September 30, 2017 (that is, discharges occurring in cost reporting periods beginning during FYs 2016 and 2017), that the payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate determined under § 412.523. In addition, we established that the payment amounts determined under § 412.522(c)(1) (the site neutral payment rate) and under § 412.523 (the LTCH PPS standard Federal rate) include any applicable adjustments, such as HCO payments, as applicable.

Section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) extended the transitional blended payment rate period for site neutral payment rate cases for 2 years, and provided for an adjustment to the payment for discharges paid under the site neutral payment rate through FY 2026. Specifically, section 51005(a) of Public Law 115–123 amended section 1886(m)(6)(B)(i) of the Act to extend the transitional blended payment rate for site neutral payment rate cases for an additional 2 years; that is, discharges occurring in cost reporting periods beginning in FYs 2018 and 2019 will continue to be paid under the blended payment rate. To codify the provisions of section 51005(a) of Public Law 115–123, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20464 through 20465), we proposed to revise our regulations at § 412.522(c)(3) to reflect the extension of the transitional blended payment rate period for discharges paid at the site neutral payment rate to include discharges occurring in cost reporting periods beginning on or before September 30, 2019.

In addition, as initially enacted, section 1886(m)(6)(B)(iii) of the Act specified that, for LTCH discharges occurring in cost reporting periods beginning during FY 2018 or later, the applicable site neutral payment rate would be the site neutral payment rate as defined in section 1886(m)(6)(B)(ii) of the Act. Section 51005(b) of Public Law 115–123 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined at section 1886(m)(6)(B)(ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026. In order to implement section 51005(b) of Public Law 115–123, in the FY 2019 IPPS/LTCH PPS proposed rule, we proposed to revise § 412.522(c)(1) by adding new paragraph (iii) to specify that, for discharges occurring in FYs 2018 through 2026, the amount payable under § 412.522(c)(1)(i) (that is, the IPPS comparable amount) will be reduced by 4.6 percent.

We also proposed to make a conforming amendment to § 412.500, which specifies the basis and scope of subpart O of 42 CFR part 412, by adding paragraph (a)(9) to reflect the provisions of section 51005 of the Bipartisan Budget Act of 2018.

Comment: Several commenters supported CMS' proposed codification of section 51005 of Public Law 115–123. However, several commenters stated that the 4.6 percent reduction to the site neutral payment rate mandated under section 51005(b) of Public Law 115–123 should begin with discharges occurring based on the beginning date of a hospital's cost reporting period rather than the Federal fiscal year. Specifically, these commenters believed that because the transitional blended payment was initially based on discharges occurring during a hospital's cost reporting period, the 4.6 percent payment reduction specified under added section 1886(m)(6)(B)(iv) of the Act should also be applied on this basis. Some commenters stated that applying the 4.6 percent payment reduction based on the Federal fiscal year is inconsistent with CMS' previous implementation of other statutes. Other commenters stated that applying the 4.6 percent payment reduction on a Federal fiscal year basis is inconsistent with the surrounding provisions of Public Law 115–123. Some commenters expressed concern regarding the brevity of CMS' proposal and the use of subregulatory guidance in implementing the statute, and urged CMS to examine the ''legislative intent'' behind the provision of section 51005(b) of Public Law 115–123. Other commenters requested that CMS delay implementation of the application of the 4.6 percent payment reduction specified under section 1886(m)(6)(B)(iv) of the Act, as added by section 51005(b) of Public Law 115–123, until FY 2020.

Response: We appreciate commenters' support for our proposals to implement and codify the provisions of section 51005 of Public Law 115–123, which added section 1886(m)(6)(B)(iv) of the Act. With regard to those commenters who questioned our application of the provision of section 51005(b), we believe that the statutory language of section 51005(b) is clear: The 4.6 percent payment reduction is to occur for discharges in each of Federal fiscal years 2018 through 2026 without reference to cost reporting periods. The transitional blended payment provision under section 51005(a), on the other hand, specifically states that the payments are to be made based on discharges in the individual hospital's cost reporting period beginning in a particular fiscal year. Given the clear statutory direction and the explicit difference between the language used in the different provisions of the statute, we do not believe that we have the authority to implement the reduction in payments specified under section 1886(m)(6)(B)(iv) of the Act, as added by

section 51005(b) of Public Law 115–123, other than on a Federal fiscal year basis.

With regard to the commenters' concern regarding the brevity of our proposal, we believe that the provisions of section 51005 of Public Law 115–123 are clear and self-implementing, and merely require updating the regulations to be consistent with the statutory directive. Therefore, because of the clear, unambiguous statutory directive in the statute, we used subregulatory guidance to implement the provision of section 51005(b) of Public Law 115–123. The statutory language of section 51005 (b) states that the amendments to Act applies for each of Federal fiscal years 2018 through 2026, and does not contain any reference to cost reporting periods. We believe that the ''legislative intent'' is defined by use of the language in the statute, which is clear and unambiguous.

With respect to the commenters' request that we delay implementation of the application of the 4.6 percent payment reduction until FY 2020, we note that the statute specifically directs us to apply the payment reduction beginning in FY 2018. Therefore, we believe that we lack the authority to delay beginning the application of the 4.6 percent payment reduction after FY 2018, again due to the explicit, unambiguous statutory direction.

We agree with the commenters that the application of the 4.6 percent payment reduction on a Federal fiscal year basis is not based on the same language as surrounding areas of the statute. However, we believe that this fact supports our interpretation and implementation manner. That is, the plain language of surrounding statutory provisions explicitly bases payment provisions on a hospital's cost reporting period, while the plain language of section 51005(b) of Public Law 115–123 expressly fails to do so with regard to the 4.6 percent payment reduction. Given this obvious difference, we believe that it is clear the 4.6 percent payment reduction specified under section 1886(m)(6)(B)(iv) of the Act, as added by section 51005(b) of Public Law 115–123, is to be applied on a Federal fiscal year basis.

In response to the commenters' opinion that CMS' application of the 4.6 percent payment reduction on a Federal fiscal year basis is inconsistent with the way in which CMS has interpreted and implemented certain other statutes, we believe that these perceived inconsistencies are sufficiently distinguishable due to the statutory language of the provisions of section 51005 of Public Law 115–123 and section 1886(m)(6)(B) of the Act. For example, some commenters cited CMS' implementation of the uncompensated care payments under section 1886(r)(2) of the Act, which the commenters stated are made on the basis of a hospital's cost reporting period. In general, under our uncompensated care payment methodology, an eligible hospital's uncompensated care payment for a Federal fiscal year is determined annually in the IPPS/LTCH PPS rulemaking. For a hospital with a cost reporting period that coincides with the Federal fiscal year, its uncompensated care payment for that cost reporting period is its uncompensated care payment for that Federal fiscal year. (Interim uncompensated care payments, which are made on a per-claim basis during the Federal fiscal year, are reconciled as needed as part of the standard cost report settlement process.) For a hospital with a cost reporting period that spans 2 Federal fiscal years, its uncompensated care payment for the cost reporting period is based on a pro rata ratio of the proportion of the cost reporting period that occurred in each applicable Federal fiscal year (78 FR 61193). While the reconciliation of interim uncompensated care payments may operationally occur based on a hospital's cost reporting period, the hospital's final uncompensated care payment is, nevertheless, a payment amount determined for each Federal fiscal year (not each cost reporting period), and, as applicable, paid proportionally when a hospital's cost reporting period spans the Federal fiscal year. Another purported example of inconsistent interpretation and manner of implementation cited by commenters is CMS' implementation of various moratoria on the establishment of LTCHs. However, we are not persuaded by this comparison because those statutory provisions required interpretation to implement. The provision of section 51005(b) of Public Law 115–123 is distinguishable in this respect. There is no impediment to implementing the 4.6 percent payment reduction exactly as written and, given the explicit statutory direction, we do not believe that we have any authority to superimpose regulatory interpretation to clear statutory direction.

After consideration of the public comments we received, we are finalizing, as proposed, the codification of the provision of section 51005(b) of Public Law 115–123 in regulations. Specifically, we are: (1) Revising § 412.522(c)(3) to extend the transitional blended payment for site neutral payment rate cases to include discharges occurring in cost reporting periods beginning on or before September 30, 2019; (2) under § 412.522(c)(1), providing for the application of a 4.6 percent payment reduction to the IPPS comparable amount for discharges occurring in FYs 2018 through 2026; and making a conforming amendment to § 412.500, which specifies the basis and scope of subpart O of 42 CFR part 412, by adding paragraph (a)(9) to reflect the provisions of section 51005 of the Bipartisan Budget Act of 2018.

We note that we received several public comments that addressed issues related to site neutral payment rate payments that were outside the scope of the provisions of the proposed rule. Therefore, we are not responding to those comments in this final rule. We will take these public comments into consideration, as feasible, in future rulemaking.

D. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2019

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.538. In this section, we discuss the factors that we used to update the LTCH PPS standard Federal payment rate for FY 2019, that is, effective for LTCH discharges occurring on or after October 1, 2018 through September 30, 2019. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCHs were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard

Federal payment rate (FY 2016 through present) as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180); FY 2016 IPPS/LTCH PPS final rule (80 FR 49634 through 49637); FY 2017 IPPS/LTCH PPS final rule (81 FR 57296 through 57310); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 58536 through 58547).

In this FY 2019 IPPS/LTCH PPS final rule, we present our policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2019.

The update to the LTCH PPS standard Federal payment rate for FY 2019 is presented in section V.A. of the Addendum to this final rule. The components of the annual update to the LTCH PPS standard Federal payment rate for FY 2019 are discussed below, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2019 as required by the statute (as discussed in section VII.E.2.c. of the preamble of this final rule). In addition, as we proposed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20592), we made an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level adjustment for FY 2019 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule).

2. FY 2019 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2013-based LTCH market basket for use under the LTCH PPS beginning in FY 2017 (81 FR 57100 through 57102). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2013-based LTCH market basket, we refer readers to section VII.D. of the preamble of the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25153 through 25167 and 81 FR 57086 through 57099, respectively).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2019

CMS has used an estimated market basket increase to update the LTCH PPS. As noted above, we adopted the 2013-based LTCH market basket for use under the LTCH PPS beginning in FY 2017. The 2013-based LTCH market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. (For additional details on the development of the 2013-based LTCH market basket, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57099).) We continue to believe that the 2013-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57100). Therefore, in this final rule, as we proposed, we used the 2013-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2019.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A). Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, ''the multifactor productivity (MFP) adjustment''). Clause (ii) of section 1886(m)(3)(A) of the Act provides for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0

for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year). These requirements are codified in the regulations at § 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this final rule.)

d. Annual Market Basket Update Under the LTCH PPS for FY 2019

Consistent with our historical practice, we estimate the market basket increase and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's second quarter 2018 forecast, the FY 2019 full market basket estimate for the LTCH PPS using the 2013-based LTCH market basket is 2.9 percent. The current estimate of the MFP adjustment for FY 2019 based on IGI's second quarter 2018 forecast is 0.8 percent.

For FY 2019, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, as we proposed, we are reducing the full estimated FY 2019 market basket increase by the FY 2019 MFP adjustment. To determine the market basket increase for LTCHs for FY 2019, as reduced by the MFP adjustment, consistent with our established methodology, we subtracted the FY 2019 MFP adjustment from the estimated FY 2019 market basket increase. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(E) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate for FY 2019 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.75 percent for FY 2019. Therefore, following application of the productivity adjustment, as we proposed, we are further reducing the adjusted market basket update (that is, the full FY 2019 market basket increase less the MFP adjustment) by the ''other adjustment'' specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP adjustment and the ''other adjustment'' required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2019, section 1886(m)(5) of the Act requires that for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, the update to the LTCH PPS standard Federal payment rate for FY 2019 for LTCHs that fail to submit quality reporting data under the LTCH QRP, the full LTCH PPS market basket increase estimate, subject to the MFP adjustment as required under section 1886(m)(3)(A)(i) of the Act and an additional reduction required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, is also further reduced by 2.0 percentage points.

In this FY 2019 IPPS/LTCH PPS final rule, in accordance with the statute, as we proposed, we reduced the FY 2019 full market basket estimate of 2.9 percent (based on IGI's second quarter 2018 forecast of the 2013-based LTCH market basket) by the FY 2019 MFP adjustment of 0.8 percentage point (based on IGI's second quarter 2018 forecast). Following application of the MFP adjustment, as we proposed, we are reducing the adjusted market basket update of 2.1 percent (2.9 percent minus 0.8 percentage point) by 0.75 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2019 of 1.35 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.9 percent, less the MFP adjustment of 0.8 percentage point, and less the 0.75 percentage point required under section 1886(m)(4)(F) of the Act). Accordingly, consistent with our proposal, we are revising § 412.523(c)(3) by adding a new paragraph (xv), which specifies that the LTCH PPS standard Federal payment rate for FY 2019 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS payment year updated by 1.35 percent, and as further adjusted, as appropriate, as described in § 412.523(d) (including the budget neutrality adjustment for the elimination of the 25-percent threshold policy under § 412.523(d)(6) discussed in section VII.E. of the preamble of this final rule). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xv) in conjunction with § 412.523(c)(4), as we proposed, we further reduced the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are establishing an annual update to the LTCH PPS standard Federal payment rate of −0.65 percent (that is, 1.35 percent minus 2.0 percentage points) for FY 2019 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, as we proposed, we used a more recent estimate of the market basket and the MFP adjustment in this final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2019 under § 412.523(c)(3)(xv). (We note that, consistent with historical practice, we also are adjusting the FY 2019 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this final rule).)

E. Elimination of the ''25-Percent Threshold Policy'' Adjustment (§ 412.538)

The ''25-percent threshold policy'' is a per discharge payment adjustment in the LTCH PPS that is applied to payments for Medicare patient discharges from an LTCH when the number of such patients originating from any single referring hospital is in excess of the applicable threshold for a given cost reporting period (such threshold is generally set at 25 percent, with exceptions for rural and urban single or MSA-dominant hospitals). If an LTCH exceeds the applicable threshold during a cost reporting period, payment for the discharge that puts the LTCH over its threshold and all discharges subsequent to that discharge in the cost reporting period from the referring hospital are adjusted at cost report settlement (discharges not in excess of the threshold are unaffected by the 25-percent threshold policy). The 25-percent threshold policy was originally established in the FY 2005 IPPS final rule for LTCH HwHs and satellites (69 FR 49191 through 49214). We later expanded the 25-percent threshold policy in the RY 2008 LTCH PPS final rule to include all LTCHs and LTCH satellite facilities (72 FR 26919 through 26944). Several laws have mandated delayed implementation of

the 25-percent threshold policy. For more details on the various laws that delayed the full implementation of the 25-percent threshold policy, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38318 through 38319).

In light of the further statutory delays and our continued consideration of public comments received in response to our proposal to consolidate and streamline the 25-percent threshold policy in the FY 2017 IPPS/LTCH PPS proposed rule, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38320), we adopted a 1-year regulatory moratorium on the implementation of the 25-percent threshold policy; that is, we imposed a regulatory moratorium on our implementation of the provisions of § 412.538 until October 1, 2018.

Since the introduction of the site neutral payment rate in FY 2016, many public commenters have asserted that the new site neutral payment rate would alleviate the policy concerns underlying the establishment of the 25-percent threshold policy. As we stated in our response to those comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57106) and in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38320), at that time, we were not convinced that this was the case. In addition, we received many public comments urging CMS to permanently rescind the 25-percent threshold policy in response to the Request for Information on CMS Flexibilities and Efficiencies that was included in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20159). These public comments also asserted that this policy is no longer necessary in light of the new dual payment rate system.

As discussed in the FY 2018 IPPS/LTCH PPS proposed and final rules (82 FR 20028 and 82 FR 38318 through 38319, respectively), the best available LTCH claims data at the time of the development of both rules (FY 2016 discharges) included many LTCH discharges that occurred during FY 2016 that were not yet subject to the site neutral payment rate because the statute provides that the site neutral payment rate be phased in, effective with LTCH cost reporting periods beginning on or after October 1, 2015 (that is, LTCH cost reporting periods beginning in FY 2016). Therefore, all FY 2016 discharges that occurred in a LTCH cost reporting period that began prior to October 1, 2016 were not subject to the site neutral payment rate.

Given these widespread concerns, the longstanding statutory delays, and the limited experience under the new dual rate payment system, we implemented the 1-year regulatory moratorium for FY 2018 to allow for the opportunity to do an analysis of LTCH admission practices under the new dual payment rate under the LTCH PPS based on more complete data. This implementation plan was, in part, intended to avoid confusion and expending unnecessary resources in implementation should our analysis ultimately conclude that the policy concerns underlying the 25-percent threshold policy have been moderated (82 FR 38320).

Since establishing the current regulatory moratorium in the FY 2018 IPPS/LTCH PPS rulemaking, we have continued to receive additional communications seeking an end to our 25-percent threshold policy. We have considered these requests, along with reconsidering the many requests and public comments received through rulemaking, as we have reviewed our policies in the context of our ongoing initiative to reduce unnecessary regulatory burden. Our review also took note of the significant changes to LTCH admission practices and the LTCH PPS payment structure since the advent of the 25-percent threshold policy's adoption, such as the introduction of the site neutral payment rate beginning in FY 2016. One effect of these changes is the creation of a financial incentive for LTCHs to limit admissions according to the criteria for payment at the LTCH PPS standard Federal payment rate. While these changes do not specifically address our regulatory requirement to ensure that an LTCH does not act as an IPPS step-down unit, we believe that the creation of these financial incentives likely results in LTCH providers closely considering the appropriateness of admitting a potential transfer to an LTCH setting, regardless of the referral source, thereby lessening the concerns that led to the introduction of the 25-percent threshold policy.

In light of these factors, we recognize that the policy concerns that led to the 25-percent threshold policy may have been ameliorated, and that implementation of the 25-percent threshold policy would place a regulatory burden on providers. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20468), we stated that we believe it was appropriate at that time to propose the removal of this payment adjustment policy. We also stated that, for these same reasons, we believe the specific regulatory framework of the 25-percent threshold policy at § 412.538 is no longer an appropriate mechanism to ensure that the statutory requirement that an LTCH does not act as a defacto unit of an IPPS hospital is not violated. Therefore, in the proposed rule, we proposed to eliminate the 25-percent threshold policy under § 412.538.

In the proposed rule, we indicated the goal of our proposal to eliminate the 25-percent threshold policy is to reduce unnecessary regulatory burden. Independent of this goal, we continue to believe aggregate LTCH PPS payments are sufficient. Therefore, we do not believe that it would be appropriate to change the aggregate amount of LTCH PPS payments on a permanent basis. As described earlier, the 25-percent threshold policy would have reduced the LTCH PPS payments for certain discharges, and if finalized, the elimination of the 25-percent threshold policy would result in an increase in aggregate LTCH PPS payments. As a result, we also stated in the proposed rule that we believe this proposal should be accomplished in a budget-neutral manner.

With respect to the issue about the adequacy of LTCH payment levels, we note that MedPAC, in each of its annual updates to Congress since 2011, has concluded that current LTCH PPS payment levels are appropriate, and thus has recommended since 2011 the elimination of the annual update to the LTCH payment rates. (For example, we refer readers to MedPAC's March 2011 ''Report to the Congress: Medicare Payment Policy,'' Chapter 10, page 246, and MedPAC's March 2018 ''Report to the Congress: Medicare Payment Policy,'' Chapter 11, page 315.) We believe application of this burden reduction-related proposal to eliminate the 25-percent threshold policy would result in an unwarranted increase in aggregate payment levels. Therefore, in the proposed rule, we stated that, if we finalized our proposal to eliminate the 25-percent threshold policy, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we also would make a one-time, permanent adjustment to the FY 2019 LTCH PPS standard Federal payment rate. That adjustment would be set such that our projection of aggregate LTCH payments in FY 2019 that would have been paid if the 25-percent threshold policy had gone into effect (that is, as if the 25-percent threshold policy under § 412.538 remained in effect during FY 2019) are equal to our projection of aggregate LTCH payments in FY 2019 payments for such cases in the absence of that policy.

To do this, we proposed to remove the provisions of § 412.538, reserving this section, and add a new paragraph (d)(6) to § 412.523 to provide for a one-time permanent budget neutrality factor adjustment to the LTCH PPS standard Federal payment rate to ensure that

removal of the 25-percent threshold policy at existing § 412.538 is budget neutral. (We note that, in proposed new § 412.523(d)(6), we refer to the 25-percent threshold policy as ''limitation on long-term care hospital admissions from referring hospitals'', which is the title of existing § 412.538.) In addition, we proposed to make conforming technical changes to remove paragraph (c)(2)(v) of § 412.522 and paragraph (d)(6) of § 412.525.

Comment: Many commenters supported CMS' proposal to eliminate the 25-percent threshold policy, but expressed concerns with the corresponding budget neutrality adjustment. Some of these commenters disagreed with CMS' proposal of applying a budget neutrality adjustment because they believed that such an adjustment is not needed. Commenters that generally opposed the application of a budget neutrality adjustment stated that: (1) CMS has not recovered payments for violations of the 25-percent threshold policy and, therefore, it would be incorrect to state that eliminating the 25-percent threshold policy would increase Medicare spending; (2) LTCHs would adjust to a fully implemented 25-percent threshold policy, thereby minimizing the penalty amount; (3) implementation of the site neutral payment rate has led to yearly decreases in LTCH payments from FY 2016 to FY 2019 due to a reduction in the overall volume of LTCH cases and this decrease in LTCH payments eliminates the need for any further budget neutrality adjustments; and (4) the statutory delay in FY 2017 (and prior years) and the regulatory delay in FY 2018 in the full implementation of the 25-percent threshold policy were never paired with a budget neutrality adjustment and, therefore, an adjustment as a result of the elimination of the policy is unwarranted. Commenters also addressed the proposed budget neutrality adjustment calculation methodology (which we discuss in detail below).

Response: We appreciate the commenters' support for our proposal to eliminate the 25-percent threshold policy. In response to the commenters who opposed the application of a budget neutrality adjustment, we disagree that a budget neutrality adjustment is not needed to maintain aggregate LTCH PPS payments at the same level that would have been if we were not eliminating this policy. As described earlier, if the 25-percent threshold policy were to go into full effect, it would reduce the LTCH PPS payments for certain discharges; therefore, an elimination of the 25-percent threshold policy would necessarily result in an increase in aggregate LTCH PPS payments. As we have stated, we believe aggregate LTCH PPS payments are sufficient and, therefore, the budget neutrality adjustment is necessary to ensure the elimination of the 25-percent threshold does not increase aggregate LTCH PPS payments. Specifically, a budget neutrality adjustment is necessary to ensure that the elimination of the 25-percent threshold policy does not increase aggregate LTCH PPS payments *in FY 2019 and future years,* and this is independent of aggregate payment levels in past years, including any adjustment (or lack of) to payments for violations of the 25-percent threshold policy. Moreover, we note that, while some LTCHs may indeed adjust to a fully implemented 25-percent threshold policy, thereby minimizing the penalty amount, this compliance with policy does not ensure budget neutrality. Similarly, any reduction in aggregate LTCH PPS payments as a result of the implementation of the site neutral payment rate, including any decrease in the annual number of LTCH cases, does not ensure that the elimination of the 25-percent threshold policy would not increase aggregate LTCH PPS payments in FY 2019 and future years.

While the statutory and regulatory delays in prior years were not implemented in a budget neutrality manner, this does not preclude the application of such an adjustment at this time. We also note that, both the past statutory and regulatory delays were temporary, unlike our proposal to permanently eliminate the 25-percent threshold policy, which differentiates our proposal from past policy.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to remove and reserve the provisions of § 412.538, add a new paragraph (d)(6) to § 412.523, and make further conforming changes to existing regulations.

As described earlier, in the proposed rule, we proposed to make a one-time, permanent adjustment to the FY 2019 LTCH PPS standard Federal payment rate, which would be set such that our projection of aggregate LTCH payments in FY 2019 that would have been paid if the 25-percent threshold policy had gone into effect (that is, as if the 25-percent threshold policy under § 412.538 remained in effect during FY 2019) are equal to our projection of aggregate LTCH payments in FY 2019 payments for such cases in the absence of that policy. We also proposed that this budget neutrality adjustment would only be applied to the LTCH PPS standard Federal payment rate (or such portion of a transitional blended payment) because payments made under the site neutral payment rate would have been unaffected by the 25-percent threshold policy. (Discharges in excess of the 25-percent threshold policy would be paid the lesser of the applicable LTCH payment or an IPPS equivalent payment. The site neutral payment rate would remain set at the lesser of the IPPS comparable amount or cost, neither of which would exceed the IPPS equivalent payment amount.) However, because the applicable site neutral payment rate for all LTCHs during all of FY 2019 is based on the transitional blended payment rate (that is, 50 percent of the site neutral payment rate and 50 percent of the LTCH PPS standard Federal payment rate), any adjustment applied to the LTCH PPS standard Federal payment rate would also need to be applied to the LTCH PPS standard Federal rate portion of payments that affect site neutral payment rate cases.

Therefore, as noted earlier, in the proposed rule, we stated that we must account for the change in payments to both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases when determining the budget neutrality adjustment. To do so, we proposed to use the following methodology to determine the budget neutrality factor that would be applied to the FY 2019 LTCH PPS standard Federal payment rate using the best available LTCH claims data (the December 2017 update of the FY 2017 MedPAR files). Consistent with historical practice, in the proposed rule, we stated that if more recent data became available, we would use such data for the final rule (83 FR 20468 through 20469).

Step 1—Simulate estimated aggregate FY 2019 LTCH PPS payments (that is, both LTCH PPS standard Federal payment rate payment cases and site neutral payment rate cases) without the 25-percent threshold policy at § 412.538.

Step 2—Estimate aggregate payments incorporating the payment reduction under the 25-percent threshold policy at § 412.538 as follows:

- *Step 2a*—Determine the applicable percentage threshold for each LTCH. In general, the applicable percentage threshold is 25 percent; however, the applicable percentage threshold is 50 percent for exclusively rural LTCHs, and LTCHs located in an MSA with an MSA-dominant hospital get an adjusted threshold (§ 412.538(e)). To determine the applicable percentage threshold for

LTCHs located in an MSA with an MSA-dominant hospital, we used IPPS claims data from the March 2017 update of the FY 2016 MedPAR files to determine, for each CBSA, the highest discharge percentage among all IPPS providers within that CBSA. (The CBSA-based geographic classifications currently used under the LTCH PPS are based on the OMB labor market area delineations based on the 2010 Decennial Census data (that is, are an MSA under § 412.503). The applicable percentage threshold for a given CBSA is this highest discharge percentage unless this percentage is higher than 50 percent or lower than 25 percent. In those cases, the threshold is 50 percent or 25 percent, respectively (§ 412.538(e)(3)).

- *Step 2b*—For each LTCH, determine the percentage of Medicare discharges admitted from any single referring IPPS hospital, consistent with § 412.538(d)(2). To do so, as discussed earlier, we used the March 2017 update of the FY 2016 MedPAR files to determine the total discharges for each LTCH and the number of applicable transfers from each referring IPPS hospital. The referring IPPS hospital's applicable transfers are the LTCH's Medicare discharges that were admitted from that single referring IPPS hospital where an outlier payment was not made to that referring hospital and for whom payment was not made by a Medicare Advantage plan. The ratio of the referring IPPS hospital's applicable transfers to the LTCH's total Medicare discharges, multiplied by 100, is the percentage of Medicare discharges admitted from any single referring IPPS hospital.
- *Step 2c*—Estimate the aggregate payment reduction under the 25-percent threshold policy:

(i) Determine the LTCH's discharges that are in excess of the applicable percentage threshold by comparing the LTCH's percentage of Medicare discharges admitted from each single referring IPPS hospital (Step 2b) to the LTCH's applicable percentage threshold (Step 2a).

(ii) Estimate the aggregate payment reduction under the 25-percent threshold policy for the Medicare discharges that caused the LTCH to exceed or remain in excess of the threshold by summing the difference between:

- The original LTCH PPS payment amount (that is, the otherwise applicable LTCH PPS payment without an adjustment under the 25-percent threshold policy); and
- The estimated adjusted payment amount under the 25-percent threshold policy. (We note that there is no payment adjustment under the 25-percent threshold policy for discharges that are not in excess of the LTCH's applicable percentage threshold.)

Step 3—Calculate the ratio of the estimated aggregate FY 2019 LTCH PPS payments with and without the estimated aggregate payment reduction under the 25-percent threshold policy to determine the adjustment factor that would need to be applied to the FY 2019 LTCH PPS standard Federal payment rate to achieve budget neutrality (that is, the adjustment that would have to be applied to the FY 2019 LTCH PPS standard Federal payment rate so that the estimated aggregate payments calculated in Step 1 are equal to the estimated aggregate payments with the reduction as calculated in Step 2). This ratio is calculated by dividing the estimated FY 2019 payments without incorporating the estimated aggregate payment reduction under the 25-percent threshold policy at § 412.538 (calculated in Step 1) by the estimated FY 2019 payments incorporating the estimated aggregate payment reduction under the 25-percent threshold policy at § 412.538 (calculated in Step 2). We note that, under Step 3, an iterative process is used to determine the adjustment factor that would need to be applied to the FY 2019 LTCH PPS standard Federal payment rate to achieve budget neutrality because the portion of estimated FY 2019 payments that are not based on the LTCH PPS standard Federal payment rate (that is, the IPPS comparable amount portion under the SSO payment methodology and the site neutral payment rate portion of the transitional blended payment rate payment for site neutral payment rate discharges in FY 2019) are not affected by the application of budget neutrality factor.

We also note that, under this step, the proposed budget neutrality adjustment factor would be applied to the FY 2019 LTCH PPS standard Federal payment rate after the application of the FY 2019 annual update and the FY 2019 area wage level adjustment budget neutrality factor.

Comment: One commenter suggested that CMS consider alternate impact methodologies for the budget neutrality adjustment to limit or avoid impacting providers who have no need of relief from the 25-percent threshold policy. Other commenters, including some commenters who opposed the budget neutrality adjustment in concept, stated that the proposed methodology for calculating the budget neutrality adjustment overstates the cost of eliminating the 25-percent threshold policy by failing to include behavioral responses or year-to-year trends in violations, as well as the full implementation of the site neutral payment rate. In particular, some commenters suggested that the estimated cost of eliminating the 25-percent threshold policy needs to be reduced in FY 2020 and subsequent years to reflect the phase-out of the transitional blended payment rate payments to site neutral payment rate cases. Some commenters believed that, if there is a budget neutrality adjustment, it should not be permanent and should only apply in FY 2019 and have no impact in FY 2020 and subsequent years. Some commenters also requested that the most recent data available be used to determine the budget neutrality adjustment, and some commenters specifically requested that FY 2017 data be used instead of FY 2016 data that were used in the calculations determined using the proposed methodology.

Response: We appreciate the commenters' input. While many commenters believed that our proposed methodology used to calculate the budget neutrality adjustment overstated the estimated cost of eliminating the 25-percent threshold policy due to a lack of accounting for certain behavioral assumptions, with one exception, commenters did not provide a methodology for quantifying such behavioral assumptions, and that suggestion does not account for other behavioral assumptions that could raise the estimated cost of the removal of the policy. The commenters' suggestion was to assume a 50-percent reduction in violations because this is the midpoint benchmark between assuming the behavioral adjustment would cause no change in behavior (a 0 percent reduction in violations) and the behavioral adjustment would lead to full compliance (a 100 percent reduction in violations), and these commenters did not provide any evidence for this assumption.

However, while we agree with the commenters that there are behavioral assumptions that could lower the estimated cost of the elimination of the 25-percent threshold policy (such as those suggested by commenters), we believe that there are equally viable behavioral assumptions that could raise the estimated cost of eliminating the 25-percent threshold policy that are also not accounted for in our proposed estimate. For example, once the 25-percent threshold policy is retired, there would be no incentive for a hospital to limit admissions from a single referring hospital, which could lead to behaviors

that would have been violations if the policy were to be fully implemented and, therefore, increase the estimated cost of elimination of the policy. In addition, the continuation of the transition to the site neutral payment system could result in a higher percentage of cases being paid under the LTCH PPS standard Federal payment rate (as opposed to the site neutral payment rate), which also could increase the costs of the elimination of the policy. Because we do not have (and commenters did not suggest) any way to use existing data or information to reasonably account for any of these behavioral assumptions, we do not believe it is appropriate to introduce unnecessary uncertainty into our estimate. On the contrary, we believe that including adjustments with insufficient support would constitute arbitrary and capricious action, in violation of the requirements of the Administrative Procedure Act. We believe that the most recent available historical data are the best basis we have to estimate the effects and costs of elimination of the 25-percent threshold policy, and do not inherently bias the estimate towards overstating or understating the cost. Therefore, we believe the most recent available historical data are the most appropriate source to use to calculate the budget neutrality adjustment, and we are adopting commenters' suggestion to use the most recent data available to determine the budget neutrality adjustment, which are claims from the March 2018 update of the FY 2017 MedPAR files.

We agree with commenters that our estimated cost of eliminating the 25-percent threshold policy based on the transitional blended payment rate for FY 2019 does not take into account that site neutral payment rate cases will no longer be paid based on a transitional blended payment basis in FY 2020 and subsequent years, and, therefore, applying a single one-time permanent budget neutrality adjustment would overly reduce payments for FY 2020 and beyond. To address this, we are modifying our proposed methodology for calculating the budget neutrality adjustment as described below to address the rolling end of the transitional blended payment rate to site neutral payment rate cases.

In this FY 2019 IPPS/LTCH PPS final rule, to account for the rolling end to the transitional blended payment rate, we are determining individual budget neutrality adjustments that correspond to the various stages of the phase-out of the transitional blended payment rate as follows:

- For FY 2019, the budget neutrality adjustment under § 412.523(d)(6) will be calculated using the estimated cost of eliminating the 25-percent threshold policy, whereby all site neutral payment rate discharges are paid the transitional blended payment rate. This temporary adjustment will only apply to the LTCH PPS standard Federal payment rate for FY 2019.
- For FY 2020, the budget neutrality adjustment will be calculated using the estimated cost of eliminating the 25-percent threshold policy, whereby all site neutral payment rate discharges that would occur in cost reporting periods beginning before October 1, 2019, are paid the transitional blended payment, and those site neutral discharges that would occur in cost reporting periods beginning on or after October 1, 2019, are paid the full site neutral payment rate. This temporary adjustment will only apply to the LTCH PPS standard Federal payment rate for FY 2020.
- For FY 2021 and beyond, the budget neutrality adjustment will be calculated using the estimated cost of eliminating the 25-percent threshold policy, whereby all site neutral payment rate discharges are paid the full site neutral payment rate. As such, the budget neutrality adjustment will be calculated using only aggregated estimated LTCH PPS standard Federal rate payments because there will be no portion of site neutral payment rate payments based on the LTCH PPS standard Federal rate for discharges occurring in FY 2021 and subsequent years. This permanent adjustment will apply to the LTCH PPS standard Federal payment rate for FY 2021 and subsequent years (consistent with our proposal prior to this modification to address the rolling end to the transitional blended payment rate).

As proposed, this budget neutrality adjustment will only be applied to the LTCH PPS standard Federal payment rate (or such portion of a transitional blended payment) because payments made under the site neutral payment rate are unaffected by the 25-percent threshold policy. We also are revising our proposed changes to § 412.523(d)(6) to reflect the a one-time, temporary budget neutrality adjustment in FY 2019 and FY 2020 and a one-time, permanent budget neutrality adjustment in FY 2021, as described above.

In summary, for the reasons discussed earlier, we are not making any adjustments to our methodology for calculating the budget neutrality adjustment for potential behavioral responses. As discussed in more detail above, we agree with the commenters that there are potential behavior responses to the full implementation of the 25-percent threshold policy, but we believe that none of these can be estimated with sufficient justification to be incorporated into an actuarial assumption in a nonarbitrary manner. We also agree with commenters that the most recent available historical data is the most appropriate source to use to calculate the budget neutrality adjustment and, as such, used claims from the March 2018 update of the FY 2017 MedPAR files for our budget neutrality calculations in this final rule. Finally, in response to public comments we received, we are modifying our proposed budget neutrality adjustment methodology so that the rolling end of the transitional blended payment rate for site neutral payment rate cases is accounted for in our estimated cost of eliminating the 25-percent threshold policy.

After consideration of the public comments we received, we are finalizing our proposed methodology, with the modification described above to account for the transitional blended payment rate payments to site neutral cases. Based on the updated LTCH claims data used for this final rule (the March 2018 update of the FY 2017 MedPAR files), we estimate that the costs of the elimination of the 25-percent threshold policy will increase aggregate LTCH PPS payments by approximately $35 million (compared to $36 million as stated in the proposed rule) in FY 2019; by approximately $33 million in FY 2020 (during the rolling end of the transitional blended payment rate for site neutral payment rate cases); and by approximately $28 million in FY 2021 and subsequent years. For this final rule, using the steps in the methodology described above, we have determined the following budget neutrality adjustment factors for the costs of the elimination of the 25-percent threshold policy:

- For FY 2019, a temporary, one-time factor of 0.990884;
- For FY 2020, a temporary, one-time factor of 0.990741; and
- For FY 2021 and subsequent years, a permanent, one-time factor of 0.991249.

To determine the budget neutrality adjustment for FY 2020, the rolling end of the transitional blended payment rate for site neutral payment rate cases in FY 2020 requires us to estimate the LTCH PPS standard Federal payment rate payments to LTCH PPS standard Federal payment rate cases and the portion of the transitional blended payment rate payments to site neutral payment rate cases that are paid based on the LTCH PPS standard Federal

payment rate in FY 2019. To do so, we used the same general method used to estimate total FY 2018 LTCH PPS payments for site neutral payment rate cases for purposes of the impact analysis in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38575 through 38576) because we continue to believe this approach is an appropriate approach to take into account the rolling end of the transitional payment method for site neutral payment rate cases.

In summary, under this approach, we grouped LTCHs based on the quarter their cost reporting periods will begin during FY 2020. For example, the 35 LTCHs with cost reporting periods that begin between October and December 2020 begin during the first quarter of FY 2020. For LTCHs grouped in each quarter of FY 2020, we modeled those LTCHs' estimated site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group would continue to be paid the transitional payment method for the site neutral payment rate cases.

For purposes of this estimate, then we assume the cost reporting period is the same for all LTCHs in each of the quarterly groups, and that this cost reporting period begins on the first day of that quarter. (For example, our first group consists of 35 LTCHs, whose cost reporting periods will begin in the first quarter of FY 2020. Therefore, for purposes of this estimate, we assumed all 35 LTCHs will begin their FY 2020 cost reporting periods on October 1, 2019.) Next, we estimated the proportion of site neutral payment rate cases in each of the quarterly groups, and we then assume this proportion is applicable for all four quarters of FY 2020. (For example, we estimate the first quarter group will discharge 6.2 percent of all FY 2020 site neutral payment rate cases and, therefore, we estimate that group of LTCHs will discharge 6.2 percent of all FY 2020 site neutral payment rate cases in each quarter of FY 2020.) Then, we used our model of estimated payments to estimate quarterly-based payments under the LTCH PPS standard Federal payment rate based on the assumptions described above.

Based on the fiscal year begin date information in the March 2018 update of the PSF and the LTCH claims from the March 2018 update of the FY 2017 MedPAR files, we found the following: 6.2 percent of site neutral payment rate cases are from 35 LTCHs whose cost reporting periods will begin during the first quarter of FY 2020; 22.2 percent of site neutral payment rate cases are from 102 LTCHs whose cost reporting periods will begin in the second quarter of FY 2020; 9.2 percent of site neutral payment rate cases are from 56 LTCHs whose cost reporting periods will begin in the third quarter of FY 2020; and 62.4 percent of site neutral payment rate cases are from 217 LTCHs whose cost reporting periods will begin in the fourth quarter of FY 2020. Therefore, the following percentages apply in the approach described above:

- First Quarter FY 2020: 6.2 percent of site neutral payment rate cases (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting periods will begin in the first quarter of FY 2020) are no longer eligible for the transitional payment method, while the remaining 93.8 percent of site neutral payment rate discharges are eligible to be paid under the transitional payment method.
- Second Quarter FY 2020: 28.4 percent of site neutral payment rate second quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting periods will begin in the first or second quarter of FY 2020) are no longer eligible for the transitional payment method, while the remaining 71.6 percent of site neutral payment rate second quarter discharges are eligible to be paid under the transitional payment method.
- Third Quarter FY 2020: 37.6 percent of site neutral payment rate third quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting periods will begin in the first, second, or third quarter of FY 2020) are no longer eligible for the transitional payment method, while the remaining 62.4 percent of site neutral payment rate third quarter discharges are eligible to be paid under the transitional payment method.
- Fourth Quarter FY 2020: 100.0 percent of site neutral payment rate fourth quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting periods will begin in the first, second, third, or fourth quarter of FY 2020) are no longer eligible for the transitional payment method. Therefore, no site neutral payment rate case discharges are eligible to be paid under the transitional payment method.

Using this approach under the modified methodology for calculating the budget neutrality adjustment described above to address the rolling end of the transitional blended payment rate to site neutral payment rate cases, as noted above, we calculated a temporary, one-time budget neutrality adjustment factor of 0.990741 that will be applied to the LTCH PPS standard Federal payment rate for FY 2020.

For all LTCH discharges occurring in FY 2021 and beyond, all site neutral payment rate discharges will be paid the full site neutral payment rate. Therefore, as described above, the permanent budget neutrality adjustment that will be applied to the LTCH PPS standard Federal payment rate for FY 2021, and subsequent years was calculated using only aggregate estimated LTCH PPS standard Federal rate payments because there will be no portion of site neutral payment rate payments based on the LTCH PPS standard Federal rate for discharges occurring in FY 2021 and subsequent years. Using the modified methodology for calculating the budget neutrality adjustment described above to address the rolling end of the transitional blended payment rate to site neutral payment rate cases, as noted above, we calculated a temporary, permanent budget neutrality adjustment factor of 0.991249 that will be applied to the LTCH PPS standard Federal payment rate for FY 2021 and subsequent years.

As noted above, using the modified methodology for calculating the budget neutrality adjustment we are adopting in this final rule, we calculated a temporary, one-time budget neutrality adjustment factor of 0.990884 for FY 2019. Accordingly, in section V. of the Addendum to this final rule, to determine the FY 2019 LTCH PPS standard Federal payment rate, as we proposed, we applied the temporary one-time budget neutrality adjustment factor of 0.990884 for the costs of the elimination of the 25-percent threshold policy. The FY 2019 LTCH PPS standard Federal payment rate shown in Table 1E reflects this adjustment.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section VIII. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20470 through 20515; 83 FR 20683 through 28604), we proposed changes to the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program;
- In section VIII.B., the PCHQR Program; and
- In section VIII.C., the LTCH QRP.

In addition, in section VIII.D. of the preamble of the proposed rule (83 FR 20515 through 20544), we proposed changes to the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for

eligible hospitals and critical access hospitals (CAHs).

We refer readers to section I.A.2. of the preamble of this final rule for a discussion of the Meaningful Measures Initiative.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of the Hospital IQR Program

The Hospital IQR Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality health care for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital IQR Program incentivizes hospitals to improve health care quality and value, while giving patients the tools and information needed to make the best decisions for them.

We seek to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of widely-agreed upon quality measures. We have worked with relevant stakeholders to define measures of quality in almost every setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and outcomes. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348) for the measures we have previously adopted for the Hospital IQR Program measure set through the FY 2019 and FY 2020 payment determinations and subsequent years.

b. Maintenance of Technical Specifications for Quality Measures

The technical specifications for chart-abstracted clinical process of care measures used in the Hospital IQR Program, or links to websites hosting technical specifications, are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the QualityNet website at: *http://www.qualitynet.org/.* We generally update the Specifications Manual on a semiannual basis and include in the updates detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required chart-abstracted clinical process of care measures.

The technical specifications for electronic clinical quality measures (eCQMs) used in the Hospital IQR Program are contained in the CMS Annual Update for Hospital Quality Reporting Programs (Annual Update). This Annual Update is posted on the Electronic Clinical Quality Improvement (eCQI) Resource Center web page at: *https://ecqi.healthit.gov/.* We generally update the measure specifications on an annual basis through the Annual Update, which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs. We refer readers to section VIII.A.11.d.(1) of the preamble of this final rule in which we discuss the transition to Clinical Quality Language (CQL) beginning with the Annual Update that was published in May 2018 and for implementation in CY 2019.

In addition, we believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program.

We recognize that some changes made to measures undergoing maintenance review are substantive in nature and might not be appropriate for adoption using a subregulatory process. For substantive measure updates, after submission to the Measures Under Consideration list and evaluation by the Measure Applications Partnership (MAP), we will continue to use rulemaking to adopt those substantive measure updates for the Hospital IQR Program. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57111) for additional discussion of the maintenance of technical specifications for quality measures for the Hospital IQR Program. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional details on the measure maintenance process.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20470), we did not propose any changes to our policies on the measure maintenance process.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act was amended by the Deficit Reduction Act (DRA) of 2005. Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the *Hospital Compare* website, *http://www.medicare.gov/hospitalcompare* after a 30-day preview period (78 FR 50776 through 50778).

Information is available to the public on the *Hospital Compare* website. *Hospital Compare* is an interactive web tool that assists beneficiaries and providers by providing information on hospital quality of care to those who need to select a hospital and to support quality improvement efforts. The Hospital IQR Program currently includes measures capturing performance data on many aspects of care provided in the acute inpatient hospital setting. For more information on measures reported on *Hospital Compare,* we refer readers to the website at: *http://www.medicare.gov/hospitalcompare.*

Other information that may not be as relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations are not reported on the *Hospital Compare* website and

may be made available on other CMS websites, such as *https://data.medicare.gov.* CMS also provides stakeholders access to archived data from the *Hospital Compare* website, which can be found at: *https://data.medicare.gov/data/archives/hospital-compare.* In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20470 through 20471), we did not propose any changes to these policies.

We note that in section VIII.A.10. of the preamble of this final rule, we discuss our efforts to provide stratified data in hospital confidential feedback reports and potentially making stratified data publicly available on the *Hospital Compare* website in the future.

d. Meaningful Measures Initiative and the Hospital IQR Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20470 through 20500), we proposed a number of new policies for the Hospital IQR Program. We developed these proposals after conducting an overall review of the Program under our new ''Meaningful Measures Initiative,'' which is discussed in more detail in section I.A.2. of the preamble of this final rule. The proposals reflected our efforts to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable). They also reflect our efforts to improve the usefulness of the data that we publicly report in the Hospital IQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how providers are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website.

As part of this review, we stated that we took a holistic approach to evaluating the Hospital IQR Program's current measures in the context of the measures used in the other IPPS quality programs (that is, the Hospital Readmissions Reduction Program, the HAC Reduction Program, and the Hospital VBP Program). We view the value-based purchasing programs together as a collective set of hospital value-based programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment of illness, and making care affordable—but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs.

The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS Survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending Per Beneficiary (MSPB)—Hospital measure (which addresses the Meaningful Measures Initiative priority of making care affordable). As part of this larger quality program strategy, we believe the Hospital IQR Program should focus on measure topics not covered in the other programs' measures. Although new Hospital VBP measures will be selected from the measures specified under the Hospital IQR Program, the Hospital VBP Program measure set will no longer necessarily be a subset of the Hospital IQR Program measure set. As discussed in section I.A.2. of the preamble of this final rule, we are engaging in efforts aimed at evaluating and streamlining regulations with the goal to reduce unnecessary costs, increase efficiencies, and improve beneficiary experience. While there may be some overlap between the Hospital IQR Program measure set and the Hospital VBP measure set, allowing removal of duplicative measures from the Hospital IQR Program once they have been adopted into the Hospital VBP Program would further these goals. We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20471), we did not propose any changes to this policy.

3. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. In the proposed rule, we did not propose any changes to these policies. We also refer readers to section I.A.2. of the preamble of this final rule, in which we describe the Meaningful Measures quality topics that we have identified as high impact measurement areas that are relevant and meaningful to both patients and providers.

Furthermore, in selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework we have developed for the Hospital VBP Program. Because measures adopted for the Hospital VBP Program must first have been adopted under the Hospital IQR Program and publicly reported on the *Hospital Compare* website for at least one year, these two programs are linked. We view the value-based purchasing programs, including the Hospital VBP Program, as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries.

4. Removal Factors for Hospital IQR Program Measures

a. Current Policy

We most recently updated our measure removal and retention factors in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643).[268] The previously adopted removal factors are:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (that is, ''topped-out'' measures): Statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10.
- Factor 2. A measure does not align with the current clinical guidelines or practice.
- Factor 3. The availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic).
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 7. It is not feasible to implement the measure specifications.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20472), we did not propose to modify any existing removal factors.

b. New Measure Removal Factor

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20472), we proposed to adopt an additional factor to consider when evaluating measures for removal from the Hospital IQR Program measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of the preamble of this final rule with respect to our new ''Meaningful Measures Initiative,'' we are engaging in efforts to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track confidential feedback preview reports and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the Hospital IQR Program, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the Hospital IQR Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including payment determination data) are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the Hospital IQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We refer readers to section VIII.A.5.b. of the preamble of this final rule, where we discuss our proposals to remove a number of measures based on this proposed removal factor.

Comment: The majority of commenters expressed support for the adoption of the new measure removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program.'' Many of these commenters supported the adoption of removal Factor 8 because they believe this factor will support efforts to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for our beneficiaries while reducing administrative and other program-related costs. Some commenters also expressed support for removal Factor 8 because it aligns with CMS' goal of

[268] As discussed above, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove, suspend, or replace a measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) for more information on the criteria we consider for removing quality measures. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) for more information on the additional factors we consider in removing quality measures and the factors we consider in order to retain measures. We note that in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we clarified the criteria for determining when a measure is ''topped-out.''

moving the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Other commenters expressed support for removal Factor 8 because it simplifies how providers are reporting and accessing data. Several commenters stated that the new measure removal factor is a long overdue addition to the program.

A number of commenters supported the adoption of removal Factor 8 because it would allow for the removal of inappropriately burdensome measures, and noted that costs are an important factor to consider when evaluating measures for removal from the Hospital IQR Program measure set. Other commenters appreciated that CMS has identified costs beyond those associated with data collection and submission as part of its evaluation of measures under this new removal factor.

Numerous commenters supported the adoption of removal Factor 8 because it would allow for the removal of measures with limited utility, such as measures that do not support program objectives of informing beneficiary decision-making and improving hospital quality of care, as well as for the removal of duplicative measures contained in multiple quality programs.

Response: We thank these commenters for their support.

Comment: Many commenters who supported the adoption of removal Factor 8 also encouraged CMS to provide additional information and transparency in this final rule on how it intends to evaluate the costs and benefits associated with a measure proposed for removal, including the criteria used in assessing costs, the nature of the burden that the removal of a measure relieves, and the methods used to assess whether the costs associated with a measure outweigh the benefits of its continued use in the program. Some of those commenters stated that costs and benefits can be difficult to define and that various stakeholders may have different perspectives on the costs and benefits of measures.

Response: We agree with commenters that various stakeholders may have different perspectives on how to define costs as well as benefits. Because of these challenges, we intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare payers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs, financial and otherwise, of maintaining the specific measure in the Hospital IQR Program. We note that we intend to assess the costs and benefits to all program stakeholders, including but not limited to, those listed above and provide a robust discussion of these costs and benefits in the proposed rules. We further note that our assessment of costs and benefits is not limited to a strictly quantitative analysis.

Comment: A few commenters requested clarification on whose benefit is being considered when evaluating whether ''the costs associated with the measure outweigh the benefit of its continued use in the program.''

Response: We intend to balance the costs with the benefits to a variety of stakeholders. These stakeholders include, but are not limited to, patients and their families or caregivers, providers, the healthcare research community, healthcare payers, and patient and family advocates. We also believe that while a measure's use in the Hospital IQR Program may benefit many entities, a key benefit is to patients and their caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. For each measure, the relative benefit to each stakeholder may vary; thus, we believe that the benefits to be evaluated for each measure are specific to the measure itself and the original rationale for including the measure in the program.

Comment: A few commenters urged CMS to develop a standardized evaluation and scoring system with significant multi-stakeholder input, to ensure that Factor 8 appropriately balances the needs of all healthcare stakeholders. One commenter further recommended that CMS convene a set of working groups in order to consider input from the provider community.

Response: While we do not currently plan to develop a standardized evaluation and scoring system for use of Factor 8, we value transparency in our processes, and continually seek input from multiple stakeholders through outreach and education efforts, such as through webinars, national provider calls, stakeholder listening sessions, as well as through rulemaking and other collaborative engagements with stakeholders. We will continue to do so in the future when proposing measures for adoption or removal from the Hospital IQR Program. Further, preliminary input from stakeholders on data collection and reporting burden was instrumental in deriving the newly proposed removal factor. As discussed above, the removal of measures under Factor 8 will function as a balancing test between the cost of ongoing maintenance, reporting/collection, and public reporting against the benefits associated with reporting that data. We intend to consider the costs and benefits to all program stakeholders. Furthermore, we intend to take multiple sources of evidence into account when proposing to remove measures under any of the removal factors and always welcome stakeholder input.

Comment: Many commenters recommended that CMS consider additional types of costs and benefits under Factor 8, including:

- Insights from stakeholders, including patients and providers, on costs and benefits, as well as potential unintended consequences of removal (such as a decline in performance, particularly if the measure would not be captured in any of the other IPPS programs);
- Benefits of consistent measure sets;
- Multiple methods of data collection and reporting;
- Costs associated with designing, developing, and implementing a measure;
- Costs associated with updating clinical processes and workflows to adapt to an updated measure set;
- Providers' costs to contract with vendors for data collection or reporting;
- Development and implementation of processes to perform well on the measure; and
- Whether measure implementation adds or duplicates tasks within provider processes.

Response: We note that in our proposal to adopt this measure removal factor (83 FR 20472), we stated that we will evaluate costs and benefits on a case-by-case basis and identified several types of costs to provide examples of costs which we would consider in our evaluation. We noted that these costs include, but are not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including maintenance and

public display; and/or (5) the provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable). This was not intended to be a complete list of the potential types of costs to consider in evaluating measures.

We also understand that while a measure's use in the Hospital IQR Program may benefit many entities, the primary benefit is to patients and caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted, and are illustrated through the domains of the Meaningful Measures Initiative. When the costs associated with a measure outweigh the evidence supporting the benefits to patients with the continued use of a measure in the Hospital IQR Program we believe it may be appropriate to remove the measure from the program.

We appreciate commenters' suggestions for other types of costs and benefits to consider when evaluating the costs and benefits of each measure on a case-by-case basis under measure removal Factor 8, and will take these into consideration for future years.

Comment: One commenter believed that cost assessments should not only consider the reporting method (for example, eCQMs, claims-based) but also whether a more efficient alternative is available to collect the performance data.

Response: We agree with the commenter that it is useful to consider whether a more efficient alternative is available to collect performance data and believe it would be appropriate to consider this in our evaluation of measures under measure removal Factor 8. We will also consider the value of longer term efficiencies when evaluating costs, such as the costs associated with creating and sustaining EHR-based measures like eCQMs.

Comment: A few commenters encouraged CMS to not remove measures simply because a previously finalized measure was too difficult to implement, thereby creating a gap in the measure set, but rather to attempt to identify ways to gather the appropriate data by different means.

Response: We note that it is not our intent to remove measures solely based on ease of implementation. Further, implementation concerns are something we take into account when proposing to adopt a measure. As discussed above, the removal of measures under the newly proposed Factor 8 will serve to balance the costs of ongoing maintenance, reporting/collection, and public reporting with the benefit associated with reporting that data, including the benefits to patients and their caregivers through incentivizing the provision of high quality care by providing publicly reported data regarding the quality of care available. We continually seek ways to improve the Hospital IQR Program measure set, including through identification of more efficient means of capturing data.

Comment: A few commenters recommended that any measures removed under Factor 8 be replaced by comparable or better measures in the same domain, such as measures that are more outcomes-oriented or easier to implement.

Response: Retaining a strong measure set that addresses critical quality issues is one benefit that we would consider in evaluating whether a measure should be potentially removed from the Hospital IQR Program measure set.

Comment: One commenter observed that many hospitals do not review feedback reports because these hospitals track quality improvement using internal systems, and therefore this cost should not be considered in a cost analysis of measures.

Response: We recognize that not all providers review the feedback reports provided through our quality reporting programs. However, a majority of providers do view and download these reports (for example, in May 2018, over 83 percent of hospitals downloaded their Hospital IQR Program hospital-specific reports for claims-based outcome measures, as tracked by our QualityNet system) in addition to their internally generated feedback reports. Therefore, we continue to believe that it is important to consider this as one cost of continued use of the measure in the Hospital IQR Program. We note that the cost of reviewing feedback reports is only one example of the costs that may be associated with a measure. We will continue to consider this cost among the other costs of a measure's continuing use in the Hospital IQR Program.

Comment: One commenter requested that CMS perform an impact analysis before finalizing the addition of removal Factor 8, particularly to take into consideration the impact of measure removals on safety-net providers, and for CMS to consider a stop-loss policy if the financial impact of these changes results in a larger than a 10 percent reduction in performance payments each year. Another commenter recommended that CMS publish annual assessments to determine how quality measures from CMS have impacted patient care and clinical outcomes.

Response: We intend to evaluate the costs and benefits of potentially removing any measure from the Hospital IQR Program under removal Factor 8 on a case-by-case basis. In our evaluation of costs and benefits, we intend to evaluate the effects on providers, including safety-net providers, of retaining or removing the measure from the Hospital IQR Program, as well as the effects on patients and their caregivers with regards to access to publicly reported data regarding the quality of care available. We do not believe that an impact analysis on whether or not to adopt the measure removal factor itself is necessary because of our intent to apply it through a case-by-case evaluation that will take into account various considerations of costs and benefits to multiple stakeholders as described above, as well as the circumstances and facts unique to a given measure.

Comment: A commenter expressed support for the simplification resulting from removing duplicative measures used in multiple quality programs, but noted that such removals would not result in provider cost reduction because hospitals would still be required to monitor those measures retained in another quality program.

Response: We recognize that hospitals would still be required to monitor measures removed from one program, but retained in another quality program. However, we believe that simplification benefits will be gained by hospitals that have been reviewing their multiple reports and will no longer be required to identify discrepancies in reporting and identify whether those discrepancies are due to differing measure specifications or due to a CMS measure calculation error. Furthermore, we believe this simplification will benefit patients and caregivers who view measure results information on the *Hospital Compare* website because they will be less likely to be confused if they see slightly different measure results for the same measures for the same hospital but through multiple programs.

Comment: Many commenters did not support the adoption of removal Factor 8. Several commenters did not support the adoption of removal Factor 8 due to the perceived lack of transparency on the methods or criteria that would be used to assess the costs and benefits associated with a measure. A number of commenters asserted that the assessment of value should also include a clear prioritization of the needs of patients.

Response: We wish to clarify that it is not our intent to remove measures that continue to benefit patients or providers solely because these measures incur administrative costs to CMS or to others. We will be transparent in our assessment of measures under this measure removal factor. As described above, there are various considerations of costs and benefits, direct and indirect, financial and otherwise, that we will evaluate in applying removal Factor 8, and we will take into consideration the perspectives of multiple stakeholders. However, because we intend to evaluate each measure on a case-by-case basis, and each measure has been adopted to fill different needs of the Hospital IQR Program, we do not believe it would be meaningful to identify a specific set of assessment criteria to apply to all measures.

In addition, we note that the benefits we will consider center around benefits to patients and caregivers as the primary beneficiaries of our quality reporting and value-based payment programs. When we propose a measure for removal under this measure removal factor, we will provide information on the costs and benefits we considered in evaluating the measure. We continue to monitor and evaluate our programs to identify their benefit with respect to quality of care and patient safety as well as their costs with respect to provider burden, potentially contradictory public information for beneficiaries to analyze in their decision making, and measure maintenance. When our analyses indicate that a measure's costs outweigh the benefit of continuing to use the measure in the program, we will propose to remove that measure through notice and comment rulemaking.

Comment: A few commenters believed that the existing seven factors are sufficient for determining whether it is appropriate to remove a measure.

Response: While we acknowledge that there are seven factors currently adopted that may be used for considering measure removal from the Hospital IQR Program, we believe the proposed new measure removal factor adds a new criterion that is not captured in the other seven factors. The proposed new measure removal factor will help advance the goals of the Meaningful Measures Initiative, which aims to improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers.

Comment: A number of commenters expressed the concern that the benefits associated with a measure proposed for removal would be determined based solely on the cost reductions associated with reduced administrative burden for hospitals. Several commenters also expressed concern that Factor 8 could result in the removal of measures based solely on cost reductions to providers and/or CMS, and thus not consider or prioritize patient perspectives. One commenter urged CMS to prioritize the needs of patients and consumers when assessing the benefits of a measure under Factor 8, by taking into consideration the public's right to quality and cost transparency, as well as consumers' reliance on publicly available information to make important healthcare decisions. Another commenter expressed the concern that costs are typically imposed on providers while benefits are rendered to beneficiaries, and therefore does not believe that costs and benefits can be compared.

Response: As described above, there are various considerations of costs and benefits, direct and indirect, financial and otherwise, that we will evaluate in applying removal Factor 8, and we will take into consideration the perspectives of multiple stakeholders. We intend to apply measure removal Factor 8 on a case-by-case basis because the costs and benefits associated with each measure are unique to that measure. We agree with the commenter that while a measure may contribute costs to many entities, providers do bear the primary cost of participation in Hospital IQR Program. However, we will assess the costs to all stakeholders, including but not limited to, patients, caregivers, providers, CMS, and other entities, in determining whether to propose removal of a measure under Factor 8. We also agree that while a measure's use in the Hospital IQR Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. We also believe that the benefits of measures can include benefits for all stakeholders, including but not limited to, patients, caregivers, providers, CMS, advocacy organizations, healthcare researchers, healthcare purchasers, and others. We intend to identify the relevant stakeholders and assess both costs and benefits to these stakeholders in our assessment of each measure.

Comment: Some commenters expressed concern that this measure removal factor could allow providers to recommend removal of measures they do not support based on the argument that these measures are costly.

Response: We agree that it is possible that providers may recommend removal of measures they do not support based on the argument that these measures are costly. However, input from providers is only part of our case-by-case evaluation of measures. We also intend to consider input from other stakeholders, including patients, caregivers, advocacy organizations, healthcare researchers, healthcare purchasers, and other parties as appropriate to each measure. We will weigh input we receive from all stakeholders with our own analysis of each measure to make our case-by-case determination of whether it would be appropriate to remove a measure based on its costs outweighing the benefit of its continued use in the program.

Comment: A few commenters expressed concern that the lack of references to patient considerations in the proposed rule appeared to suggest that this measure removal factor does not take into account the value of a measure to beneficiaries, and noted that the Factor 8 does not appear to include the following benefits associated with patient perspectives:

- Saving lives;
- Ensuring high quality care;
- Ensuring patient safety; and
- Facilitating consumer access to information.

Response: We intend to consider all benefits of measure, similar to our intent to consider all costs, when assessing whether the costs outweigh the benefits of the measure's continued use in the Hospital IQR Program. The likelihood of a measure to significantly improve patient well-being is a non-quantifiable benefit that would be weighed against potential costs to ensure that measures that save lives and ensure patient safety are retained when appropriate. We agree with the commenters that these benefits are all potential benefits associated with a measure's continued use in the Hospital IQR Program and will continue to consider these and other benefits in our evaluations.

Comment: A few commenters urged CMS to retain measures that, while costly or burdensome, hold value to beneficiaries, because in these cases the benefits would justify the cost. A few commenters noted certain measures of value to beneficiaries, such as measures that continuously monitor the aspects of care quality that are deemed essential to high-quality patient care or have serious consequences if done poorly. Some of these commenters further recommended that measures of such value to beneficiaries should never be removed from quality programs, even if they are topped-out.

Response: We appreciate the commenters' feedback. We intend to consider all benefits of a measure, including the ability of a measure to promote patient safety and experience, when assessing whether the costs outweigh the benefits of the measure's continued use in the Hospital IQR Program.

Comment: One commenter questioned how measures that were not too costly to implement could now be too costly to maintain in the program. Another commenter asserted the value of measures is self-evident in their initial adoption, and that the removal of any measure would thereby decrease the ability of that measure to improve patient care and reduce Medicare costs, and concluded that the removal of a measure, by definition, would decrease the effectiveness of the program itself.

Response: There are several ways that a measure for which the benefit once outweighed costs may now have the costs outweigh its benefit. As one example, measures that incentivize providers to update clinical workflows or adopt specific infrastructure may become less beneficial over time as an increasing number of providers adopt the appropriate processes into their workflows and performance approaches or reaches topped-out status. Under this example, the measure was highly beneficial upon adoption but may become less beneficial as it incentivizes a smaller number of providers. Therefore, such measures may still cost the same, but because of their now reduced benefit these costs may now outweigh the benefit of continuing to maintain and require reporting on these measures.

We also disagree with the assertion that removing measures from the program inherently decreases the effectiveness of the program itself. We believe one of the Hospital IQR Program's primary benefits to patients and the public is its ability to collect and publicly report data for patients to use in making decisions about their care. We further believe maintaining an unnecessarily large or complicated measure set including measures that are not meaningful to patients hampers the program's effectiveness at presenting valuable data in a useful or usable manner. For this reason, we believe it is in the interest of patients for the Hospital IQR Program to ensure an individual measure continues to benefit patients. Furthermore, we note that removal of such measures would free up CMS programmatic resources to focus on other priority measures or areas of the Hospital IQR Program.

Comment: A few commenters expressed concern that this factor is not supported by scientific criteria.

Response: We believe it is important to adequately weigh the potential benefits of a measure in determining whether the costs outweigh those benefits. However, we disagree that this can only be achieved by applying scientific criteria. We believe that an appropriate measure set for a specific program is achieved by applying a balanced set of factors and taking into consideration the potential impact to multiple stakeholders to ensure that each measure serves a purpose in the program, and this is one element of that set of factors.

After consideration of the public comments we received, we are finalizing our proposal to adopt measure removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program,'' beginning with the effective date of the FY 2019 IPPS/LTCH PPS final rule as proposed.

5. Removal of Hospital IQR Program Measures

We refer readers to section VIII.A.4. of the preamble of this final rule for a discussion of our current and proposed measure removal criteria. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20472 through 20485), we proposed to remove a total of 39 measures from the Hospital IQR Program across the FYs 2020, 2021, 2022, and 2023 payment determinations. In this final rule, we are finalizing removal of all 39 of those measures with some modification as discussed below.

a. Removal of Measure—Removal Factor 4, Performance or Improvement on a Measure Does Not Result in Better Patient Outcomes: Hospital Survey on Patient Safety Culture

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20473), we proposed to remove the Hospital Survey on Patient Safety Culture measure beginning with the CY 2018 reporting period/FY 2020 payment determination based on removal Factor 4, ''performance or improvement on a measure does not result in better patient outcomes.'' The Hospital Survey on Patient Safety Culture measure was adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49662 through 49664) for the FY 2018 payment determination and subsequent years, to allow us to assess whether and which patient safety culture surveys were being utilized by hospitals and the frequency of their use. In that rule, we stated our belief that this would be a time-limited measure that would assist us in assessing the feasibility of implementing a single survey on patient safety culture in the future (80 FR 49661). When we adopted the measure, we acknowledged that we had not yet determined for how many years we would keep the measure in the Hospital IQR Program (80 FR 49664). By design, this structural measure does not provide information on patient outcomes, because hospitals are asked only whether they administer a patient safety culture survey, and therefore, does not result in better patient outcomes, removal Factor 4.

Our data indicate that 98 percent of hospitals have reported they use some version of a patient safety culture survey; a large majority of hospitals (69.6 percent) that reported on the measure for the CY 2016 reporting period/FY 2018 payment determination use the AHRQ Surveys on Patient Safety Culture (SOPS).[269] While we proposed to remove this measure, the data already collected would still help inform consideration of a potential future patient safety culture measure for the Hospital IQR Program. However, at this time, we believe that the burden of reporting this measure outweighs the benefits of continued data collection. Therefore, we proposed to remove the Hospital Survey on Patient Safety Culture measure for the CY 2018 reporting period/FY 2020 payment determination (for which the data submission period is April 1, 2019 through May 15, 2019) and subsequent years.

Comment: A majority of commenters supported CMS' proposal to remove the Hospital Survey on Patient Safety Culture measure from the Hospital IQR Program beginning with the CY 2018 reporting period/FY 2020 program year. One commenter specifically noted its opinion that collecting, analyzing, and reporting data on this measure is burdensome. A few commenters stated their belief the measure no longer has value. Another commenter supported removal of the Hospital Survey on Patient Safety Culture measure, but recommended CMS evaluate opportunities to adopt another measure that utilizes the data gathered under this

[269] The Agency for Healthcare Research and Quality (AHRQ) sponsored the development of patient safety culture assessment tools for various healthcare organizations which assess patient safety culture in a health care setting. Patient safety culture is the extent to which an organization's culture supports and promotes patient safety. The survey tools are measured by what is rewarded, supported, and accepted, expected, and accepted in an organization as it relates to patient safety. (*https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/index.html*).

survey, as opposed to the current structural measure.

Response: We thank the commenters for the support. While we continue to believe that patient safety culture is an important topic for hospitals, as a structural measure, this particular measure no longer meets the needs of the Hospital IQR Program. We appreciate the commenter's suggestion and we intend to evaluate opportunities to adopt another non-structural measure utilizing the data gathered under this survey.

Comment: A number of commenters did not support CMS' proposal to remove the Hospital Survey on Patient Safety Culture measure from the Hospital IQR Program beginning with the CY 2018 reporting period/FY 2020 program year. Several commenters expressed concern that removing this measure would encourage hospitals to stop assessing patient safety culture, whereas requiring the measure incentivizes hospitals to improve their patient safety culture, and asserted their belief that there is a strong correlation between safety culture assessment and improved clinical outcomes.

Response: We acknowledge commenters' concerns that some hospitals might stop assessing patient safety culture; however, we believe most hospitals are committed to assessing and improving their patient safety culture and will continue to survey employees regarding patient safety culture. Our data indicate that 98 percent of hospitals use some version of a patient safety culture survey, such that no further incentive is required to encourage hospitals to implement patient safety culture surveys.

Comment: Despite opposing the removal of the hospital survey on patient safety culture, one commenter acknowledged that these surveys have become a part of routine operational assessments and expressed their belief that most organizations will continue to conduct the survey regardless of whether it is required by the Hospital IQR Program. Another commenter asserted that requiring the measure allows for meaningful comparisons between hospitals. A third commenter expressed their belief that CMS should prioritize patient safety culture, and further stated that surveys are the most effective means of capturing hospital employees' feedback on the safety culture.

Response: We agree with commenters that assessing patient safety culture has become a routine part of operational safety assessments, and further agree that surveys can be an effective way of capturing employee feedback on a hospital's patient safety culture. We therefore believe that hospitals will continue to survey their employees about patient safety culture after this measure is removed from the Hospital IQR Program.

However, we disagree that the measure allows for meaningful comparisons between hospitals due to its design as a structural measure. The Hospital Survey on Patient Safety Culture measure does not collect data on either a hospital's survey results or those results' impact on patient safety outcomes. As a result, comparisons between hospitals on this measure only inform the public about whether or not hospitals use a patient safety culture survey. Because the data indicate 98 percent of hospitals are now administering patient safety culture surveys, we believe continuing to collect and publicly report this data does not capture information that will incentivize specific improvements for hospitals or provide valuable information for use by patients in making decisions about where to seek care. Therefore, we do not believe continuing to collect—or, conversely, ceasing to collect—data under this measure will assess or affect the patient safety culture within hospitals.

Comment: A number of commenters suggested refining the measure instead of removing it. One commenter highlighted that there are a variety of methods to survey and report data that allow hospitals to use a mechanism that minimizes burden while generating important information to manage patient safety culture. Another commenter recommended modifying the measure to reflect a more meaningful measure of actions taken to promote a strong patient safety culture, or modifying the measure to have hospitals report scores on a particular safety culture domain that is consistent across safety culture surveys. A third commenter suggested implementing this measure as an outcomes measure instead of a structural measure. Another commenter recommended that the survey be conducted bi-annually rather than annually because hospital safety culture can be slow to change.

Response: We appreciate commenters' recommendations regarding potential refinements to this measure. We agree that patient safety cultures generally do not change overnight. While we are finalizing removal of this measure, we believe the data already collected could help inform consideration and/or development of a potential future patient safety culture measure that might assess patient safety culture in more detail, as commenters recommended. We will therefore take these recommendations into consideration for future measure development.

After consideration of the public comments we received, we are finalizing removal of the Hospital Survey on Patient Safety Culture from the Hospital IQR Program measure set beginning with the CY 2018 reporting period/FY 2020 payment determination as proposed.

b. Removal of Measures—Removal Factor 8, the Costs Associated With a Measure Outweigh the Benefit of Its Continued Use in the Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20473 through 20484), we proposed to remove a number of measures under our proposed new removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, across the FYs 2020, 2021, 2022, and 2023 payment determinations. These proposals are presented by measure type: (1) Structural measure: Safe Surgery Checklist Use; (2) patient safety; (3) claims-based readmission; (4) claims-based mortality; (5) hip/knee complications; (6) Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158); (7) clinical episode-based payment; (8) chart-abstracted clinical process of care; and (9) eCQMs. These are discussed in detail below.

(1) Structural Measure: Safe Surgery Checklist Use

We refer readers to the FY 2013 IPPS/LTCH PPS final rule where we adopted the Safe Surgery Checklist Use measure (77 FR 53531 through 53533). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20473 through 20474), we proposed to remove the Safe Surgery Checklist Use measure beginning with the CY 2018 reporting period/FY 2020 payment determination under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We refer readers to section VIII.A.4.b. of the preamble of the proposed rule, where we acknowledge that costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, we believe it may be unnecessarily costly for health care providers to report a measure for which our analyses show that there is no meaningful difference in performance or there is little room for continued improvement.

Based on our review of reported data on this measure, there is no meaningful difference in performance or there is little room for continued improvement. Our analysis is captured by the table below:

Payment determination	Encounters	Number of hospitals	Rate	75th percentile	90th percentile	Truncated COV
FY 2017	CY 2015 Q1–Q4	3,201	0.961	100.00	100.00	0.201
FY 2018	CY 2016 Q1–Q4	3,195	0.968	100.00	100.00	0.181

Based on the analysis above, the national rate of ''Yes'' response for this measure is nearly 1.0, or 100 percent, nationwide, and has remained at this level for the last two years, such that there is no distinguishable difference in hospital performance between the 75th and 90th percentiles. In addition, the truncated coefficient of variation (COV) has decreased such that it is trending towards 0.10. Our analysis indicates that performance on this measure is trending towards topped-out status, that is to say, safe surgery checklists for surgical procedures are widely in use and there is little room for improvement on this structural measure.

In addition, we believe this measure is of more limited utility for internal hospital quality improvement efforts. This structural measure of hospital process determines whether a hospital utilizes a safe surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods. For the measure, hospitals indicate by ''Yes'' or ''No'' whether or not they use a safe surgery checklist for surgical procedures that includes safe surgery practices during each of the aforementioned perioperative periods. The measure does not require a hospital to report whether it uses a checklist in connection with each individual inpatient procedure.

Furthermore, removal of this measure would alleviate burden to hospitals associated with reporting on this measure. We anticipate a reduction in information collection burden because reporting on this measure takes hospitals approximately two minutes each year (77 FR 53666). As such, we believe the costs associated with reporting on this measure outweigh the associated benefits of keeping it in the Hospital IQR Program because it no longer meaningfully supports the Program objective of informing beneficiary choice since safe surgery checklists are widely in use.

Therefore, we proposed to remove the Safe Surgery Checklist Use measure beginning with the CY 2018 reporting period/FY 2020 payment determination, for which the data submission period is April 1, 2019 through May 15, 2019, under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We also refer readers to the CY 2018 OPPS/ASC PPS final rule in which the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs finalized removal of the Safe Surgery Checklist Use measure beginning with the CY 2018 reporting period/CY 2020 payment determination for the Hospital OQR Program and with the CY 2019 payment determination for the ASCQR Program (82 FR 52363 through 52364; 82 FR 52571 through 52572; and 82 FR 52588 through 52589).

Comment: Many commenters supported CMS' proposal to remove the Safe Surgery Checklist Use measure from the Hospital IQR Program beginning with the CY 2018 reporting period/FY 2020 payment determination. A few commenters specifically supported CMS' position that the cost of collecting and reporting data under the measure outweighs the benefit of retaining it in the Hospital IQR Program. Other commenters noted that the measure's nature as a structural measure hinders its ability to provide data on whether the communication among surgical team members was effective in translating anticipated critical events or improving patient outcomes.

One commenter stated that while there is value in ensuring quality communication during critical phases of the surgical patient experience, the high level of compliance for this measure strongly suggests that the measure is deeply embedded in clinical workflows and processes, leaving little to be gained from continued reporting of the measure. The commenter agreed that use of a safe surgery checklist has been widely adopted by hospitals, but asserted that there is little evidence demonstrating that the measure provides educational opportunities for improving the ongoing competency of surgical teams regarding patient harm prevention. The commenter asserted that education aimed at reducing near-miss events has been proven to be effective and recommended that CMS revisit and refine the measure criteria to ensure that it requires education to be provided and to demonstrate improved communication ongoing surgical team competency.

Response: We thank commenters for their support. We agree that the high level of compliance for this measure strongly suggests that safe surgery checklist use is deeply embedded in clinical workflows and processes, indicating there is little room for improvement under the current measure. We also appreciate commenters' recommendations for future measures of perioperative communication, and will take these into consideration for future years.

Comment: A number of commenters opposed CMS' proposal to remove the Safe Surgery Checklist Use measure from the Hospital IQR Program beginning with the CY 2018 reporting period/FY 2020 payment determination. A few commenters expressed their concern about the potential adverse impact removing this measure might have on patient care, asserting that hospitals may stop using safe surgery checklists if the measure is removed. One commenter asserted that the potential negative impact of removal outweighs any projected benefit associated with no longer collecting the information, and recommended that the measure be kept as a reminder to the surgical community to practice good communication in the operating room. Another commenter asserted that the rate of ''never events'' occurring in hospitals indicates the measure is not topped out, and further expressed their concern that many hospitals may only use safe surgery checklists in a cursory or rote manner. The commenter therefore recommended that CMS ensure never events and wrong site surgeries be adequately monitored through another IPPS quality program to avoid negative patient outcomes before removing the Safe Surgery Checklist Use measure. Another commenter recommended that CMS delay removing the measure until use of a safe surgery checklist has been added as a Condition of Participation for hospitals.

Response: While we understand commenters' position that retaining the measure may add some value to the program, we would like to make clear that high performance on the Safe Surgery Checklist Use measure is not

intended to indicate whether perioperative communication among surgical team members is effective. This measure is not specified to assess the effectiveness of a team's communication, only whether a safe surgery checklist is used. Therefore, we do not believe continuing to collect *or* ceasing to collect data under this measure will assess or affect the effectiveness of perioperative communication within hospitals. As a result, we believe the administrative burden to hospitals associated with collecting and reporting this data to CMS outweighs the benefit of publicly reporting this data. We will also take commenters' recommendations regarding updates to the Conditions of Participation and monitoring of never-events into consideration as we continue to implement the Meaningful Measures initiative across CMS' quality programs.

Comment: One commenter recommended that for measures on which providers continually have high scores, CMS should improve the measures instead of removing them from the Hospital IQR Program entirely.

Response: We appreciate the recommendation to revise this measure and will take this into consideration as we continue to develop and refine measures for the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing removal of the Safe Surgery Checklist Use measure from the Hospital IQR Program measure set beginning with the CY 2018 reporting period/FY 2020 payment determination as proposed.

(2) Patient Safety Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20474 through 20475), we proposed to remove the Patient Safety and Adverse Events Composite [270] (PSI 90) beginning with the CY 2018 reporting period/FY 2020 payment determination and five National Health and Safety Network (NHSN) hospital-acquired infection (HAI) measures beginning with the CY 2019 reporting period/FY 2021 payment determination under the proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

[270] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS quality programs.

In this final rule, we wish to clarify that our proposals in the FY 2019 IPPS/LTCH PPS proposed rule, and ultimately, our finalized policy as discussed below, to remove these measures from the Hospital IQR Program will not end or otherwise interfere with collection or public reporting of these data. The HAI data will continue to be made publicly available on a quarterly basis and the PSI 90 data on an annual basis in a consumer-friendly manner on the *Hospital Compare* website and through downloadable files under the HAC Reduction Program. We refer readers to section IV.J.4.h. of the preamble of this final rule where this is discussed in the HAC Reduction Program. We will also strive to minimize disruptions to preexisting processes and timelines for publicly reporting these data, as discussed further below in our responses to comments received.

(a) Removal for CY 2018 Reporting Period/FY 2020 Payment Determination—Patient Safety and Adverse Events Composite (PSI 90) (NQF #0531) (Adopted at 73 FR 48602, Refined at 81 FR 57128 Through 57133)

We proposed to remove the PSI 90 measure beginning with the FY 2020 payment determination (which would use a performance period of July 1, 2016 through June 30, 2018). As the PSI 90 measure is a claims-based measure, it uses claims and administrative data to calculate the measure without any additional data collection from hospitals. Thus, operationally, we would be able to remove the PSI 90 measure sooner than the NHSN HAI measures. Our reasons for proposing to remove this measure are discussed further below.

(b) Removals for the CY 2019 Reporting Period/FY 2021 Payment Determination

- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (adopted at 76 FR 51630 through 51631);
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (adopted at 76 FR 51616 through 51618);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (adopted at 75 FR 50200 through 50202);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-Resistant *Staphylococcus Aureus* Bacteremia (MRSA) Outcome Measure (NQF #1716) (adopted at 76 FR 51630); and
- American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSIs) (adopted at 75 FR 50200 through 50202).

We proposed to remove the CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI measures from the Hospital IQR Program beginning with the CY 2019 reporting period/FY 2021 payment determination. These measures would remain in the Hospital IQR Program until that time, and their reporting would still be tied to FY 2019 and FY 2020 payment determinations under the Hospital IQR Program. Although we proposed to remove these measures from the Hospital IQR Program, we did not propose to remove them from the HAC Reduction Program, and they will continue to be tied to the payment adjustment under that program (section IV.J.1. of the preamble of the proposed rule). After removal from the Hospital IQR Program, these measures would continue to be reported on the *Hospital Compare* website under the public reporting requirements of the HAC Reduction Program. We proposed to remove these measures beginning with the FY 2021 payment determination because hospitals already would have collected and reported data for the first three quarters of the CY 2018 reporting period for the FY 2020 payment determination by the time of publication of the FY 2019 IPPS/LTCH PPS final rule. Removing these five NHSN HAI measures in the proposed timeline would allow us to use the data already reported by hospitals in the CY 2018 reporting period for purposes of the FY 2020 payment adjustment.

We proposed to remove these six patient safety measures under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We believe that removing the PSI 90, CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures from one program would eliminate development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of this final rule where we discuss examples of the costs associated with implementing and maintaining these measures for the

programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across multiple programs. Hospitals currently review multiple feedback reports for the NHSN HAI measures from three different hospital quality programs that use three different reporting periods, which result in interpreting slightly different measure rates for the same measures (under the Hospital IQR Program, a rolling four quarters of data are used to update the *Hospital Compare* website; under the Hospital VBP Program, 1-year periods are used for each of the baseline period and the performance period; and under the HAC Reduction Program, a 2-year performance period is used). Beneficiaries may also find it confusing to see public reporting on the same measures in different programs. In addition, maintaining the specifications for the measures, as well as the tools we need to collect, validate, analyze, and publicly report the measure data result in costs to CMS.

We stated in the proposed rule that we believe the costs as discussed above outweigh the associated benefit to maintaining these measures in multiple programs, because that information can be captured through inclusion of these measures in the HAC Reduction Program. Although we are finalizing our proposals to remove these six patient safety measures from the Hospital IQR Program, we continue to recognize that improving patient safety and reducing NHSN HAIs is a critical quality area for which continued progress and improvement is needed, and that patient safety should be a high priority focus of quality programs. For these reasons, and as discussed below, we will continue to use these measures in the HAC Reduction Program and we will not finalize their removal from the Hospital VBP Program. (We refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss retaining these safety measures in the Hospital VBP Program.) Unlike the Hospital IQR Program, performance data on measures maintained in the HAC Reduction and Hospital VBP Programs are used both to assess the quality of care provided at a hospital and to calculate incentive payment adjustments for a given year of each respective program based on performance. Also, the HAC Reduction and Hospital VBP Programs' incentive payment structures tie hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the above measures sufficiently incentivizing high performance as well as performance improvement on these measures among participating hospitals. By keeping the measures in the HAC Reduction and Hospital VBP Programs, patients, hospitals, and the public also continue to receive information about the quality of care provided with respect to these measures.

We discussed in the proposed rule that we believed removing these measures from the Hospital IQR Program, while keeping them in the HAC Reduction Program, would strike an appropriate balance of benefits in driving improvement on patient safety and costs associated with retaining these measures in more than one program, while continuing to keep patient safety improvement and reducing NHSN HAIs as high priorities. We refer readers to section IV.J.1. of the preamble of this final rule where we discuss safety measures included in the HAC Reduction Program and section IV.I.2.c.(2) of the preamble of this final rule for this discussion in the Hospital VBP Program. As discussed in section VIII.A.4.b. of the preamble this final rule, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We believe retaining these measures in the HAC Reduction Program and the Hospital VBP Program addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.[271] In addition, as discussed in more detail below, we believe keeping these measures in the Hospital IQR Program would not align with our goal of not adding unnecessary complexity or cost with duplicative measures.

In the proposed rule, we proposed to remove the: (1) PSI 90 measure for the FY 2020 payment determination (which applies to the performance period of July 1, 2016 through June 30, 2018) and subsequent years; and (2) CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures for the CY 2019 reporting period/FY 2021 payment determination and subsequent years.

Comment: Many commenters did not support removal of the patient safety measures from the Hospital IQR Program, because although the reporting burden on hospitals associated with these measures may be significant, they believe the cost of infections to patients and to the economy is greater. Commenters noted that these measures are critical because hospital iatrogenic infections, accidents, errors, and injuries together are a leading cause of death in the United States.

Response: We agree with commenters that hospital-acquired conditions can pose substantial financial costs, as well as cause severe negative effects on patients' health and well-being.[272] It is for this reason that we did not propose to remove the PSI 90, CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures, collectively referred to as the patient safety measures, from the HAC Reduction Program, and we are not finalizing their proposed removal from the Hospital VBP Program. (We refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss retaining these safety measures in the Hospital VBP Program.) Because many commenters agreed with our assessment that there are costs associated with using the same measures in multiple programs, to providers, to CMS, and to patients and consumers trying to understand information about the same measures used in different programs, we are finalizing our proposal to remove the PSI 90 measure for the FY 2020 payment determination as proposed. We are also finalizing our proposal to remove the five NHSN HAI measures (that is, the CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures) but with modification to remove the five NHSN HAI measures from the Hospital IQR Program one year later than proposed beginning with the CY 2020 reporting period/FY 2022 payment determination and for subsequent years. These policies are discussed in more detail below.

Comment: A few commenters did not support removal of the patient safety measures because they believed the rationale under proposed removal Factor 8 contradicts the Meaningful Measures Initiative priority of making

[271] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[272] Zimlichman E, et al. Health Care—Associated Infections A Meta-analysis of Costs and Financial Impact on the US Health Care System. *JAMA Intern Med.* 2013;173(22):2039–2046.

clinically meaningful improvement to patient care with measurable reductions in patient safety events. Some commenters expressed concern that CMS may be inappropriately prioritizing the cost for those who collect the information over the benefits of the information to patients or direct care providers and recommended that protecting and improving the health of the public be central to decisions made regarding measure removals, particularly with regard to measures of patient safety.

Response: Because we continue to consider patient safety and reducing hospital-acquired conditions as high priorities (as reflected in the Meaningful Measures Initiative quality priority of making care safer by reducing harms caused in the delivery of care), we are not finalizing our proposed to remove these six patient safety measures from the Hospital VBP Program. We refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss retaining these safety measures in the Hospital VBP Program. We are also finalizing a modified version of our proposal under the Hospital IQR Program, such that instead of removing the five NHSN HAI measures (that is, the CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures) for the CY 2019 reporting period/FY 2021 payment determination and subsequent years as proposed, we are delaying removal for one additional year, until the CY 2020 reporting period/FY 2022 payment determination and subsequent years. By delaying removal of these measures from the Hospital IQR Program by one year, we will ensure consistency in collection and reporting of these data for continued use in the Hospital VBP Program and until such time when the collection, reporting, and validation of these data are transitioned to the HAC Reduction Program.

Because these measures will be publicly reported under the HAC Reduction and Hospital VBP Programs while also being used to assess hospital performance and impose payment adjustments on hospitals that perform poorly on these measures, we believe retaining the measures in two value-based purchasing programs and removing them from the Hospital IQR Program, will at least partly address the concerns of both the commenters who want to retain these measures and the commenters who supported their removal and de-duplication. We are, however, removing the PSI 90 measure for the FY 2020 payment determination (which applies to the performance period of July 1, 2016 through June 30, 2018) and subsequent years as proposed, because the data used to assess performance under this measure are collected via claims and therefore require no additional collection processes. We reiterate that removing the patient safety measures from the Hospital IQR Program beginning with the CY 2020 reporting period/FY 2022 payment determination for the five NHSN HAIs, and beginning with the FY 2020 payment determination for the PSI 90 measure, will not end or otherwise interfere with collection or public reporting of these data under other CMS quality programs. Under the HAC Reduction Program: (1) The NHSN HAI measures data will continue to be made publicly available on the *Hospital Compare* website on a quarterly basis, and (2) the PSI 90 data will continue to be made public on an annual basis, with all of these measures publicly reported in a consumer-friendly manner as well as through downloadable files. We refer readers to sections IV.J.4.e. and IV.J.4.h.(1) of the preamble of this final rule for discussions of data collection and public reporting in the HAC Reduction Program. We note that section 1886(p)(6) of the Act requires the HAC Reduction Program to make information available to the public regarding hospital-acquired conditions of each applicable hospital on the *Hospital Compare* website in an easily understandable format. Furthermore, section 1886(o)(10)(A) of the Act requires the Hospital VBP Program to make information available to the public regarding the performance of individual hospitals, including performance with respect to each measure, on the *Hospital Compare* website in an easily understandable format. We refer readers to section IV.J.4.h.(1) of the preamble of this final rule for discussion of public reporting under the HAC Reduction Program. We will continue to monitor hospital performance on these measures under both the HAC Reduction and Hospital VBP Programs, including any unintended consequences that may be associated with removing the measures from the Hospital IQR Program.

Comment: Several commenters specifically supported the removal of the NHSN HAI measures from the Hospital IQR Program to minimize redundancy in the programs and to reduce the costs associated with tracking and previewing reports in multiple programs, while noting that the cost and burden of infection surveillance, NHSN case identification, NHSN program maintenance, and data submission would not change. One commenter noted the benefit of removing the measures from the Hospital IQR Program, which only encourages reporting of quality data, while retaining them in the HAC Reduction Program, which directly ties payment to quality outcomes. A few commenters supported removing the NHSN HAI measures from the Hospital IQR Program, but encouraged CMS to maintain transparency of individual NHSN HAI measures by continuing to publicly report performance data on the *Hospital Compare* website. A few commenters expressed hope that removal of these measures from the Hospital IQR Program would not weaken incentives for facilities to report HAI surveillance data to the NHSN because conducting HAI surveillance using NHSN methods and maintaining quality infection prevention and control programs improves patient safety. Commenters recommended that CMS work with other agencies, experts, and State health departments to continue to improve quality around patient safety.

Response: We thank the commenters for their support of our proposal to de-duplicate the NHSN HAI measures (that is, the CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures) from the Hospital IQR Program. As noted previously, we will continue to publicly report hospital performance data on these measures under the HAC Reduction and Hospital VBP Programs in a manner that is transparent and easily understood by patients. As noted above, we refer readers to sections IV.J.4.h.(1) and IV.I.2.c.(2) of the preamble of this final rule where we detail our policies for these measures in the HAC Reduction and Hospital VBP Programs. Specifically, the NHSN HAI data will continue to be made available on a quarterly basis in a consumer-friendly manner on *Hospital Compare* and also through downloadable files. We will also strive to minimize disruptions to preexisting processes and timelines for publicly reporting these data. We further believe removing the NHSN HAI measures from the Hospital IQR Program will have no impact on the incentive to report these measure data because the measures will remain in both the HAC Reduction and Hospital VBP Programs' measure sets, under which hospitals are subject to payment adjustments based on their performance.

Comment: Several commenters supported removal of the measures from the Hospital IQR Program but recommended that the measures, and their associated validation, scoring, and public reporting requirements, be retained in the Hospital VBP Program instead of the HAC Reduction Program

because the Hospital VBP Program provides incentives for each facility's performance improvement as well as penalties for poor performance, whereas the HAC Reduction Program only penalizes hospitals in the worst-performing quartile (25 percent) of program performance. One commenter similarly supported only retaining the NHSN HAI measures in the Hospital VBP Program because the HAC Reduction Program's risk adjustment strategies are limited and may not appropriately account for facility-specific populations, leading to the over-penalization of hospitals that serve predominately high-risk patients. If retaining the NHSN HAI measures only in the Hospital VBP Program were not possible, one commenter recommended modifying the HAC Reduction Program to incorporate an incentive structure like that used in the Hospital VBP Program.

Response: We thank the commenters for their comments. As discussed above, we are finalizing removal of the NHSN HAI and PSI 90 measures from the Hospital IQR Program with modification and retaining them in both the HAC Reduction and Hospital VBP Programs. In connection with these measure removals from the Hospital IQR Program, we are finalizing our proposals to adopt HAI data collection and validation processes under the HAC Reduction Program that align with those currently used in the Hospital IQR Program. We refer readers to section IV.J.4.e. of the preamble of this final rule where we discuss the HAI data collection and validation processes under the HAC Reduction Program in further detail.

While we recognize that the payment structures of the HAC Reduction Program and Hospital VBP Program are different, particularly in that the Hospital VBP Program scoring methodology scores hospitals on the higher of improvement or achievement on each measure, and incentivizes all hospitals to improve and achieve high performance with both positive and negative payment adjustments. Because many commenters have expressed this similar concern about the potential reduced incentive for hospitals to continue to improve and achieve high performance on these safety measures, we are not finalizing our proposal to remove these measures from the Hospital VBP Program and refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss this decision in detail.

We note that the HAC Reduction Program was designed to include risk-adjusted measures that are reflective of hospital performance (78 FR 50712 through 50715). We will continue to consult with the CDC and take this feedback into consideration for measure maintenance and future refinement of measure specifications. Furthermore, we will continue to monitor hospital performance on these measures under both the HAC Reduction and Hospital VBP Programs, including any unintended consequences. We will take the commenter's feedback regarding the HAC Reduction Program incentive structure into consideration for future years to the extent authorized under section 1886(p) of the Act.

Comment: Several commenters disagreed that the patient safety measures in the Hospital IQR Program are duplicative of measures in other programs and further recommended that more patient safety measures should be added to quality reporting programs out of concern that quality and cost-effectiveness are nullified when safety is absent. One commenter noted that by virtue of being housed in the Hospital IQR Program, virtually all hospitals report on and are accountable to the public for these measures and, if removed from the Hospital IQR Program, many hospitals might choose to no longer report on these measures. Moreover, some commenters expressed concern that if the patient safety measures were removed from the Hospital IQR Program, then hospitals would not be given the payment incentive for full reporting, creating a financial disincentive to report the measures because the HAC Reduction Program only penalizes hospitals that perform in the lowest quartile of performance, potentially resulting in increased infections and patient safety issues. Several commenters expressed concern that if these measures are retained only in the HAC Reduction Program, and the HAC Reduction Program was repealed (through a repeal of the Patient Protection and Affordable Care Act), that hospitals would be left with nothing to incentivize reporting on patient safety measures.

Response: We seek to clarify that these patient safety measures previously finalized for the Hospital IQR, Hospital VBP, and HAC Reduction Programs are the same six measures, and that subsection (d) hospitals are subject to all three programs. Because the HAC Reduction Program imposes a 1 percent payment penalty on all hospitals scoring in the worst-performing quartile of all subsection (d) hospitals (and hospitals that do not report measures and do not have a waiver receive the worst-possible score for those measures, (79 FR 50098 and 81 FR 57013)) and the Safety domain using patient safety measures comprises 25 percent of a hospital's Total Performance Score under the Hospital VBP Program, we believe there are sufficiently strong incentives to ensure hospitals continue to report and strive for high performance on these patient safety measures. We note that the payment adjustment associated with not reporting data to the Hospital IQR Program is a one-quarter reduction in the hospital's annual payment update (APU). There is no positive payment adjustment associated with either reporting data to the program or a hospital's performance on a measure collected under the Hospital IQR Program.[273] We refer readers to the table below for more information on average APU percentages since FY 2015 when the financial risk for failure to report data under the Hospital IQR Program became a one-fourth reduction of the annual payment update:

FY	APU	One-fourth of APU
2015	1.4	0.35
2016	0.9	0.23
2017	0.95	0.24
2018	1.2	0.3
Average	1.11	0.28

[273] Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary.

In order to ensure continuity under the HAC Reduction Program for the public reporting of the NHSN HAI data quarterly and to assess payment penalties based on hospitals' performance on the measures, we believe it is appropriate to transfer collection of these patient safety measure data to that program. We further note that in retaining these measures in the Hospital VBP Program, performance on these measures will also continue to be tied to that program's payment incentive structure, reinforcing improvement and high achievement on the measures, and providing positive as well as negative payment adjustments. We acknowledge commenters' concern regarding future potential statutory changes, and would address any such changes in future rulemaking.

Comment: A few commenters did not support removal of the patient safety measures, asserting that retaining the measures in only one program would not alleviate any significant burden on hospitals because there is no burden associated with data submission for claims-based measures, such as the PSI 90 measure, and hospitals submit data to the NHSN only once for multiple programs in the case of the NHSN HAI measures.

Response: While we agree with commenters that removal of these measures from the Hospital IQR Program may not significantly reduce the information collection burden of reporting associated with these measures due to either their claims-based collection or their continued use in another program, the costs associated with a measure also include those associated with reviewing multiple preview reports, which would be reduced by streamlining measure sets. Further, as discussed in section VIII.A.4.b. of the preamble of this final rule, when evaluating the removal of a measure under removal Factor 8, we consider costs beyond the information collection burden, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable). As stated above, in response to many commenters, we are not finalizing their proposed removal from the Hospital VBP Program. We refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss retaining these safety measures in the Hospital VBP Program. We also note that, as discussed above, we are finalizing a modified version of our proposal, such that we are delaying removal of the NHSN HAI measures from the Hospital IQR Program for one year such that removal begins with the CY 2020 reporting period/FY 2022 payment determination in order to ensure consistency in data collection and reporting while we work to establish data collection policies for these measures under the Hospital VBP Program. This will also help to have a more seamless transition for data collection, validation, and public reporting under the HAC Reduction Program.

Comment: Many commenters did not support removal of the patient safety measures due to concerns about transparency in public reporting. These commenters expressed concern that if the patient safety measures were removed from the Hospital IQR Program, that public reporting of the measure data would no longer be available, decreasing the information available to the public, and thereby, disincentivizing related hospital quality improvement efforts, leading to endangering the lives and safety of vulnerable patients. A few commenters noted that informing the public of hospital quality performance is a central purpose of the Hospital IQR Program; public reporting of these measures helps focus and strengthen efforts to improve healthcare safety and quality. One commenter asserted that 90 percent of the measures in the Hospital IQR Program have seen improvement, a record unparalleled in any other health quality programs. Several commenters further expressed concern that even if these measures are retained in another CMS quality program, the resulting data may not be reported in an easily accessible manner. Therefore, commenters urged CMS to prioritize transparency throughout its programs, particularly as it relates to patient safety measures, by continuing to publicly report patient safety measure data on the *Hospital Compare* website to enable hospitals to compare their performance with other hospitals to drive quality improvement efforts and for patients to make informed decisions about their health care.

Response: We appreciate the commenters' concerns and reiterate that we will continue to report measure-level data for all of CMS' quality programs in a manner that is transparent and easily understood by patients and consumers. As noted above, under the HAC Reduction Program, data on the NHSN HAI measures will continue to be made publicly available on the *Hospital Compare* website as they have been on a quarterly basis; furthermore, data on the PSI 90 measure will continue to be published on an annual basis, with all of these measures publicly reported in a consumer-friendly manner and also through downloadable files. We will also strive to minimize disruptions to preexisting processes and timelines for publicly reporting these data. We refer readers to section IV.J.4.h.(1) of the preamble of this final rule where this is discussed in more detail for the HAC Reduction Program.

Comment: Several commenters did not support removal of the patient safety measures from the Hospital IQR Program because it provided the original statutory mechanism requiring quality data to be made public on the *Hospital Compare* website and because it has served as the primary vehicle for public reporting of hospital performance data. One commenter asserted its interpretation that measures not reported through the Hospital IQR Program cannot, by statute, be used in other payment programs, noting that CMS attempted to report a set of Deficit Reduction Act (DRA)-HAC measures removed from the Hospital IQR Program on the *Hospital Compare* website, but concluded the HAC Reduction Program lacked the statutory authority because measures not in the Hospital IQR Program could not be reported on the *Hospital Compare* website.

Response: Under the holistic approach of evaluating the measures used in the four inpatient hospital quality programs—the Hospital IQR, Hospital VBP, HAC Reduction, and Hospital Readmissions Reduction Programs—as discussed above and in the preamble of the proposed rule, the Hospital IQR Program will continue to serve as the primary quality reporting program for quality and cost measures that are important for data collection and public reporting, but may not be ready or appropriate for use in one of the other value-based purchasing programs. As required under sections 1886(o)(2)(A) and 1886(o)(2)(C)(i) of the Act, we will continue to select measures for the Hospital VBP Program that have been specified for the Hospital IQR

Program and refrain from beginning the performance period for any new measure until the data on that measure have been posted on *Hospital Compare* for at least one year. We note the statute does not require a measure that has met these statutory requirements to remain in the Hospital IQR Program at the same time as the Hospital VBP Program. The HAC Reduction and Hospital Readmissions Reduction Programs do not have any similar statutory requirements.

We believe removing measures that have transitioned to a value-based purchasing program from the Hospital IQR Program will better enable us to focus on new quality measures and collecting and publicly reporting these data for both patients and providers without imposing additional cost or burden on providers for duplicative measures unless the benefits outweigh the costs. (For example, we refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss retaining these patient safety measures in the Hospital VBP Program.)

We would like to clarify that the payment provision established by section 5001(c) of the Deficit Reduction Act (DRA) of 2005 (also known as DRA–HAC or the Hospital-Acquired Conditions (Present on Admission Indicator) payment provision), is a policy under which hospitals no longer receive additional payment for cases in which one of a selected set of HACs occurred but was not present on admission.[274] [275] While CMS does calculate and report rates for a subset of the conditions included in the DRA–HAC payment provision under DRA HAC Reporting via public use files, this payment policy and associated reporting are separate and distinct from the Hospital IQR and HAC Reduction Programs discussed in this final rule.

We further disagree that the HAC Reduction Program lacks statutory authority to publicly report measures that are not also in the Hospital IQR Program, and refer readers to section 1886(p)(6) of the Act, which specifically requires the Secretary to make publicly available information regarding hospital acquired conditions under the HAC Reduction Program and to post such information on *Hospital Compare* in an easily understandable format. We also refer readers to sections IV.J.4.b. and IV.J.4.h.(1) of the preamble of this final rule where we address in detail how the NHSN HAI measures will be publicly reported on *Hospital Compare* under the HAC Reduction Program.

Comment: Several commenters expressed concern that removing these measures could negatively impact States that have structured their laws to align with CMS regulations.

Response: We acknowledge commenters' concern, but we disagree because, as stated above, these measure data will continue to be collected under HAC Reduction Program and made publicly available—the NHSN HAI data on a quarterly basis and PSI 90 data on an annual basis—in a consumer-friendly manner on *Hospital Compare* and also through downloadable files which can be accessed by all stakeholders, including States and public health agencies.

Comment: Several commenters expressed particular concern regarding removal of the PSI 90 measure. Specifically, one commenter worried that the measure's 10 individual component indicators of the composite measure may no longer be publicly reported with the same level of granularity if the measure were removed from the Hospital IQR Program. This commenter recommended CMS continue to publicly report both the full composite score for the PSI 90 measure as well as the scores of individual indicators comprising the measure, because the commenter believed that the PSI 90 measure represents important patient safety outcomes data. Another commenter recommended that CMS delay the removal of the PSI 90 measure from the Hospital IQR Program until the measure steward transfer from AHRQ to CMS is completed.

Response: As discussed above, we believe retaining the PSI 90 measure in the HAC Reduction Program, which specifically focuses on reducing hospital-acquired conditions and improving patient safety outcomes, as well as not finalizing removal of this measure from the Hospital VBP Program, while finalizing its removal as proposed from the Hospital IQR Program will at least partly address the concerns of both commenters who want to retain this measure and commenters who supported its removal and de-duplication. We reiterate that removing this measure from the Hospital IQR Program will not end or otherwise interfere with public reporting of these data. We refer readers to section IV.J.4.h. of the preamble of this final rule in which the HAC Reduction Program is finalizing its proposal to make data available in the same form and manner as currently displayed under the Hospital IQR Program. The data will continue to be made available in a consumer-friendly manner on *Hospital Compare,* with the same granularity, and also through downloadable files. We therefore continue to believe that removing this measure from the Hospital IQR Program as proposed while retaining it in two value-based purchasing programs strikes the appropriate balance of benefits and costs associated with using the PSI 90 measure across the programs. We further believe it is unnecessary to delay removal of the PSI 90 measure from the Hospital IQR Program until after measure stewardship has transitioned from AHRQ to CMS because the measure specifications as previously adopted for both the HAC Reduction Program and Hospital IQR Program remain unchanged.[276]

Comment: One commenter suggested modifying the patient safety measures to include bidirectional case reporting, which the commenter believed incentivizes public health reporting and is important to public health agencies.

Response: We thank the commenter for its suggestion. We interpret the commenter's reference to ''bidirectional case reporting'' as the NHSN system allowing data from public health agencies to populate NHSN and the NHSN system allowing public health agencies access to NHSN data. We will consult with the CDC and evaluate whether bidirectional case reporting is feasible and consider this option in the future if feasible and appropriate to do so.

Comment: Several commenters supported the removal of the patient safety measures from the Hospital IQR Program for the following reasons: (1) To reduce the costs associated with reporting the same measure in multiple programs with differing reporting periods; (2) to reduce the confusion associated with reviewing multiple reports from multiple programs for the same measures; and (3) to streamline quality reporting requirements. Some commenters supported the removal of patient safety measures from the Hospital IQR Program, but recommended that we continue to

[274] Additional information about the DRA–HAC payment provision is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html.*

[275] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Downloads/FAQ-DRA-HAC-PSI.pdf.*

[276] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS quality programs. The 2018 measure specifications for PSI 90 as it is used in both the HAC Reduction Program and the Hospital IQR Program can be found at: *https://qualityindicators.ahrq.gov/Modules/PSI_TechSpec_ICD10_v2018.aspx.*

publicly report these measures on the *Hospital Compare* website under the HAC Reduction Program, because commenters believed these measures are of great interest to the public.

Response: We thank the commenters for their support of our proposal to de-duplicate the patient safety measures from the Hospital IQR Program. As discussed above, we are finalizing removal of these measures from the Hospital IQR Program with modification to delay removal of the NHSN HAI measures for one year and retaining them in the HAC Reduction and Hospital VBP Programs.

Comment: One commenter recommended that whichever quality program retains the patient safety measures should retain the administrative requirements previously provided under the Hospital IQR Program, including data collection requirements, validation requirements, and scoring associated with data completeness, timeliness, and accuracy, as well as public reporting of the data on *Hospital Compare* website. Another commenter specifically supported the removal of the PSI 90 measure from the Hospital IQR Program and retention in the HAC Reduction Program because the HAC Reduction Program will be the program primarily focusing on safety of care quality for the inpatient hospital setting. In addition, the commenter recommended that the PSI 90 measure be validated and publicly reported on the *Hospital Compare* website.

Response: We appreciate the first commenter's suggestion and note that while the patient safety measures are being removed from the Hospital IQR Program, they are being retained in the HAC Reduction Program and the Hospital VBP Program and will be subject to the administrative requirements and scoring methodologies of those programs. Further, we refer readers to section IV.J.4.h. of the preamble of this final rule in which the HAC Reduction Program is finalizing its proposal to make data available in the same form and manner as currently displayed under the Hospital IQR Program. We reiterate that the PSI 90 measure will be publicly reported on the *Hospital Compare* website, however, it will not be included in the HAC Reduction Program validation process because it is a claims-based measure for which hospitals do not submit any additional quality measure data for validation.

Comment: A few commenters expressed support specifically for the removal of the PSI 90 measure from the Hospital IQR Program to reduce: (1) Redundant and duplicative work for providers; and (2) costs associated with reporting and remaining in compliance with the requirements of quality reporting programs. One commenter supported removal of the PSI 90 measure from the Hospital IQR Program because it believed that it is unclear whether recent measure modifications might affect hospital performance. Further, the commenter did not believe that such population-based measures are appropriate for hospital accountability, and recommended that the effects of the modification on performance and ranking be explored before implemented in any of the quality reporting programs.

Response: We thank the commenters for their support of our proposal to de-duplicate the PSI 90 measure from the Hospital IQR Program. As discussed above, we are finalizing removal of this measure from the Hospital IQR Program as proposed because the cost of keeping the measure in three CMS programs outweighs the benefits. We acknowledge the commenter's concern about the impact of the recent measure modifications, which we interpret as referencing the ICD–10 change and broadening of the cohort (81 FR 57128 through 57133). However, we continue to believe this measure as specified is valid and reliable, and therefore, appropriate for use in other CMS quality programs. We appreciate the commenter's feedback regarding population-based measures and will take that into consideration for future program years.

Comment: One commenter opposed the inclusion of the PSI 90 measure in any quality program and recommended that CMS not reintroduce the measure until it meets the standards of the National Quality Forum.

Response: We note the PSI 90 measure (NQF #0531) is currently endorsed by the National Quality Forum (NQF).[277] As stated above, we continue to believe this measure is a valid and reliable measure of potentially preventable hospital-related events associated with harmful outcomes for patients. We further note that the PSI 90 measure remains in the HAC Reduction Program, as well as the Hospital VBP Program beginning with the FY 2023 program year (we refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss not finalizing our proposal to remove the PSI 90 measure from the Hospital VBP Program).

Comment: One commenter recommended that CMS carefully consider whether or not to include NHSN CDI in performance programs because the commenter believed that it is notably flawed due to variable documentation, surveillance, and testing practices among organizations.

Response: While we acknowledge variability in hospital documentation, reporting, and sensitivity of laboratory testing methods may make a difference in the event data hospitals report, the CDC's Multidrug-Resistant Organism & *Clostridium difficile* Infection (CDI) Module provides guidelines for identifying, documenting, and reporting events under this measure.[278] In addition, we believe the validation process established for the NHSN CDI measure and other NHSN measures is the best approach for us to systematically identify candidates that are likely to yield a high proportion of cases that should have been reported to NHSN.[279] As discussed in section IV.J.4.e. of the preamble of this final rule, the HAC Reduction Program is finalizing its proposal to begin validating the NHSN HAI measures following their removal from the Hospital IQR Program. We believe transitioning this validation process to a payment program will provide sufficient incentives for hospitals to ensure diligent and accurate reporting of CDI events; however, we will also consult with the CDC to take the commenter's concerns into consideration for future program years.

After consideration of the public comments we received, we are finalizing our proposal to remove the PSI 90 measure beginning with the FY 2020 payment determination (which applies to the performance period of July 1, 2016 through June 30, 2018) as proposed. Furthermore, we are finalizing our proposals to remove the CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures with modification; instead of removing them beginning with the CY 2019 reporting period/FY 2021 payment determination as proposed, we are finalizing a delay in the removal of these measures until the CY 2020 reporting period/FY 2022 payment determination.

[277] For a full history of the PSI 90 measure's NQF review and endorsement, we refer readers to the NQF Quality Positioning System page for this measure, available at: *http://www.qualityforum.org/QPS/0531*.

[278] We refer readers to the CDC's Multidrug-Resistant Organism & *Clostridium difficile* Infection Module for a detailed discussion of how to report these events. Available at: *https://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf*.

[279] 78 FR 50829 through 50834.

(3) Claims-Based Readmission Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20475 through 20476), we proposed to remove the following seven claims-based readmission measures beginning with the FY 2020 payment determination:

- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (READM–30–AMI) (adopted at 73 FR 68781);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (READM–30–CABG) (adopted at 79 FR 50220 through 50224);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (READM–30–COPD) (adopted at 78 FR 50790 through 50792);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330) (READM–30–HF) (adopted at 73 FR 48606);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) (READM–30–PN) (adopted at 73 FR 68780 through 68781);
- Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (READM–30–THA/TKA) (adopted at 77 FR 53519 through 53521); and
- 30-Day Risk-Standardized Readmission Rate Following Stroke Hospitalization (READM–30–STK) (adopted at 78 FR 50794 through 50798).

We proposed to remove READM–30–AMI, READM–30–CABG, READM–30–COPD, READM–30–HF, READM–30–PN, and READM–30–THA/TKA under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. (The READM–30–STK measure is discussed further below.) We believe removing these measures from the Hospital IQR Program would eliminate costs associated with implementing and maintaining these measures for the program, and in particular, development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of the proposed rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measures in different programs. In addition, maintaining the specifications for the measures, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs as described above outweigh the associated benefit to beneficiaries of receiving the same information from multiple programs, because that information can be captured through inclusion of these measures solely in the Hospital Readmissions Reduction Program. We believe the benefit to beneficiaries of keeping this measure in the Hospital IQR Program is limited because the public would continue to receive measure information via another CMS quality program.

Because we continue to believe these measures provide important data on patient outcomes following inpatient hospitalization (addressing the Meaningful Measures Initiative quality priority of promoting effective communication and coordination of care), we will continue to use these measures in the Hospital Readmissions Reduction Program. By keeping the measures in the Hospital Readmissions Reduction Program, patients, hospitals, and the public would continue to receive information about the quality of care provided with respect to these measures.

Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital Readmissions Reduction Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital Readmissions Reduction Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the above measures which are already in the Hospital Readmissions Reduction Program, sufficiently incentivizing performance improvement on these measures among participating hospitals. As discussed in section VIII.A.4.b. of the preamble of the proposed rule, one of our main goals is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe removing these measures from the Hospital IQR Program is the best way to achieve this. In addition, as discussed in section I.A.2. of the preamble of this final rule, we believe keeping these measures in both programs no longer aligns with our goal of not adding unnecessary complexity or cost with duplicative measures across programs.

Furthermore, we proposed to remove the READM–30–STK measure under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. The READM–30–STK measure collects important hospital-level, risk-standardized readmission rates following inpatient hospitalizations for strokes (78 FR 50794). However, these data also are captured in the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) adopted into the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528), because that measure comprises a single summary score, derived from the results of different models for each of the following specialty cohorts: Medicine; surgery/gynecology; cardiorespiratory; cardiovascular; and neurology (77 FR 53522). These cohorts cover conditions and procedures defined by the AHRQ Clinical Classification Software (CCS), which collapsed more than 17,000 different ICD–9–CM diagnoses and procedure codes into 285 clinically-coherent, mutually-exclusive condition categories and 231 mutually-exclusive procedure categories (77 FR 53525). The transition of the CCS-based measure specifications to the ICD–10–CM version of the CCS is underway. The ICD–10 to CCS map and tools for its use are currently available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs10/ccs10.jsp*. Readmission rates following inpatient hospitalizations for strokes are captured in that information, specifically, the neurology cohort. We believe that the costs associated with interpreting the requirements for two measures with overlapping data points

outweigh the benefit to beneficiaries of the additional information provided by this measure, because the measure data are already captured within another measure in the Hospital IQR Program. Also, maintaining the specifications for this measure, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. Thus, removing the READM–30–STK measure would help to reduce duplicative data and produce a more harmonized and streamlined measure set. As discussed in section VIII.A.4.b. of the preamble of this final rule, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe removing this measure from the Hospital IQR Program is the best way to do that.

We recognize, however, that including condition- and procedure-specific clinical quality measure data can provide hospitals with actionable feedback to better equip them to implement targeted improvements in comparison to an overall quality measure. In addition, condition- and procedure-specific measures can provide valuable data to specialty societies by clearly assessing performance for their specialty, and may be valuable to persons and families who prefer information on certain conditions and procedures relevant to them. The Hospital-Wide Readmission measure, unlike condition- and procedure-specific measures, also requires improvement in quality across multiple service lines to produce improvement in the overall rate, which may give the perception of slower or smaller gains in hospital quality. Conversely, hospitals would still have a strong motivation to improve stroke readmissions performance if they want to improve their overall performance on the Hospital-Wide Readmission measure posted on *Hospital Compare*.

Therefore, we proposed to remove the READM–30–AMI, READM–30–CABG, READM–30–COPD, READM–30–HF, READM–30–PN, READM–30–THA/TKA, and READM–30–STK measures for the FY 2020 payment determination (which would apply to the performance period of July 1, 2015 through June 30, 2018) and subsequent years.

We invited public comment on our proposal to remove these measures from the Hospital IQR Program as well as feedback on whether there are reasons to retain one or more of the measures in the Hospital IQR Program.

Comment: A number of commenters supported CMS' proposals to remove seven claims-based readmission measures beginning with the FY 2020 payment determination. One commenter supported removal of the readmission measures because they are less applicable to its patient population. One commenter supported the removal of these measures, but highlighted its belief that removing them would not reduce burden because hospitals will still report most of these measures to the Hospital Readmissions Reduction Program.

Response: We thank commenters for their support of the removal of these measures. We respectfully disagree that removing these measures will not reduce the costs associated with these measures. We believe that removing these measures would reduce costs for providers by eliminating the need to monitor the same measures used in multiple programs, including tracking confidential feedback, preview reports, and publicly reported information on these measures. Beneficiaries may also find it confusing to see public reporting on the same measures in different programs. In addition, costs to CMS would be reduced by no longer having to maintain the tools needed to analyze and publicly report the measure data for multiple programs. We refer readers to section VIII.A.4.b. of the preamble of this final rule where we discuss examples of the costs associated with implementing and maintaining these measures.

Comment: One commenter supported CMS' proposals to remove READM–30–AMI, READM–30–CABG, READM–30–COPD, READM–30–HF, READM–30–PN, and READM–30–THA/TKA for the following reasons: (1) Reducing duplication, which will in turn reduce administrative burden as well as patient and provider confusion; and (2) preventing hospitals from being penalized or rewarded for the same measure across multiple programs.

Response: We thank the commenter for its support of the removal of READM–30–AMI, READM–30–CABG, and READM–30–HF and agree with the reasons.

Comment: One commenter supported CMS' proposals to remove READM–30–AMI, READM–30–CABG, and READM–30–HF for purposes of administrative simplification, and recommended that CMS eliminate use of those three measures from all quality programs altogether. The commenter also expressed their opinion that READM–30–HF may not be an appropriate indicator of quality based on emerging literature.

Response: We thank commenters for their support of the removal of READM–30–AMI, READM–30–CABG, and READM–30–HF measures from the Hospital IQR Program. While we continue to believe these measures as specified are valid and reliable (adopted at 73 FR 68781, 79 FR 50220, and 73 FR 48606 respectively), we are removing them from the Hospital IQR Program because the costs associated with these measures outweigh the benefits of their continued use in the Hospital IQR Program.

We note that, as discussed in section IV.H.4. of the preamble of this final rule, these measures will continue to be used in the Hospital Readmissions Reduction Program. However, we will take commenters' recommendations into consideration as we continue to evaluate the other quality programs' measure sets in future years.

Comment: One commenter specifically supported the proposal to remove READM–30–HF from the Hospital IQR Program because it would reduce the reporting burden on hospitals without compromising the measure in the Hospital Readmissions Reduction Program.

Response: We thank the commenter for its feedback.

Comment: A few commenters specifically supported the proposal to remove READM–30–THA/TKA. One commenter agreed that it is appropriate to address THA and TKA readmissions through the Hospital Readmissions Reduction Program.

Response: We thank the commenters for their feedback.

Comment: A few commenters supported CMS' proposal to remove the READM–30–STK measure for the following reasons: (1) The loss of condition-specific, hospital-level risk-standardized information is outweighed by the more important overarching goal of maintaining the least burdensome and most harmonized measure set; (2) the associated data will be used in aggregated form in the Hospital-Wide All-Cause Unplanned Readmission measure; and (3) the measure was never NQF endorsed.

Response: We thank the commenters for their feedback. We note that the Hospital IQR Program considers NQF endorsement when adopting measures into the measure set. Even if a measure is not NQF endorsed, the Hospital IQR Program may adopt it into the program under the exclusion authority in section 1886(b)(3)(B)(IX)(bb) of the Act, by considering other available topical measures that have been endorsed or adopted by a consensus organization.

Comment: A few commenters did not support CMS' proposals to remove the seven readmission measures. One commenter opposed removal of the seven condition-specific readmission measures due to concerns that their removal could result in a lack of public access to user-friendly condition-specific outcomes information, and suggested that measure-level reporting continue on *Hospital Compare* under the Hospital IQR Program to ensure that future improvements in public reporting can be adopted consistently across publicly reported measures.

Response: We thank the commenters for their concerns and reiterate that we will continue to publicly report measure-level data for all of CMS' quality programs in a manner that is transparent and easily understood by patients, as well as through downloadable files. These measures will continue to be included in the Hospital Readmissions Reduction Program, and we note that section 1886(q)(6) of the Act requires the Hospital Readmissions Reduction Program to make information available to the public regarding readmission rates of each subsection (d) hospital on the *Hospital Compare* website in an easily understandable format. We will also strive to minimize disruptions to preexisting processes and timelines for publicly reporting this data. We refer readers to section IV.H.4. of the preamble of this final rule where we discuss these measures under the Hospital Readmissions Reduction Program.

Comment: One commenter did not support CMS' ''holistic'' view of the hospital quality programs. The commenter stated that initially adopting measures into the Hospital IQR Program allows for a period of measure validation, and for health systems to gain familiarity with the measures before they are moved into value-based purchasing programs, and expressed concern that CMS' ''holistic'' view would allow new measures to be adopted immediately into the value-based purchasing programs without this time for familiarization and validation. The commenter stated their belief that adopting measures directly into the value-based purchasing programs would result in significant harm, undue hardship, and potentially financial penalties on healthcare systems.

Response: We thank the commenter for its comment, but emphasize that our proposal to remove duplicative measures from the Hospital IQR Program does not affect the underlying statutory requirements of the Hospital VBP, HAC Reduction, or Hospital Readmissions Reduction Programs. Those programs will continue to select new measures as required by their statutory authority. For instance, the Hospital VBP Program will continue to select measures that have been specified under the Hospital IQR Program and refrain from beginning the performance period for any new measure until the data on that measure have been posted on *Hospital Compare* for at least one year. We note the HAC Reduction and Hospital Readmissions Reduction Programs do not have any similar statutory requirements in this regard as the Hospital VBP Program. We therefore disagree that these removals could result in harm, undue hardship, or financial penalties to hospitals because they do not alter the processes associated with adopting new measures into the Hospital VBP, HAC Reduction, or Hospital Readmissions Reduction Programs. We will, however, continue to consider on a case-by-case basis for each new measure whether it would be appropriate to propose the measure for the Hospital IQR Program before proposing to use it in either the HAC Reduction Program or the Hospital Readmissions Reduction Program.

Comment: One commenter did not support removal of the READM–30–AMI, READM–30–HF, and READM–30–PN measures because the commenter believed they are essential health and safety measurements, key to hospital accountability and incentivizing quality care. The commenter also expressed its opinion that the removal would decrease transparency and public accountability.

Response: We appreciate the commenter's concerns and reiterate that we will continue to publicly report measure-level data for all of CMS' quality programs in a manner that is transparent and easily understood by patients. The readmissions measures will continue to be publicly reported on *Hospital Compare* as they have been. We will also strive to minimize disruptions to preexisting processes and timelines for publicly reporting this data. Because the READM–30–AMI, READM–30–CABG, READM–30–COPD, READM–30–HF, READM–30–PN, and READM–30–THA/TKA measures will be retained in the Hospital Readmissions Reduction Program, which ties hospital performance on the measures to payment adjustments, we believe hospitals will continue to be strongly incentivized to improve on the measures. We refer readers to section IV.H.7. of the preamble of this final rule where we discuss these policies under the Hospital Readmissions Reduction Program. In addition, because readmission rates for stroke patients will continue to be captured by the Hospital-Wide Readmission measure that is being retained in the Hospital IQR Program, we believe hospitals will continue to be strongly incentivized to improve on this measure as well.

After consideration of the public comments we received, we are finalizing removal of the READM–30–AMI, READM–30–CABG, READM–30–COPD, READM–30–HF, READM–30–PN, READM–30–THA/TKA, and READM–30–STK measures from the Hospital IQR Program measure set beginning with the FY 2020 payment determination as proposed.

(4) Claims-Based Mortality Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20476 through 20477), we proposed to remove five claims-based mortality measures across the FYs 2020, 2021, and 2022 payment determinations and subsequent years:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230) (MORT–30–AMI) beginning with the FY 2020 payment determination (adopted at 71 FR 68206);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization Surgery (NQF #0229) (MORT–30–HF) beginning with the FY 2020 payment determination (adopted at 71 FR 68206);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) (NQF #1893) (MORT–30–COPD) beginning with the FY 2021 payment determination (adopted at 78 FR 50792 through 50794);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (NQF #0468) (MORT–30–PN) beginning with the FY 2021 payment determination (adopted at 72 FR 47351); and
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (MORT–30–CABG) beginning with the FY 2022 payment determination (adopted at 79 FR 50224 through 50227).

We proposed to remove MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN, and MORT–30–CABG under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. Removing these measures from the Hospital IQR Program would eliminate costs associated with implementing and maintaining these measures for the program, and in particular, development

and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals for both the Hospital IQR and Hospital VBP Programs. We refer readers to section VIII.A.4.b. of the preamble of this final rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measures using different reporting periods in different programs. In addition, maintaining the specifications for the measures, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs associated with reviewing multiple feedback reports on these measures for more than one program outweigh the associated benefit to beneficiaries of receiving the same information from multiple programs, because that information can be captured through inclusion of these measures solely in the Hospital VBP Program.

We continue to believe these measures provide important data on patient outcomes following inpatient hospitalization (addressing the Meaningful Measures Initiative quality priority of promoting effective prevention and treatment of chronic disease), which is why we will continue to use these measures in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the above listed measures, sufficiently incentivizing performance improvement on these measures among participating hospitals. By keeping the measures in the Hospital VBP Program, patients, hospitals, and the public continue to receive information about the quality of care provided with respect to these measures.

As discussed in section VIII.A.4.b. of the preamble of this final rule, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing incentivize improvement in the quality of care provided to patients, and we believe removing these measures from the Hospital IQR Program is the best way to achieve that goal. In addition, as discussed in section I.A.2. of the preamble of this final rule, we believe keeping these measures in both programs no longer aligns with our goal of not adding unnecessary complexity or cost with duplicative measures across programs.

We note that the Hospital VBP Program has adopted the MORT–30–COPD measure beginning with the FY 2021 program year (80 FR 49558), the MORT–30–PN measure (modified with the expanded cohort) beginning with the FY 2021 program year (81 FR 56996), and the MORT–30–CABG measure beginning with the FY 2022 program year (81 FR 56998). Therefore, we proposed to stagger the beginning date of the removals of these measures from the Hospital IQR Program to avoid a gap in public reporting of measure data. For the Hospital IQR Program, we proposed to remove the: (1) MORT–30–AMI and MORT–30–HF measures for the FY 2020 payment determination (which would use a performance period of July 1, 2015 through June 30, 2018) and subsequent years; (2) MORT–30–COPD and MORT–30–PN measures for the FY 2021 payment determination (which would use a performance period of July 1, 2016 through June 30, 2019) and subsequent years; and (3) MORT–30–CABG measure for the FY 2022 payment determination (which would use a performance period of July 1, 2017 through June 30, 2020) and subsequent years.

Comment: A number of commenters supported CMS' proposals to remove five claims-based mortality measures. One commenter specifically agreed with removing these measures under the new removal Factor 8 while continuing to use them in the Hospital VBP Program. One commenter expressed support for CMS' proposals to remove MORT–30–AMI, MORT–30–HF, and MORT–30–CABG because it would reduce the burden of information collection and review for hospitals and would eliminate beneficiary confusion. One commenter specifically supported CMS' proposal to remove the MORT–30–HF measure from the Hospital IQR Program because it would reduce the reporting burden on hospitals without compromising the measure in the Hospital VBP Program.

Response: We thank the commenters for their support of removal of the five claims-based mortality measures.

Comment: One commenter supported the removal of these measures but noted that it did not believe burden would be reduced because the measures would still be reported in the Hospital VBP Program.

Response: We respectfully disagree that removing these measures will not reduce the costs associated with these measures. We believe that removing these measures would reduce the costs associated with tracking confidential feedback reports, preview reports, and publicly reported information for these measures in multiple programs. Healthcare providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used in multiple programs. Beneficiaries may also find it confusing to see public reporting on the same measures in different programs. In addition, costs to CMS would be reduced by no longer having to maintain the measure specifications, as well as the tools need to analyze and publicly report the measure data for multiple programs. We refer readers to section VIII.A.4.b. of the preamble of this final rule where we discuss examples of the costs associated with implementing and maintaining these measures.

Comment: One commenter sought clarification on whether removing these five mortality measures would also end public reporting on those measures. One commenter recommended that these measures continue to be publicly reported on *Hospital Compare.* A few commenters opposed CMS' proposals to remove five condition-specific mortality measures. A few commenters expressed concern that removing these measures would reduce program transparency and could result in a lack of public access to user-friendly condition-specific outcomes information. A few commenters recommended that measure-level reporting continue on *Hospital Compare* under the Hospital IQR Program, including frequency of reporting, for all measures in the Hospital VBP Program to ensure no loss of information to the public, and that future improvements in public reporting can be adopted consistently across publicly reported measures.

Response: We thank the commenters for their concerns and reiterate that we

will continue to publicly report measure-level data for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN, and MORT–30–CABG measures on the *Hospital Compare* website under the Hospital VBP Program, in accordance with its policies and in a manner that is transparent and easily understood by patients. Section 1886(o)(10)(A) of the Act requires the Hospital VBP Program to make information available to the public regarding the performance of individual hospitals, including performance with respect to each measure, on the *Hospital Compare* website in an easily understandable format. These measures will continue to be reported on *Hospital Compare* as they have been for the Hospital IQR Program, but under the requirements of the Hospital VBP Program. We will also strive to minimize disruptions to preexisting processes and timelines for publicly reporting these data.

Comment: One commenter did not support CMS' ''holistic'' view of the hospital quality programs. This commenter stated that initially adopting measures into the Hospital IQR Program allows for a period of measure validation, and for health systems to gain familiarity with the measures before they are moved into value-based purchasing programs, and expressed concern CMS' ''holistic'' view would allow new measures to be adopted immediately into the value-based purchasing programs without this time for familiarization and validation. The commenter stated its belief that adopting measures directly into the value-based purchasing programs would result in significant harm, undue hardship, and potentially financial penalties on healthcare systems.

Response: We thank the commenter for its comment, but emphasize that our proposal to remove duplicative measures from the Hospital IQR Program does not affect the underlying statutory requirements for adding new measures to the Hospital VBP, HAC Reduction, or Hospital Readmissions Reduction Programs. Those programs will continue to select measures as required by their statutory authority. For instance, the Hospital VBP Program will continue to select measures that have been specified under the Hospital IQR Program and refrain from beginning the performance period for any new measure until the data on that measure have been posted on *Hospital Compare* for at least one year, as required by section 1886(o)(2)(C)(i) of the Act. We note the HAC Reduction and Hospital Readmissions Reduction Programs do not have any similar statutory requirements in this regard as the Hospital VBP Program. We therefore disagree that these removals could result in harm, undue hardship, or financial penalties to hospitals because they do not alter the processes associated with adopting new measures into the Hospital VBP, HAC Reduction, or Hospital Readmissions Reduction Programs. We will, however, continue to consider on a case-by-case basis for each new measure whether it would be appropriate to propose the measure for the Hospital IQR Program before proposing to use it in either the HAC Reduction Program or the Hospital Readmissions Reduction Program.

Comment: One commenter did not support CMS' proposals to remove the MORT–30–AMI, MORT–30–HF, and MORT–30–PN measures because the commenter believed they are essential health and safety measurements, key to hospital accountability and incentivizing quality care. The commenter also expressed its opinion that the removal would decrease transparency and public accountability.

Response: We agree that these measures provide important information that can be used to promote accountability and to incentivize quality care. To further those goals, we will continue to include these measures in the Hospital VBP Program, which will both publicly report hospital performance on these measures and assess payment incentives to hospitals based on their performance on these and other quality measures. We refer readers to sections IV.I.2.d. and IV.I.2.e. of the preamble of this final rule where we list the measures used in the Hospital VBP Program. We appreciate the commenter's concerns and reiterate that we will continue to publicly report measure-level data for all of CMS' quality programs in a manner that is transparent and easily understood by patients. We will also strive to minimize disruptions to preexisting processes and timelines for publicly reporting this data.

After consideration of the public comments we received, we are finalizing removal of MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN, and MORT–30–CABG from the Hospital IQR Program measure set across the FYs 2020, 2021, and 2020 payment determinations as proposed.

(5) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications) Measure

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20477 through 20478), we proposed to remove one complications measure, Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications), beginning with the FY 2023 payment determination, under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We refer readers to FY 2013 IPPS/LTCH PPS final rule (77 FR 53516 through 53518), where we adopted this measure.

We believe that removing this measure from the Hospital IQR Program would eliminate costs associated with implementing and maintaining the measure for the program, and in particular, development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of this final rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on this measure as we also use the measure in the Hospital VBP Program and the Comprehensive Care for Joint Replacement model (CJR model). Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measure in different programs. In addition, maintaining the specifications for the measure, as well as the tools we need to analyze and publicly report the measure data result in cost to CMS. We believe the costs as discussed above outweigh the associated benefit to beneficiaries of receiving the same information from more than one program, because that information can be captured through inclusion of this measure in the Hospital VBP Program.

As discussed in section VIII.A.4.b. of the preamble of this final rule, one of our main goals is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe removing this measure from the Hospital IQR Program is the best way to achieve this goal. We believe retaining the Hip/Knee Complications measure in both the Hospital IQR Program and the Hospital VBP Program no longer aligns with our current goal of not adding unnecessary complexity or cost with duplicative measures across programs, as stated in section I.A.2. of the preamble of this final rule.

We continue to believe this measure provides important data on patient outcomes following inpatient hospitalization (addressing the Meaningful Measures Initiative quality priority of promoting effective treatment), which is why we will continue to use this measure in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the Hip/Knee Complications measure, sufficiently incentivizing performance improvement on this measure among participating hospitals. By keeping the measure in the Hospital VBP Program, patients, hospitals, and the public continue to receive information about the quality of care provided with respect to this measure.

Therefore, we proposed to remove the Hip/Knee Complications measure from the Hospital IQR Program beginning with the FY 2023 payment determination (which applies to the performance period of April 1, 2018 through March 31, 2021) and subsequent years. We chose to propose this timeframe because the Comprehensive Care for Joint Replacement model (CJR model) previously adopted the same measure and requires use of data collected under the Hospital IQR Program through the FY 2022 payment determination (which would use a performance period of April 1, 2017 through March 31, 2020) (80 FR 73507). After removal from the Hospital IQR Program, we note that this measure would continue to be reported on the *Hospital Compare* website under the public reporting requirements of the Hospital VBP Program.

Comment: Many commenters supported CMS' proposal to remove the Hip/Knee Complications measure beginning with the FY 2023 payment determination. One commenter stated that including this measure in the Hospital VBP Program provides a stronger incentive for hospitals to focus on performance improvement.

Response: We thank the commenters for their support for the removal of this measure and agree that retaining this measure in the Hospital VBP Program incentivizes providers to perform well on this measure.

Comment: One commenter opposed CMS' proposal to remove the Hip/Knee Complications measure due to concerns that its removal will reduce program transparency and could result in a lack of public access to user-friendly condition-specific outcome information. The commenter recommended that measure-level data reporting continue on *Hospital Compare* under the Hospital IQR Program, including the frequency of reporting, for all measures in the Hospital VBP Program to ensure no loss of information to the public and that future improvements in public reporting can be adopted consistently across publicly reported measures.

Response: We thank the commenter for sharing its concerns, and reiterate that we will continue to publicly report measure-level data for the Hip/Knee Complications measure on the *Hospital Compare* website under the Hospital VBP Program according to program policies in a manner that is transparent and easily understood by patients. Section 1886(o)(10)(A) of the Act requires the Hospital VBP Program to make information available to the public regarding the performance of individual hospitals, including performance with respect to each measure, on the *Hospital Compare* website in an easily understandable format. We will also strive to minimize any disruptions to preexisting processes and timelines for publicly reporting this data.

After consideration of the public comments we received, we are finalizing removal of the Hip/Knee Complications measure from the Hospital IQR Program measure set beginning with the FY 2023 payment determination and for subsequent years as proposed.

(6) Medicare Spending per Beneficiary (MSPB)—Hospital Measure (NQF #2158) (MSPB)

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20478 through 20479), we proposed to remove one resource use measure, Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158) (MSPB), from the Hospital IQR Program beginning with the FY 2020 payment determination, under the proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618) where we adopted this measure.

We believe that removing this measure from the Hospital IQR Program would eliminate costs associated with implementing and maintaining the measure, and in particular, development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of this final rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on this measure as we use the measure in the Hospital VBP Program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measure in different programs. In addition, maintaining the specifications for the measure, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs as discussed above outweigh the associated benefit to beneficiaries of receiving the same information from multiple programs, because that information can be captured through inclusion of this measure solely in the Hospital VBP Program.

As discussed in section VIII.A.4.b. of the preamble this final rule, one of our main goals is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to

patients, and we believe removing this measure from the Hospital IQR Program helps achieve that goal. In addition, as discussed in section I.A.2. of the preamble of this final rule, we believe keeping this measure in both programs no longer aligns with our goal of not adding unnecessary complexity or cost with duplicative measures across programs.

We continue to believe this measure provides important data on resource use (addressing the Meaningful Measures Initiative priority of making care affordable), which is why we will continue to use this measure in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the MSPB measure, sufficiently incentivizing performance improvement on this measure among participating hospitals. By keeping the measure in the Hospital VBP Program, patients, hospitals, and the public continue to receive information about the quality of care provided with respect to these measures.

Therefore, we proposed to remove the MSPB measure from the Hospital IQR Program beginning with the FY 2020 payment determination (which applies to the performance period of January 1, 2018 through December 31, 2018) and subsequent years. As a claims-based measure, which uses claims and administrative data to calculate the measure without any additional data collection from hospitals, we can operationally remove the MSPB measure sooner than certain other measures we proposed for removal in the proposed rule.

Comment: A few commenters expressed their support for CMS' proposal to remove the MSPB measure from the Hospital IQR Program.

Response: We thank the commenters for their support.

Comment: One commenter did not support CMS' proposal to remove the MSPB measure from the Hospital IQR Program based on their concern that CMS' ''holistic'' view would allow new measures to be adopted immediately into the value-based purchasing programs without adequate time for familiarization and validation. Specifically, the commenter stated that initially adopting measures into the Hospital IQR Program allows for a period of measure validation, and for health systems to gain familiarity with the measures before they are moved into value-based purchasing programs. The commenter stated its belief that adopting measures directly into the value-based purchasing programs would result in significant harm, undue hardship, and potentially financial penalties on healthcare systems.

Response: We thank the commenter for its feedback. We note that the MSPB measure has been used in the Hospital VBP Program since the FY 2015 program year. We also emphasize that our proposal to remove duplicative measures from the Hospital IQR Program does not affect the underlying statutory requirements of adding new measures to the Hospital VBP, HAC Reduction, or Hospital Readmissions Reduction Programs. Those programs will continue to select new measures as required by their statutory authority. For instance, the Hospital VBP Program will continue to select measures that have been specified under the Hospital IQR Program, like the MSPB measure, and refrain from beginning the performance period for any new measure until the data on that measure have been posted on *Hospital Compare* for at least one year, as required by section 1886(o)(2)(C)(i) of the Act. We note the HAC Reduction and Hospital Readmissions Reduction Programs do not have any similar statutory requirements in this regard as the Hospital VBP Program. We therefore disagree that these removals could result in harm, undue hardship, or financial penalties to hospitals because they do not alter the processes associated with adopting new measures into the Hospital VBP, HAC Reduction, or Hospital Readmissions Reduction Programs. We will, however, continue to consider on a case-by-case basis for each new measure whether it would be appropriate to propose the measure for the Hospital IQR Program before proposing to use it in either the HAC Reduction Program or the Hospital Readmissions Reduction Program. We also note that we assess the reliability and validity of measures before proposing to adopt them into any program, and will continue to do so.

After consideration of the public comments we received, we are finalizing our proposal to remove the Medicare Spending Per Beneficiary—Hospital (NQF #2158) (MSPB) measure from the Hospital IQR Program, beginning with the FY 2020 payment determination as proposed.

(7) Clinical Episode-Based Payment Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20479 through 20480), we proposed to remove six clinical episode-based payment measures from the Hospital IQR Program beginning with the FY 2020 payment determination:

- Cellulitis Clinical Episode-Based Payment Measure (Cellulitis Payment) (adopted at 80 FR 49664 through 49674);
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (GI Payment) (adopted at 80 FR 49664 through 49674);
- Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure (Kidney/UTI Payment) (adopted at 80 FR 49664 through 49674);
- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment) (adopted at 81 FR 57133 through 57142);
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure (Chole and CDE Payment) (adopted at 81 FR 57133 through 57142); and
- Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment) (adopted at 81 FR 57133 through 57142).

We proposed to remove the Cellulitis Payment, GI Payment, Kidney/UTI Payment, AA Payment, Chole and CDE Payment, and SFusion Payment measures under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We refer readers to section VIII.A.4.b. of the preamble of this final rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. Specifically, maintaining the specifications for the measure, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs associated with interpreting the requirements for multiple measures with overlapping data points outweigh the benefit to beneficiaries and providers of the additional information provided by these measures, because the measure data are already captured within the overall hospital MSPB measure, which will be retained in the Hospital VBP Program.

These measures are clinically coherent groupings of health care services that can be used to assess providers' resource use associated with the clinically coherent groupings (80 FR

49664). Specifically, these measures all use Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for a clinical issue associated with the respective clinical groupings (80 FR 49664 through 49668; 81 FR 57133 through 57140). However, these data also are captured in the MSPB measure, which uses claims data for hospital discharges, including Medicare Part A and Part B payments for services rendered to Medicare beneficiaries during the Medicare spending per beneficiary episode surrounding an index hospitalization (76 FR 51618 through 51627). Although the MSPB measure does not provide the same level of granularity that these individual measures do, the most essential data elements will be captured by and publicly reported under the MSPB measure in the Hospital VBP Program. We understand that some hospitals may appreciate receiving more granular payment measure data from individual episode-based payment measures, while other hospitals may not benefit from the use of individual measures in addition to MSPB because they do not have a sufficient number of cases for those measures to be calculated. We proposed to remove these measures because we believe that in balancing the costs of keeping these measures in the program compared to the benefit, providers would prefer to focus their improvement efforts on total payment, rather than both total payment and the payments associated with these individual types of clinical episodes. While we proposed to remove the MSPB measure from the Hospital IQR Program as discussed in the section above, the measure would continue to be included in the Hospital VBP Program (section IV.I.2.e. of the preamble of this final rule). We also note that the Hospital IQR Program will retain certain condition- and procedure-specific payment measures (specifically, focusing on patients hospitalized for heart failure, AMI, pneumonia, and elective hip and/or knee replacement procedures) with readmissions and mortality measure data for the same patient cohorts. Since the MSPB measure would still be reported for the Hospital VBP Program, patients, hospitals, and the public would continue to receive information about the data provided by these resource measures. Thus, removing these six measures from the Hospital IQR Program would help to reduce duplicative data and produce a more harmonized and streamlined measure set. Further, and as explained above, the Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the MSPB measure, sufficiently incentivizing performance improvement on this measure among participating hospitals.

As discussed in section VIII.A.4.b. of the preamble of this final rule, above, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe that removing these measures from the Hospital IQR Program helps achieve that goal. We recognize, however, that including specific episode-based payment measure data can provide hospitals with actionable feedback to better equip them to implement targeted improvements in comparison to an overall payment measure. In addition, these measures were only recently implemented in the Hospital IQR Program in the FY 2017 IPPS/LTCH PPS final rule and data have not yet become publicly available on the *Hospital Compare* website. However, because these episode-based payment measures are not tied directly with other clinical quality measures that could contribute to the overall picture of providers' clinical effectiveness and efficiency, we believe that the data derived from these measures may be of lower utility to patients in deciding where to seek care, as well as to providers in gaining feedback to reduce cost and improve efficiency while maintaining high quality care; they address resource use which is not directly tied to clinical quality, unless combined with other clinical quality measures (81 FR 57133 through 57134).

Therefore, we proposed to remove the Cellulitis Payment, GI Payment, Kidney/UTI Payment, AA Payment, Chole and CDE Payment, and SFusion Payment measures for the FY 2020 payment determination (which applies to the performance period of January 1, 2018 through December 31, 2018) and subsequent years. Because these are claims-based measures, operationally, we are able to remove them sooner than certain other measures we proposed for removal in the proposed rule.

We invited public comment on our proposal to remove these measures from the Hospital IQR Program as well as feedback on whether there are reasons to retain one or more of the measures in the Hospital IQR Program.

Comment: A number of commenters supported CMS' proposals to remove the clinical episode-based payment measures from the Hospital IQR Program. These commenters asserted that these clinical episode-based payment measures are of limited value to beneficiaries because without being tied directly to corresponding clinical quality measures, these measures only address resource use, and cost alone does not provide sufficient data for an assessment of the value of care provided. A few commenters also expressed support for removal of the clinical episode-based payment measures due to their overlap with the MSPB measure. One commenter asserted that the clinical episode-based payment measures should be removed because the commenter believes they have not been adequately assessed to address methodological issues such as attribution and the lack of social risk factor adjustments.

Response: We thank the commenters for their support, and appreciate the feedback on additional considerations for removing the clinical episode-based payment measures from the Hospital IQR Program. While we continue to believe that these measures as specified are valid and reliable as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49661; 80 FR 49664 through 49674) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57133 through 57142), we are finalizing their removal because we believe the costs outweigh the benefits supporting the continued use of these measures in the Hospital IQR Program. We also refer readers to section VIII.A.10. of the preamble of this final rule for a discussion of our ongoing efforts to account for social risk factors in the Hospital IQR Program.

Comment: One commenter expressed particular support for CMS' proposal to remove the Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment) from the Hospital IQR Program. The commenter noted that the measure was not supported by the MAP for adoption in the Hospital IQR Program and is not NQF-endorsed, and further stated their belief that due to the high rate of innovation and the ongoing introduction of new technologies and medical devices for treatment of aortic aneurysms, it is not an appropriate clinical area for cost measurement.

Response: We thank the commenter for its support.

Comment: A few commenters supported CMS' proposal to remove the Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment) from the Hospital IQR Program. One commenter supported removal because

the measure data are captured within the overall hospital MSPB measure, which will be retained in the Hospital VBP Program. Another commenter specifically supported removal because the data derived from this clinical episode-based payment measure, in its current form, may be of lower utility to patients and providers since the measure is not tied directly with any other clinical quality measures, and thus does not provide a complete picture of providers' clinical effectiveness and efficiency.

Response: We thank the commenters for their support.

Comment: A few commenters did not support CMS' proposals to remove the clinical episode-based payment measures from the Hospital IQR Program because these commenters believe the MSPB measure, which is being retained in the Hospital VBP Program, is too broad of a measure to tie to specific existing quality measures and too general to be meaningful to providers. One commenter noted the lack of a demonstrated linkage between spending and outcomes under the MSPB measure. Some commenters also noted that the clinical episode-based payment measures allow hospitals to receive more precise and contextual data on healthcare costs, and asserted that this information cannot be derived from the MSPB measure. One commenter stated that the clinical episode-based payment measures, while not currently linked to corresponding clinical quality measures, have the potential to improve coordination and transitions of care and thereby increase the efficiency of care across the full continuum.

Response: We thank the commenters for their feedback. We understand commenters' appreciation for the more granular payment measure data derived from individual clinical episode-based payment measures rather than the MSPB measure, as we recognize that specific clinical episode-based payment measure data can provide hospitals with actionable feedback to better equip them to implement targeted improvements in comparison to an overall payment measure. However, we also understand that other hospitals may not benefit from the use of individual clinical episode-based payment measures because they lack a sufficient number of cases for those measures to be calculated. Although the MSPB measure does not provide the same level of granularity as the individual clinical episode-based payment measures, we believe the most essential data elements are captured by and publicly reported under the MSPB measure in the Hospital VBP Program. As stated in the proposed rule, we believe that in balancing the costs of keeping these measures in the program compared to the benefit, providers would prefer to focus their improvement efforts on total payment, rather than both total payment and the payments associated with these specific types of clinical episodes. Furthermore, while we recognize the MSPB [280] measure is not currently tied to a specific existing quality measure, we respectfully disagree with commenters' assertions that the measure is too general to be meaningful to providers, as we continue to believe the MSPB measure provides valuable information that captures a wide range of services provided in the inpatient hospital setting and immediately post-discharge, and addresses the Meaningful Measures Initiative priority of making care affordable, which is why we will continue to use this measure in the Hospital VBP Program.

Finally, we agree that the clinical episode-based payment measures, if tied to corresponding clinical quality measures, have the potential to improve coordination and transitions of care and thereby increase the efficiency of care across the full continuum, and will take these recommendations into consideration for future program years. However, as the clinical episode-based payment measures are not currently tied directly to other clinical quality measures, we believe that the data derived from these measures may be of lower utility to patients in deciding where to seek care, as well as to providers in receiving feedback to reduce cost and improve efficiency while maintaining high quality care.

After consideration of the public comments we received, we are finalizing our proposal as proposed to remove the six clinical episode-based payment measures from the Hospital IQR Program beginning with the FY 2020 payment determination: (1) Cellulitis Clinical Episode-Based Payment Measure (Cellulitis Payment); (2) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (GI Payment); (3) Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure (Kidney/UTI Payment); (4) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment); (5) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure (Chole and CDE Payment); and (6) Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment).

[280] For a detailed discussion of our adoption of the MSPB measure in the Hospital IQR Program, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627).

(8) Chart-Abstracted Clinical Process of Care Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20480 through 20481), we proposed to remove the Influenza Immunization, Incidence of Potentially Preventable Venous Thromboembolism, Median Time from ED Arrival to ED Departure for Admitted ED Patients, and Admit Decision Time to ED Departure Time for Admitted Patients measures as discussed in detail below. Manual abstraction of these chart-abstracted measures is highly burdensome. We have previously stated our intent to move away from chart-abstracted measures in order to reduce this information collection burden (78 FR 50808; 79 FR 50242; 80 FR 49693). We refer readers to our discussion below and to section XIV.B.3.b. of the preamble of the proposed rule, where we discuss the information collection burden associated with each of these measures with greater specificity.

We invited public comment on our proposals and received the following general comments. Measure-specific comments are discussed further below.

Comment: Several commenters supported CMS' proposal to remove the chart-abstracted Clinical Process of Care (CPOC) measures IMM–2, VTE–2, ED–1, and ED–2 because they are duplicative to measures in other programs and are burdensome to report. Commenters noted that measures should provide value in data generated in proportion to intensity of data collection effort. A few commenters expressed that while they supported the removal of these particular CPOC measures, they are not opposed to the use of chart-abstraction to gather data when necessary to achieve quality improvement goals, even though this data collection method represents the greatest reporting burden for hospitals. One commenter supported removal of the CPOC measures, but expressed concern about the SEP–1 Sepsis Management Bundle being the only measure subject to validation in the Hospital IQR Program because SEP–1 is extremely complex and a relatively new measure.

Response: We thank the commenters for their support and appreciate the feedback regarding the potential future adoption of chart-abstracted measures when necessary to achieve important quality improvement goals. We agree with commenters that removal of these four chart-abstracted CPOC measures from the Hospital IQR Program will

reduce reporting burden for hospitals, and we note that their removal will also reduce the costs and burden related to the validation of these measures, so that hospitals may direct resources to more meaningful measures such as the SEP–1 measure, which hospitals began reporting under the Hospital IQR Program with 4th quarter 2015 data. While we acknowledge the commenter's concern about the SEP–1 measure remaining as the only measure subject to chart-abstracted validation under the Hospital IQR Program, we note that the SEP–1 measure has been a part of the Hospital IQR Program for a number of years,[281] which we believe has given hospitals sufficient time to become familiar with the reporting and validation requirements for this measure to ensure they are accurately reporting data for this measure. Furthermore, because ensuring proper and timely care for patients with severe sepsis and septic shock aligns with the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care, we believe it is appropriate to continue incentivizing proper reporting of sepsis measure data through our current data validation policies.

Comment: One commenter did not support CMS' proposals to remove the IMM–2, ED–1, and ED–2 measures because it stated that these measures are part of the core measure set for the Medicare Beneficiary Quality Improvement Project (MBQIP) administered by HRSA, and they are both relevant to rural care delivery and resistant to low case volume. The commenter noted that removal of these measures would leave CAHs with very limited options in terms of relevant inpatient metrics for engagement in public reporting and demonstrating quality.

Response: We acknowledge that facilitating quality improvement for rural hospitals and CAHs presents unique challenges and is a high priority under the Meaningful Measures Initiative. However, as discussed in the proposed rule, in assessing the continued use of these specific measures in the Hospital IQR Program, we determined that the costs associated with these measures, particularly the data collection burden for hospitals, outweigh the benefit of their continued use in the program. We note that the eCQM version of ED–2 remains available under the Hospital IQR Program, as well as the Promoting Interoperability Program's eCQM measure set for reporting by CAHs. In addition, we are exploring opportunities to develop more relevant measures and less burdensome methods to collect quality measure data for use by small and rural hospitals. For more information about quality measurement efforts for rural health settings, we refer readers to the MAP Rural Health Workgroup at: *http://www.qualityforum.org/MAP_Rural_Health_Workgroup.aspx*. For more information about the reporting and use of MBQIP data, including the MBQIP measure set, we refer readers to the National Rural Health Resource Center at: *https://www.ruralcenter.org/tasc/mbqip/data-reporting-and-use*.

Comment: One commenter requested clarification about whether the 2018 eCQM reporting requirements also means that CAHs are required to submit chart-abstracted measures to the Hospital IQR Program.

Response: We clarify that under section 1886(b)(3)(B)(viii) of the Act, only subsection (d) hospitals are required to submit data to the Hospital IQR Program. CAHs are neither required to submit chart abstracted measure data to the Hospital IQR Program, nor subject to any payment reduction. CAHs participating in the Promoting Interoperability Programs have eCQM reporting requirements with respect to those programs; we refer readers to section VIII.D. of the preamble of this final rule where that is discussed.

(a) Influenza Immunization Measure (NQF #1659) (IMM–2)

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50211) where we adopted the Influenza Immunization measure (NQF #1659) (IMM–2). In the proposed rule, we proposed to remove IMM–2 beginning with the CY 2019 reporting period/FY 2021 payment determination under removal Factor 1—topped-out measure and under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

Hospital performance on IMM–2 is statistically ''topped-out''—removal Factor 1. The Hospital IQR Program previously finalized two criteria for determining when a measure is ''topped out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 50203). Our analysis indicates that performance on this measure has been topped-out for the past three payment determination years and also for Q1 and Q2 of 2017 encounters. This analysis is captured by the table below:

Payment determination	Encounters	Number of hospitals	Mean	75th percentile	90th percentile	Truncated COV
FY 2016	2014 (Q1–Q4)	3,326	0.9292	0.9867	0.9965	0.0560
FY 2017	2015 (Q1–Q4)	3,293	0.9372	0.9890	0.9970	0.0494
FY 2018	2016 (Q1–Q4)	3,258	0.9370	0.9890	0.9970	0.0500

Our topped-out analysis shows that administration of the influenza vaccination to admitted patients is widely in practice and there is little room for improvement. We believe that hospitals will continue this practice even after the measure is removed; thus, utility in the program is limited.

Moreover, we proposed to remove this measure under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We believe the information collection burden associated with manual chart abstraction, as discussed above, outweighs the associated benefit to beneficiaries of receiving this information, because: (1) It is topped out and there is little room for improvement (discussed above); and (2) it does not directly measure patient outcomes.

As discussed in section I.A.2. of the preamble of this final rule, one of the goals of the Meaningful Measures Initiative is to reduce costs associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. Another goal of the Meaningful Measures Initiative is to utilize measures that are ''outcome-based where possible.'' IMM–2 is a

[281] We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50236 through 50241), where the SEP–1 measure was adopted into the Hospital IQR Program.

process measure that tracks patients assessed and given an influenza vaccination with their consent, but does not directly measure patient outcomes.

We recognize and agree that influenza prevention is an important public health issue. We note that the Influenza Vaccination Coverage Among Healthcare Personnel (HCP) measure (adopted at 76 FR 51631 through 51633), which assesses the percentage of healthcare personnel at a facility who receive the influenza vaccination, remains in the Hospital IQR Program. Although the HCP measure is focused on vaccination of providers and other hospital personnel and not beneficiaries, it promotes improved health outcomes among beneficiaries because: (1) Health care personnel that have received the influenza vaccination are less likely to transmit influenza to patients under their care; and (2) vaccination of health care personnel reduces the probability that hospitals may experience staffing shortages as a result of illness that would impact ability to provide adequate patient care. Thus, we believe the costs associated with reporting this chart-abstracted measure outweighs the associated benefits of keeping it in the Hospital IQR Program.

We proposed to remove the IMM–2 measure beginning with the CY 2019 reporting period/FY 2021 payment determination (which applies to the performance period of January 1, 2019 through December 31, 2019) because hospitals already would have collected and reported data for the first three quarters of the CY 2018 reporting period for the FY 2020 payment determination by the time of publication of the FY 2019 IPPS/LTCH PPS final rule. In addition, there are operational limitations associated with updating CMS systems in time to remove this measure sooner for the CY 2018 reporting period/FY 2020 payment determination. This proposed timeline (that is, beginning with the CY 2019 reporting period/FY 2021 payment determination) would subsequently allow us to use the data already reported by hospitals in the CY 2018 reporting period for public reporting on our *Hospital Compare* website and for data validation.

Therefore, we proposed to remove the IMM–2 measure from the Hospital IQR Program for the CY 2019 reporting period/FY 2021 payment determination and subsequent years.

Comment: Several commenters supported CMS' proposal to remove the chart-abstracted IMM–2 measure because it is topped-out, although they acknowledged vaccination in the hospital is beneficial to protect against the influenza and expressed the hope that removing the IMM–2 measure does not impact overall vaccination efforts and public health efforts during the influenza season. One commenter also noted that the IMM–2 measure does not directly measure patient outcomes.

Response: We thank commenters for their support.

Comment: Several commenters did not support CMS' proposal to remove the chart-abstracted IMM–2 measure because they believed there is still a need for improvement in immunization rates and the measure has significant public health implications. A few commenters expressed concern that there has been little progress toward the CDC Healthy People 2020 goal of 70 percent for influenza vaccinations with a current rate of 38.1 percent for 2014, and that once measures are removed, performance may deteriorate below the baseline.

Response: We recognize and agree that influenza prevention is an important public health issue. However, even though, as commenters suggest, there is significant room for improvement in nationwide vaccination rates toward the national immunization goals set by CDC Healthy People 2020,[282] the IMM–2 measure is a process measure that tracks only whether inpatients are assessed and given an influenza vaccination with their consent prior to discharge, if indicated. As a result, this measure does not directly assess patient outcomes and is limited to incentivizing immunization of patients admitted to an acute care hospital—a small subset of the total U.S. population. In addition, the IMM–2 measure has been topped-out for the past three reporting periods, indicating the rate of acute care hospitals assessing admitted patients for influenza vaccination is significantly higher than the national average. Because the IMM–2 measure, as specified, is limited to patients admitted to an acute care hospital, we do not believe continued use of this measure is likely to result in additional improvement in rates of influenza vaccination assessment among admitted hospital patients.

Comment: One commenter noted that accountable care organizations (ACOs) are also required to report on an influenza immunization measure. Accordingly, they may be able to contract with hospitals to incorporate processes or standing orders to immunize patients for influenza, and the alignment between the measures reported by ACOs and hospitals would reinforce incentives to improve immunization rates. Another commenter suggested that the IMM–2 measure should remain in the Program as a required chart-abstracted measure until such a time that CMS develops an eCQM to replace it.

Response: We appreciate the commenter's suggestion that ACOs may be able to contract with hospitals to incorporate processes to immunize for influenza and the recommendation to develop an eCQM version of IMM–2. We will continue to assess opportunities to address influenza vaccination rates outside of the hospital quality programs or through other types of measures.

Comment: One commenter noted that the rationale to remove the IMM–2 measure from the Hospital IQR Program because the HCP measure will be retained contradicts the rationale to remove the HCP measure from the IPFQR Program.

Response: We disagree with the commenter's assertion that removal of IMM–2 contradicts the rationale to retain the HCP measure in the Hospital IQR Program. We believe that the burden of reporting the HCP measure is greater for IPFs compared to the relative burden for acute care hospitals participating in the hospital quality reporting and value-based purchasing programs. The entire burden of registering for and maintaining access to the CDC's NHSN system for IPFs, especially independent or freestanding IPFs, is due to one measure (HCP); whereas a hospital participating in the hospital quality reporting and value-based purchasing programs, for example, must register and maintain NHSN access for purposes of submitting data for several, not just one, healthcare safety measures for the hospital quality reporting and value-based purchasing programs in which it participates. Furthermore, because the topic is addressed in other initiatives, such as state laws [283] and employer programs, we believe that the costs and burden of this measure on IPFs, especially independent or freestanding IPFs, outweighs the benefit of retaining the measure in the IPFQR Program.

Comment: A few commenters did not agree with the timing of the removal of IMM–2 because as proposed, the removal does not align with the collection and reporting of IMM–2 data. Commenters noted that immunization

[282] For more information about the national immunization goals under CDC Healthy People 2020, we refer readers to: *https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases.*

[283] CDC, Menu of State Hospital Influenza Vaccination Laws. Available at: *https://www.cdc.gov/phlp/docs/menu-shfluvacclaws.pdf.*

data is not collected for the ''first three quarters'' of the CY reporting period, but rather influenza data is only collected in Q1 and Q4. Therefore, by removing the measure beginning with the CY 2019 reporting period/FY 2021 payment determination, hospitals would already have collected and reported data in Q4 2018, which is half of the measure's flu season.

Response: We recognize that the influenza season spans the winter months from Q4 to Q1 and those are the data used for public reporting purposes on the *Hospital Compare* website, however, data collection occurs on a quarterly basis for the entire calendar year.[284] Therefore, if this measure were to be removed beginning with the CY 2018 reporting period/FY 2020 payment determination, hospitals would already have collected data for Q4 2017 and Q1 2018, as well as Q2 2018 and Q3 2018, but would not receive credit for reporting that information. Although hospitals would only have collected half of the data that would be used for public reporting purposes by the time of publication of the FY 2019 IPPS/LTCH PPS final rule, removing this measure beginning with the CY 2019 reporting period/FY 2021 payment determination would enable hospitals to get credit for the half-year of data already collected. Therefore, in the interest of ensuring that resources already expended do not go to waste, we believe that removing this measure beginning with the CY 2019 reporting period/FY 2021 payment determination is most appropriate.

After consideration of the public comments we received, we are finalizing our proposal to remove the IMM–2 measure from the Hospital IQR Program for the CY 2019 reporting period/FY 2021 payment determination and subsequent years as proposed.

(b) Incidence of Potentially Preventable Venous Thromboembolism Measure (VTE–6); Median Time From ED Arrival to ED Departure for Admitted ED Patients Measure (NQF #0495) (ED–1); and Admit Decision Time to ED Departure Time for Admitted Patients Measure (NQF #0497) (ED–2)

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51634 through 51636), where we adopted the Incidence of Potentially Preventable Venous Thromboembolism measure (VTE–6), and to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50210 through 50211), where we adopted both the chart-abstracted version of the Median Time from ED Arrival to ED Departure for Admitted ED Patients measure (NQF #0495) (ED–1) and the Admit Decision Time to ED Departure Time for Admitted Patients measure (NQF #0497) (ED–2). In the proposed rule, we proposed to remove VTE–6 and the chart-abstracted version of ED–1 beginning with the CY 2019 reporting period/FY 2021 payment determination; in addition, we proposed to remove the chart-abstracted version of ED–2 beginning with the CY 2020 reporting period/FY 2022 payment determination. We proposed to remove these three measures under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As discussed in section I.A.2. of the preamble of this final rule, one of the goals of our Meaningful Measures Initiative is to reduce costs associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. We believe the information collection burden associated with manual chart abstraction, as discussed above, outweighs the associated benefit to beneficiaries of receiving information provided by these measures because much of the information provided by these measures is available through other Program measure data (as further discussed below).

Furthermore, in the case of ED–2, hospitals still would have the opportunity to submit data since the eCQM version will remain part of the Hospital IQR Program measure set. We note that in section VIII.A.5.b.(9)(c) of the preamble of the proposed rule, we proposed to remove the eCQM version of ED–1, but to retain the eCQM version of ED–2 due to the continued importance of assessing ED wait times for admitted patients. Although ED–1 is an important metric for patients, ED–2 has greater clinical significance for quality improvement because it provides more actionable information such that hospitals have greater ability to allocate resources to consistently reduce the time between decision to admit and time of inpatient admission. Hospitals have somewhat less control to consistently reduce wait time between ED arrival and decision to admit, as measured by ED–1, due to the need to triage and prioritize more complex or urgent patients. Also, the Hospital OQR Program includes an ED throughput measure, OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (81 FR 79755), which publicly reports similar data as captured by ED–1. Therefore, we believe the costs to providers for submitting data on the chart-abstracted ED–1 and ED–2 measures outweigh the associated benefits of keeping the measures in the program given that other measures in the Hospital IQR Program and in other CMS hospital quality programs are able to capture actionable data on ED wait times.

Furthermore, although the eCQM version of VTE–6 is not included in the Hospital IQR Program, hospitals still would have the opportunity to submit data for two other VTE related measures (eCQMs), which were already adopted in the Hospital IQR Program measure set—Venous Thromboembolism Prophylaxis (VTE–1) (NQF #0371) eCQM (adopted at 78 FR 50809) and Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE–2) (NQF #0372) eCQM (adopted at 78 FR 50809). The VTE–1 eCQM assesses the number of patients who received venous thromboembolism (VTE) prophylaxis or have documentation why no VTE prophylaxis was given the day of or day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission; the VTE–2 eCQM assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given on the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). The VTE–1 and VTE–2 measures will be retained in the Hospital IQR Program to encourage best clinical practices to those patients in this high risk population by providing prophylactic steps which will decrease the incidence of preventable VTE. In contrast, the VTE–6 measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date. While awareness of the occurrence of preventable VTE is valuable knowledge, the prevention of the initial occurrence is more actionable and meaningful for both providers and beneficiaries. Therefore, we believe the costs to providers of submitting data on this chart-abstracted measure outweigh its limited clinical utility given other VTE measures in the Program are able to capture more actionable data on VTE.

As discussed in section VIII.A.4.b. of the preamble of this final rule, one of our main goals is to move the program

[284] We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures.

forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Therefore, we believe removing the chart-abstracted versions of the VTE–6, ED–1, and ED–2 measures from the Hospital IQR Program measure set helps achieve that goal.

We proposed to remove the VTE–6 measure and chart-abstracted version of the ED–1 measure beginning with the CY 2019 reporting period/FY 2021 payment determination, because hospitals already would have collected and reported data for the first three quarters of the CY 2018 reporting period for the FY 2020 payment determination by the time of publication of the FY 2019 IPPS/LTCH PPS final rule. Moreover, we would not be able to overcome operational limitations associated with updating our systems in time to support removal of the VTE–6 and chart-abstracted version of the ED–1 measures for the CY 2018 reporting period/FY 2020 payment determination. In addition, we proposed to remove the chart-abstracted version of the ED–2 measure beginning with the CY 2020 reporting period/FY 2022 payment determination, because the first results from validation of ED–2 eCQM data will be available beginning with the FY 2021 payment determination. We believe it is important to keep the chart-abstracted version of ED–2 in the program until after the validated data from the eCQM version of ED–2 is available for comparative analysis to evaluate the accuracy and completeness of the eCQM data. Further, removing these three measures on the proposed timelines would allow us to use the data already reported by hospitals in the CY 2018 reporting period for public reporting on our *Hospital Compare* website and for data validation.

Therefore, we proposed to remove: (1) VTE–6 and the chart-abstracted version of ED–1 beginning with the CY 2019 reporting period/FY 2021 payment determination; and (2) the chart-abstracted version of ED–2 beginning with the CY 2020 reporting period/FY 2022 payment determination.

Comment: A few commenters specifically supported CMS' proposal to remove the chart-abstracted version of the VTE–6 measure because it is burdensome and duplicative of other quality measures. Another commenter supported CMS' proposal to remove the chart-abstracted version of the VTE–6 measure, but disagreed with the rationale using proposed removal Factor 8. Instead, the commenter suggested using removal Factor 5—the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic—because the chart-abstracted versions of VTE–1 and VTE–2 measures have previously been removed from the Hospital IQR Program using removal Factor 5.

Response: We thank commenters for their support. With regard to the commenter's suggestion that we remove the VTE–6 measure using removal Factor 5 rather than removal Factor 8, because the chart-abstracted versions of the VTE–1 and VTE–2 measures have previously been removed from the Hospital IQR Program using removal Factor 5, we do not believe this rationale would be appropriate in this case because the eCQM versions of the VTE–1 and VTE–2 measures were retained in the Hospital IQR Program, as the ''measures more strongly associated with desired patient outcomes for the particular topic,'' whereas there is no equivalent eCQM measure to replace VTE–6 remaining in the Program. More generally, we note that applicability of the removal factors is not mutually exclusive and there can be situations where more than one removal factor may apply.

Comment: One commenter suggested that if a related measure replaces the current VTE–6 measure, that the measure steward should modify the list of acceptable VTE risk assessment tools to include the ''three-bucket'' Risk Assessment Model (RAM).

Response: The ''three-bucket'' RAM is a tool that allows hospital providers to categorize patients into one of three groups based on whether they are at low, moderate, or high risk of getting a VTE.[285] The VTE RAM is completed by the physician in a simple order sheet on admission, post-op, and/or transfer. We thank the commenter for its suggestion to modify the list of acceptable VTE risk assessment tools, should we propose a new VTE measure in future rulemaking to replace VTE–6. However, we note that at this time we have no plans to add additional VTE measures to the Hospital IQR Program. We will take this suggestion into consideration if additional VTE measures are proposed for addition to the Hospital IQR Program in the future.

Comment: Another commenter supported CMS' proposal to remove the current VTE–6 measure, but recommended the measure be revised and readopted as an eCQM because it is a clinically important issue, relevant for purposes of improving the quality of care provided in the acute care setting, and one of few outcome measures in the Program. This commenter acknowledged that the cost of the chart-abstracted version of the VTE–6 measure outweighs the benefit of its continued use; however, abstraction burden would be reduced and the measure more cost-effective as an eCQM. The commenter suggested that an eCQM could capture VTE prevention process failures during the hospital stay by measuring an undesirable outcome as patients who are not assessed for VTE risk, not prescribed prophylaxis, miss one or more doses of prescribed prophylaxis, and develop a pulmonary embolism or VTE during the hospitalization. In addition, the commenter urged development of a risk-adjustment model for an eCQM version of the VTE–6 measure, since this is an outcome measure.

Response: We will continue to assess opportunities to address this clinically important issue through other types of measures. We note, however, that a VTE–6 eCQM was previously adopted in the Hospital IQR Program (78 FR 50784) and subsequently removed (81 FR 57120) because a majority of hospitals did not have the ability to capture required data elements, such as diagnostic study results/reports and location of the specific vein in which deep vein thrombosis was diagnosed, in discrete structured data fields to support these eCQMs, because they are often found as free text in clinical notes instead. We also note that we are removing the VTE–6 measure because the VTE–1 and VTE–2 eCQMs will be retained in the Hospital IQR Program to encourage best clinical practices to those patients in this high risk population by providing prophylactic steps which will decrease the incidence of preventable VTE.

Comment: Several commenters supported CMS' proposals to remove the chart-abstracted versions of the ED–1 and ED–2 measures to reduce costs and eliminate overlapping reporting requirements between eCQM and chart-abstracted versions of the same measures. One commenter supported CMS' proposal to remove the chart-abstracted versions of the ED–1 and ED–2 measures, but disagreed with the rationale using proposed removal Factor 8. Instead, the commenter suggested using removal Factor 5—the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic—because the eCQM versions of ED–1 and

[285] Venous Thromboembolism (VTE) Prevention in the Hospital, AHRQ. Available at: *https://archive.ahrq.gov/professionals/quality-patient-safety/quality-resources/value/vtepresentation/maynardtxt.html.*

ED–2 represent measures ''that is more strongly associated with desired patient outcomes for the particular topic.''

Response: We thank the commenters for their support of these removals. We appreciate the commenters' recommendation to remove these measures under removal Factor 5; however, because we are finalizing our proposal to remove the ED–1 eCQM, Factor 5 would not apply to the removal of the chart-abstracted version of the ED–1 measure. We further believe removal Factor 8 is an appropriate removal factor for this measure. More generally, we note that applicability of the removal factors is not mutually exclusive and there can be situations where more than one removal factor may apply.

Comment: One commenter supported CMS' proposal to remove the chart-abstracted version of the ED–1 measure beginning with the CY 2019 reporting period/FY 2021 payment determination and the chart-abstracted version of the ED–2 measure beginning with the CY 2020 reporting period/FY 2022 payment determination, as proposed, in order to complete the validation process for the eCQM versions of the measure and to compare to chart-abstracted measure results before removing the chart-abstracted version of ED–2. Several commenters supported CMS' proposal to remove the chart-abstracted versions of the ED–1 and ED–2 measures, but encouraged CMS to remove both measures in the same year. These commenters argued that the patient's chart must still be reviewed for the ED–2 measure, even when the chart-abstracted version of the ED–1 measure is retired and therefore, retiring one before the other does not reduce provider burden or workload.

Response: We thank the commenter that supported removing the chart-abstracted versions of the ED–1 and ED–2 measures on the proposed timeline and agree that it is a benefit to complete the validation process for the eCQM versus chart-abstracted measure before removing the chart-abstracted version of the ED–2 measure. We appreciate the commenters' position that the chart-abstracted versions of the ED–1 and ED–2 measures should be removed in the same year; however, we disagree that removing one measure before the other will not reduce provider burden. We acknowledge that patient charts will still need to be abstracted to report on the chart-abstracted version of the ED–2 measure up to the CY 2020 reporting period/FY 2022 payment determination, however, the abstractors would only need to review the charts for the ED–2 measure elements, and not the ED–1 elements, which we believe will result in some reduction in provider cost.

Comment: One commenter noted that comparison of ED–2 eCQM data with the ED–2 chart-abstracted data is not feasible because many organizations sample chart-abstracted data due to the large volume of patients, meaning analysis would be comparing the median time of approximately 90 cases per quarter versus over 10,000 eCQM cases. The commenter expressed concern that the median values between the two sets never match and can vary greatly. In addition, the specifications for the admit date/time do not match as the eCQM is limited to selecting a specific data field typically from a registration system and the chart-abstracted version requires an abstractor to take the first documented time in the chart.

Response: We thank the commenter for its feedback on the challenges of direct comparisons between the chart-abstracted and the eCQM versions of the ED–2 measure. We will continue to review and take these concerns into consideration.

Comment: A few commenters did not support CMS' proposals to remove the chart-abstracted versions of the ED–1 and ED–2 measures because the Maryland Health Services Cost Review Commission uses these measures to incentivize progress in improving ED wait times.

Response: We acknowledge the commenters' concern. We clarify that Maryland hospitals do not participate in the Hospital IQR Program, though they do report data pursuant to the all-payer model agreement.[286] We also refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50789) for more detailed discussions of Maryland hospitals in relation to the Hospital IQR Program. As discussed in the proposed rule, in assessing the continued use of these specific measures in the Hospital IQR Program, we determined that the costs associated with these measures, particularly the data collection burden for hospitals, outweigh the benefit of their continued use in the program. However, we note that the removal of these measures from the Hospital IQR Program does not preclude their use in other CMS and non-CMS quality programs.

After consideration of the public comments we received, we are finalizing our proposals to remove the VTE–6 measure and the chart-abstracted version of ED–1 beginning with the CY 2019 reporting period/FY 2021 payment determination and the chart-abstracted version of ED–2 beginning with the CY 2020 reporting period/FY 2022 payment determination, as proposed.

(9) Removal of Electronic Clinical Quality Measures (eCQMs)

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20481 through 20484), in alignment with the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and CAHs, we proposed to reduce the number of electronic Clinical Quality Measures (eCQMs) in the Hospital IQR Program eCQM measure set from which hospitals must select four to report, by proposing to remove seven eCQMs (of the 15 measures currently in the measure set) beginning with the CY 2020 reporting period/FY 2022 payment determination. The seven eCQMs we proposed to remove are:

- Primary PCI Received Within 90 Minutes of Hospital Arrival (AMI–8a) (adopted at 79 FR 50246);
- Home Management Plan of Care Document Given to Patient/Caregiver (CAC–3) (adopted at 79 FR 50243 through 50244);
- Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF #0495) (ED–1) (adopted at 78 FR 50807 through 50710);
- Hearing Screening Prior to Hospital Discharge (NQF #1354) (EHDI–1a) (adopted at 79 FR 50242);
- Elective Delivery (NQF #0469) (PC–01) (adopted at 78 FR 50807 through 50810);
- Stroke Education (STK–08) (adopted at 78 FR 50807 through 50810); and
- Assessed for Rehabilitation (NQF #0441) (STK–10) (adopted at 78 FR 50807 through 50810).

We proposed to remove all seven eCQMs under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. As discussed in section I.A.2. of the preamble of this final rule, two of the goals of our Meaningful Measures Initiative are to: (1) Reduce costs associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology; and (2) to apply a parsimonious set of the most meaningful measures available to track patient outcomes and impact. In section VIII.A.11.d.(2) of the preamble of this final rule, for the CY 2019 reporting

[286] For more information regarding the Maryland All-Payer Model, we refer readers to: *https://innovation.cms.gov/initiatives/Maryland-All-Payer-Model/.*

period/FY 2021 payment determination, we discuss our proposal to extend the same eCQM reporting requirements finalized for the CY 2018 reporting period/FY 2020 payment determination, such that hospitals submit one, self-selected calendar quarter of data on four self-selected eCQMs. Thus, we anticipate the collection of information burden associated with eCQM data reporting for the CY 2019 reporting period/FY 2021 payment determination will be the same as for the CY 2018 reporting period/FY 2020 payment determination. However, in section VIII.A.4.b. of the preamble of this final rule, we discuss our belief that costs associated with program requirements are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the measures for the Program, such as staying current on clinical guidelines and maintaining measure specifications in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program. With respect to eCQMs, we believe that a coordinated reduction in the overall number of eCQMs in both the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) would reduce costs and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs, while still allowing hospitals some flexibility to select which eCQMs to report that best reflect their patient populations and support internal quality improvement efforts. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57116 through 57120) where we previously removed 13 eCQMs from the eCQM measure set in order to develop a smaller, more specific subset of eCQMs.

In order to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, we believe it is appropriate to propose to remove additional eCQMs at this time to develop an even more streamlined set of the most meaningful eCQMs for hospitals. In selecting which eCQMs to propose for removal, we considered the relative benefits and costs associated with each eCQM in the measure set. Individual eCQMs are discussed in more detail below.

(a) AMI–8a

We proposed to remove AMI–8a because the costs associated with implementing and maintaining this eCQM outweigh the associated benefit to beneficiaries because too few hospitals select to report on this measure. Only a single hospital reported on this measure for the CY 2016 reporting period. Because we do not receive enough data to conduct meaningful, statistically significant analysis, we believe the costs of maintaining this measure in the Program outweigh any associated benefit to patients, consumers, and providers—proposed removal Factor 8.

(b) CAC–3, STK–08, and STK–10

We proposed to remove the CAC–3, STK–08, and STK–10 eCQMs, because we believe the costs associated with implementing and maintaining these eCQMs outweigh the benefit to beneficiaries because they do not provide information evaluating the clinical quality of the activity. Home Management Plan of Care Document Given to Patient/Caregiver (CAC–3) assesses the proportion of pediatric asthma patients discharged from an inpatient hospital stay with a Home Management Plan of Care (HMPC) document given to the pediatric asthma patient/caregiver. Stroke Education (STK–08) captures ischemic or hemorrhagic stroke patients or their caregivers who were given educational materials during the hospital stay and at discharge. Assessed for Rehabilitation (STK–10) captures ischemic or hemorrhagic stroke patients who were assessed for rehabilitation.

We have issued guidance that measure developers should avoid selecting or constructing measures that can be met primarily through documentation without evaluating the clinical quality of the activity—often satisfied with a checkbox, date, or code—for example, a completed assessment, care plan, or delivered instruction.[287] CAC–3, STK–08, and STK–10 are examples of those types of measures. In our effort to create a more parsimonious measure set, we assessed which measures are the least costly to report and most effective in particular priority areas, including stroke, and we believe these measures provide less benefit to providers and Beneficiaries, relative to their costs.

Furthermore, we stated that if our proposals to remove the STK–08 and STK–10 eCQMs are finalized as proposed, we believe the resulting set of four stroke eCQMs (STK–02, STK–03, STK–05, and STK–06) will be more meaningful to both patients and providers because they capture the proportion of ischemic stroke patients who are prescribed a statin medication,[288] specific anti-thrombolytic therapy,[289] and/or anticoagulation therapy [290] at hospital discharges, which would address follow-up care and promote future preventative actions. Moreover, these remaining stroke eCQMs continue to be meaningful because ischemic strokes account for 87 percent of all strokes, and strokes are the fifth leading cause of death and disability.[291] We also note that the STK–08 and STK–10 eCQMs already have been removed from The Joint Commission's eCQM measure set.[292]

(c) ED–1

We proposed to remove the Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) eCQM because we believe that among the ED measures in the eCQM measure set, Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) is more effective at driving quality improvement. We note that in section VIII.A.5.b.(8)(b) of the preamble of the proposed rule, we proposed to remove the chart-abstracted versions of ED–1 and ED–2. As stated above, we believe that although ED–1 is an important metric for patients, ED–2 has greater clinical significance for quality improvement because it provides more actionable information—hospitals have greater ability to allocate resources and align inter-departmental communication to consistently reduce the time between decision to admit and time of inpatient admission. Hospitals have somewhat less ability to consistently reduce wait time between ED arrival and decision to admit, as measured by ED–1, due to the need to triage and prioritize more complex or urgent patients, which might inadvertently prolong ED wait times for less urgent patients. Also, the Hospital OQR Program includes an ED

[287] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-120.pdf.*

[288] Measure specifications for STK–06 are available at: *https://ecqi.healthit.gov/ecqm/measures/cms105v6.*

[289] Measure specifications for STK–02 and STK–05 are available at: *https://ecqi.healthit.gov/ecqm/measures/cms104v6* and *https://ecqi.healthit.gov/ecqm/measures/cms072v6.*

[290] Measure specifications for STK–03 available at: *https://ecqi.healthit.gov/ecqm/measures/cms071v7.*

[291] *http://www.strokeassociation.org/STROKEORG/AboutStroke/Impact-of-Stroke-Stroke-statistics_UCM_310728_Article.jsp.*

[292] *https://www.jointcommission.org/the_joint_commission_measures_effective_january_1_2018/.*

throughput measure, OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (81 FR 79755), which publicly reports similar data as captured by ED–1. Therefore, we believe the costs of implementing and maintaining the eCQM, as discussed above, outweigh the limited benefits of keeping the measure in the Program given that other measures in the Hospital IQR Program and in other CMS hospital quality programs are able to capture actionable data on ED wait times.

(d) EHDI–1a

We proposed to remove the EHDI–1a eCQM because we believe the costs associated with implementing and maintaining the measure, as discussed above, outweigh the benefits to beneficiaries because newborn hearing screening is already widely practiced by hospitals as the standard of care and already mandated by many State laws. Forty-three States currently have statutes or rules related to newborn hearing screening and 28 of the 43 States require babies to be screened.[293] Thus, this measure may be duplicative with local regulations for most hospitals. Therefore, we believe the costs associated with the measure outweigh the associated benefits of keeping the measure in the Hospital IQR Program.

(e) PC–01

We proposed to remove the eCQM version of PC–01. Due to the importance of child and maternal health, we did not propose to also remove the chart-abstracted version of the measure because we believe all hospitals with a sufficient number of cases should be required to report data on this measure (adopted at 77 FR 53530). Although we have expressed in section XIII.A.4.b.ii.(8) of the preamble of the proposed rule our intent to move away from the use of chart-abstracted measures in quality reporting programs, our previously adopted policy requires that hospitals should need less time to submit data for this measure because, unlike the other chart-abstracted measures, hospitals are only required to submit several aggregate counts instead of potentially numerous patient-level charts. We note that submission of this measure places less information collection burden on hospitals than the other chart-abstracted measures because of the ease with which hospitals can simply submit their aggregate counts using our Web-Based Measure Tool through the QualityNet website (77 FR 53537). In addition, if the chart-abstracted version of this measure were removed from the Program, and hospitals could only elect to report the eCQM version of this measure as one of four required eCQMs, we believe that due to the low volume of patients relative to total adult hospital population, we would not receive enough data to produce meaningful analyses. Also, PC–01 is one of only two measures of child and maternal health in the Hospital IQR Program measure set (PC–05 eCQM being the other) and since eCQM data are not currently publicly reported, the chart-abstracted version of PC–01 is currently the only publicly reported measure of child and maternal health in the Program. However, retaining this measure in both eCQM and chart-abstracted form may be duplicative and costly. Consequently, we proposed to remove the eCQM version of PC–01 while retaining the chart-abstracted version of PC–01.

Therefore, we believe the costs associated with implementing and maintaining the eCQM, as discussed above, outweigh the associated benefit to beneficiaries because the information is already collected and publicly reported in the chart-abstracted form of this measure for the Hospital IQR Program.

Thus, we proposed to remove seven eCQMs as discussed above beginning with the CY 2020 reporting period/FY 2022 payment determination. If our proposals are finalized as proposed, the eCQMs remaining in the eCQM measure set would focus on: (a) ED wait times for admitted patients (ED–2), which addresses the Meaningful Measures Initiative quality priority of promoting effective communication and coordination of care; (b) Exclusive Breast Milk Feeding (PC–05), which addresses the Meaningful Measures Initiative quality priority that care is personalized and aligned with patients' goals; and (c) stroke care (STK–02, STK–03, STK–05, and STK–06) and VTE care (VTE–1 and VTE–2), which address the Meaningful Measures Initiative quality priority of promoting effective prevention and treatment.

In crafting our proposals to remove these seven eCQMs from the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years, we also considered proposing to remove these seven eCQMs one year earlier, beginning with the CY 2019 reporting period/FY 2021 payment determination. We establish program requirements considering all hospitals that participate in the Hospital IQR Program at a national level, which involves a wide spectrum of capabilities and resources with respect to eCQM reporting. In establishing our eCQM policies, we must balance the needs of hospitals with variable preferences and capabilities. Overall, across the range of capabilities and resources for eCQM reporting, stakeholders have expressed that they want more time to prepare for eCQM changes. Specifically, as noted in the FY 2018 IPPS/LTCH PPS final rule, we have continued to receive frequent feedback (via email, webinar questions, help desk questions, and conference call discussions) from hospitals and health IT vendors about ongoing challenges of implementing eCQM reporting, including, ''a need for at least one year between new EHR requirements due to the varying 6- to 24-month cycles needed for vendors to code new measures, test and institute measure updates, train hospital staff, and rollout other upgraded features (82 FR 38355).''

We recognize that some hospitals and health IT vendors may prefer earlier removal in order to forgo maintenance on those eCQMs proposed for removal. In preparation for the proposed rule, we weighed the relative burdens and costs associated with removing these measures beginning with the CY 2019 reporting period/FY 2021 payment determination or beginning with the CY 2020 reporting period/FY 2022 payment determination. Ultimately, in order to be responsive to the previous stakeholder feedback we have received, we proposed to remove these seven eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years, even if as a result some hospitals may have to perform measure maintenance on measures that would be removed the following year. We believe our proposal to remove these eCQMs would spare hospitals that have already allocated and expended resources in 2018 in preparation for the CY 2019 reporting period that begins January 1, 2019 from the burden of unnecessarily expended resources or expending additional time and resources to update their EHR systems or adjust the eCQMs they selected to report for the CY 2019 reporting period/FY 2021 payment determination.

In the proposed rule, we noted that we are striving to establish program requirements that reflect the wide range of capabilities and resources of hospitals for eCQM reporting. Our proposal would allow more advanced notice of eCQMs that would and would not be available to report for the CY 2020 reporting period/FY 2022 payment determination. Therefore, we proposed

[293] *http://www.infanthearing.org/ehdi-ebook/2017_ebook/1b%20Chapter1EvolutionEHDI2017.pdf.*

to remove the AMI–8a, CAC–3, ED–1, EHDI–1a, PC–01, STK–08, and STK–10 eCQMs from the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We refer readers to section VIII.A.5.b.(9) of the preamble of the proposed rule for our proposals to remove these seven eCQMs from the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). We also refer readers to sections VIII.A.11.d. of the preamble of this final rule for our proposals on the eCQM reporting requirements for the CY 2019 reporting period/FY 2021 payment determination, including further discussion on the 2015 Edition of CEHRT.

We invited public comment on our proposal as discussed above, including the specific measures proposed for removal and the timing of removal from the program.

Comment: Many commenters supported CMS' proposals to remove seven eCQMs from the Hospital IQR Program because removal: (1) Aligns with the Meaningful Measures framework to reduce reporting burden by examining measures through a lens that identifies meaningful, outcome-based measures; (2) creates a streamlined measure set and makes it easier for vendors to maintain specifications for the available eCQMs; (3) satisfies the aims of removal Factor 8, in that the expense of implementing and maintaining these measures outweighs the benefit to the healthcare team and Medicare beneficiaries; and (4) gives hospitals more time and resources to accommodate new reporting requirements by enabling them to focus on a more specific subset of eCQMs, while still allowing flexibility in measure selection to best reflect patient populations and support internal quality improvement efforts. Specifically, one commenter supported reducing the number of reportable eCQMs, and instead consolidating some of these additional quality measures into cost metrics such as the Medicare Spending Per Beneficiary (MSPB). Another commenter supported removing these seven eCQMs and further recommended CMS remove all existing eCQMs as they believe they do not fully support the Meaningful Measures framework and moving towards value-based care.

Response: We thank commenters for their support. We appreciate commenters' suggestions to remove additional eCQMs and to consolidate or replace them with more meaningful, outcomes-based measures. It is one of our goals to expand EHR-based quality reporting in the Hospital IQR Program using more meaningful measures, which we believe will ultimately reduce burden on hospitals as compared with chart-abstracted data reporting and improve patient outcomes by providing more robust data to support quality improvement efforts. We intend to introduce additional eCQMs into the program as eCQMs that support our program goals become available and would propose any such measures through future rulemaking.

Comment: A few commenters specifically supported CMS' proposal to remove the AMI–8a eCQM because with a limited number of hospitals reporting this measure, there is a lack of significant data for analysis of patient care and the costs outweigh the benefits. One commenter supported removal of the AMI–8a eCQM, but disagreed with the rationale for removal asserted under proposed removal Factor 8.

Response: We thank commenters for their support and we believe removal Factor 8 provides the appropriate rational for removal of the AMI–8a eCQM because, as some commenters observed, the lack of data reported on the measure precludes meaningful data analysis, and therefore the costs outweigh the benefits of retaining the measure.

Comment: A few commenters specifically supported CMS' proposal to remove the CAC–3 eCQM because it is a ''checkbox'' measure that is based on documentation without evaluation of clinical quality. One commenter supported removal of the CAC–3 eCQM, but disagreed with the rationale for removal asserted under proposed removal Factor 8.

Response: We thank commenters for their support and we believe removal Factor 8 provides the appropriate rational for removal of the CAC–3 eCQM because, as some commenters observed, it is based on documentation without evaluation of clinical quality, and therefore the costs outweigh the benefits of retaining the measure.

Comment: A few commenters specifically supported CMS' proposals to remove the STK–08 and STK–10 eCQMs because they are ''checkbox'' measures that are based on documentation without evaluation of clinical quality. One commenter supported removal of the STK–08 and STK–10 eCQMs, but disagreed with the rationale for removal asserted under proposed removal Factor 8. Another commenter noted that The Joint Commission removed the STK–08 and STK–10 eCQMs for the 2017 reporting year, acknowledging that their value was limited.

Response: We thank commenters for their support and we believe removal Factor 8 provides the appropriate rational for removing the STK–08 and STK–10 eCQM s because, as some commenters observed, they are based on documentation without evaluation of clinical quality, and therefore the costs outweigh the benefits of retaining the measures.

Comment: A few commenters specifically supported CMS' proposals to remove the ED–1 measures (both eCQM and chart-abstracted versions) and ED–2 (chart-abstracted version), as well as removal of the ED–2 eCQM (which was not proposed for removal) due to cost. One commenter explained that their system cannot pull the required times from the required locations (found in algorithm) so it is very difficult to get the true length of wait times. Despite efforts to change the system and educate the staff, the commenter believed these measures fail to improve quality of care because until patients stop misusing the ED and jamming up the system, the measure will not effectuate change. For these reasons, the commenter suggested that although the ED–2 eCQM was not proposed for removal, the ED–2 eCQM should also be removed.

Response: We thank the commenters for their support of these removals. We appreciate the commenter's feedback regarding the difficulty that may be experienced in identifying true length of ED wait times. We will take into consideration the feedback on the ED eCQMs as part of measure maintenance on the ED–2 eCQM. We believe ED–2 is clinically significant because it provides actionable information for quality improvement purposes such that it is important to retain the eCQM version in the measure set; however, we will also take into consideration the recommendation to remove the ED–2 eCQM from the Hospital IQR Program into consideration for future program years.

Comment: One commenter encouraged CMS to exclude CAHs with low ED volume from reporting both chart-abstracted and eCQM versions of the ED–2 measure.

Response: We appreciate the commenter's feedback, but note that under section 1886(b)(3)(B)(viii) of the Act, only subsection (d) hospitals are required to submit data to the Hospital IQR Program, not CAHs. However, we acknowledge that facilitating quality improvement for rural hospitals and small hospitals, such as CAHs, can present unique challenges and is a high

priority under the Meaningful Measures Initiative.

Comment: A few commenters specifically supported CMS' proposal to remove the EHDI–1a eCQM because there is little benefit to measuring a widely practiced standard of care. One commenter supported CMS' proposal to remove the EHDI–1a eCQM, but disagreed with the rationale for removal asserted under proposed removal Factor 8.

Response: We thank commenters for their support and we believe removal Factor 8 provides the appropriate rational for removal of the EHDI–1a eCQM because, as some commenters observed, it is of little benefit to measure a widely practiced standard of care, and therefore the costs outweigh the benefits of retaining the measure.

Comment: A few commenters specifically supported CMS' proposal to remove the PC–01 eCQM because the chart-abstracted version of the measure would be retained. Another commenter specifically supported CMS' proposal to remove PC–01, but requested that removal be aligned with removal of the chart-abstracted version of the measure from the Hospital VBP Program in the same performance year. The commenter asserted the belief that if a measure is topped out or removed in one format, it is most likely topped out in the other format as well.

Response: We thank commenters for their support. We appreciate the suggestion that removal of the PC–01 eCQM from the Hospital IQR Program be aligned with the removal of the chart-abstracted version of the PC–01 measure from the Hospital VBP Program; however, we believe that removing the PC–01 eCQM from the Hospital IQR Program beginning with the CY 2020 reporting period/FY 2022 payment determination and removing the chart-abstracted version of the PC–01 measure from the Hospital VBP Program beginning with the CY 2019 reporting period/FY 2021 payment determination as proposed is the appropriate timeline for removal of each measure from their respective programs. As stated above, we are removing eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination as a result of stakeholder feedback requesting more notice before making changes to the eCQM measure set in order to give hospitals additional time to select alternate eCQMs, and to modify workflows and systems as necessary, in the case that eCQMs they had previously been reporting are being removed.

We refer readers to section IV.I.2.c.(1) of the preamble of this final rule for a discussion of the reasons we are removing the chart-abstracted version of the PC–01 measure from the Hospital VBP Program as soon as practicable, beginning with the CY 2019 performance period for the FY 2021 program year. We note that the chart-abstracted version of the PC–01 measure will continue to be included in the Hospital IQR Program and therefore, removing the chart-abstracted version of the PC–01 measure from the Hospital VBP Program will have no effect on hospital data collection burden whether it occurs beginning with the CY 2019 performance period or the CY 2020 performance period.

Comment: One commenter was neutral on the proposed removal of the eCQMs, but indicated that it would implement any replacement measures if necessary.

Response: We appreciate the commenter's support.

Comment: One commenter urged CMS to maintain a reasonable proportion of eCQMs applicable in primary care, retain eCQMs that are essential to Federally Qualified Health Center patient populations, and continue to implement measures that are relevant to medically underserved populations.

Response: We acknowledge that facilitating quality improvement for medically underserved patient populations, such as those served by Federally Qualified Health Centers, presents unique challenges and eliminating disparities is a one of the strategic goals under the Meaningful Measures Initiative. For more information about Federal Qualified Health Centers, we refer readers to: *https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html.* As stated above, it is also one of our goals to reduce reporting burden by expanding EHR-based quality reporting in the Hospital IQR Program using more meaningful measures, which we believe will ultimately reduce burden on hospitals as compared with chart-abstracted data reporting and improve patient outcomes by providing more robust data to support quality improvement efforts. We intend to introduce additional eCQMs that support our program goals as they become available.

Comment: One commenter expressed concern that reducing the number of required measures may not result in reduced administrative burden for clinicians and staff and urged CMS to reduce the operational burden each specific measure places on clinicians and their medical practice staff by continuing to evaluate associated documentation requirements for measures to effectively reduce the administrative burden facing clinicians.

Response: We believe in enabling hospitals to focus on a smaller, more specific subset of eCQMs, while still allowing hospitals some flexibility to select which eCQMs to report that best reflect their patient populations and support internal quality improvement efforts. In order to move the program forward in the least burdensome manner possible while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, we believe it is appropriate to remove additional eCQMs at this time to develop an even more streamlined set of the most meaningful eCQMs for hospitals. Creating a streamlined measure set reduces burden by making it easier for vendors to maintain specifications for the available eCQMs and giving hospitals more time and resources to accommodate new reporting requirements, while still allowing flexibility in measures selection to best reflect patient populations and support internal quality improvement efforts. In addition, we will continue to evaluate measure specifications and associated documentation requirements for the eCQMs we are retaining and for potential future eCQMs to ensure that we are moving the Program forward in the least burdensome manner possible while continuing to encourage improvement in the quality of care provided to patients.

Comment: Several commenters did not support removal of the seven eCQMs because of the burden on hospitals associated with selecting different measures to report if they had previously reported on the measures proposed for removal. The remaining measures are being collected, but additional work is needed to streamline data collection and discrete data analysis. One commenter explained that it has a few of the measures proposed for removal built in their system. The commenter expressed concern the measure removals would occur before hospitals have had significant time to really learn how to effectively build, review, and evaluate the eCQMs. A few commenters expressed concern that hospitals would need to fully redevelop measures, pulling scarce resources from ongoing quality improvement efforts and recommended that CMS keep the current set of eCQMs, make the program data public, and allow the industry to learn how to best use the current set of

measures before further modifications are made.

Response: We understand the commenters' concern with removing eCQMs that have been previously reported and implemented in an existing EHR workflow, and we acknowledge the time, effort, and resources that hospitals expend on reporting these measures. However, we believe that removal of these seven eCQMs will be less burdensome to hospitals overall than continuing to keep them in the Hospital IQR Program. As part of agency-wide efforts under the Meaningful Measures Initiative to use a parsimonious set of the most meaningful measures for patients and clinicians in our quality programs and the Patients Over Paperwork initiative to reduce burden, cost, and program complexity as discussed in section I.A.2. of the preamble of this final rule, our decision to remove measures from the Hospital IQR Program is an extension of our programmatic goal to continually refine the measure set.

We will continue working to provide hospitals with the education, tools, and resources necessary to help reduce eCQM reporting burden and more seamlessly account for the removal/addition of eCQMs. Further, we will consider the issues associated with new software, workflow changes, training, et cetera as we continue to improve our education and outreach efforts for eCQM submission and validation. We note that, as stated in the proposed rule, these eCQMs would not be removed until the CY 2020 reporting period/FY 2022 payment determination as a result of stakeholder feedback requesting more notice before making changes to the eCQM measure set in order to give hospitals additional time to select alternate eCQMs, and to modify workflows and systems as necessary, in the case that eCQMs they had previously been reporting are being removed. We will try to be as proactive as possible in providing lead time about the removal of measures from the Hospital IQR Program measure set.

Comment: One commenter did not support CMS' proposals to remove the seven eCQMs because there may be cases where individual eCQMs have value, even if topped out, or that there may be a risk of ''back sliding'' due to a shift in resources from topped-out measures to a new eCQM(s). Another commenter added that some evidence suggests removing certain technological and practice interventions leads to a reduction in desired clinical behavior. The commenter recommended that CMS monitor and evaluate how behaviors may change when eCQMs are removed through the process CMS finalized in its FY 2015 IPPS/LTCH PPS final rule.

Response: We respectfully disagree with the commenter that the removal of ''topped-out'' measures will necessarily result in hospitals no longer focusing on maintaining a high level of performance. We have confidence that hospitals are committed to providing good quality care to patients and we do not have any indication that they will stop doing so in these areas for which the quality of care measured has become standard practice. We also note that the eCQMs we are finalizing for removal are either duplicative of other measures in the program, or are of little benefit in assessing a widely practiced standard of care, or are based on documentation without evaluation of clinical quality, and therefore the costs outweigh the benefits of retaining these measures. We encourage commenters to submit to CMS any evidence suggesting that removing certain technological and practice interventions leads to a reduction in desired clinical behavior.

Comment: Some commenters did not support CMS' proposals to remove the seven eCQMs because they believed the remaining eCQMs do not represent populations for small community hospitals. A few commenters observed that many small and rural hospitals triage and transfer stroke patients (four of the remaining eCQMs), less than half have labor and delivery units (two of the remaining eCQMs), and few have ICUs (one of the remaining eCQMs). A few commenters expressed their belief that for most CAHs, only two of the remaining eCQMs are relevant (ED–2 and VTE–1). Commenters reiterated the need for CMS to develop measures that are relevant for rural hospitals, because removing measures for which hospitals have a reasonable initial population results in a lack of options for hospitals with respect to eCQM reporting. Although hospitals that do not have a sufficient number of patients may submit a zero denominator exemption, commenters noted there is no value to quality or improvement efforts if hospitals are exempted. Commenters believe hospitals need flexibility to choose the measures that are most representative of their patient populations.

In addition, a few commenters noted that reducing the number of available eCQMs may present a challenge for hospitals to select measures that are well developed in data collection, workflow, and add value to the patient population of the organization. Commenters urged CMS to continue to work with stakeholders to develop measures that focus on quality and safety, and to ensure that eCQMs truly provide comparable data across institutions to better assist our hospitals in understanding the methodology and ways to improve patient care.

Response: We acknowledge that facilitating quality improvement for rural hospitals, small hospitals, and CAHs [294] can present unique challenges and is a high priority under the Meaningful Measures Initiative. We understand the commenters' concern that the ability to submit a zero denominator exemption does not provide direct information for supporting quality improvement efforts and that hospitals need flexibility to choose the measures that are most representative of their patient populations. It is one of our goals to expand EHR-based quality reporting in the Hospital IQR Program using more meaningful measures, which we believe will ultimately reduce burden on hospitals as compared with chart-abstracted data reporting and improve patient outcomes by providing more robust data to support quality improvement efforts. We intend to introduce additional eCQMs into the program as ones that support our program goals become available. We also intend to continue to work with stakeholders to develop measures that focus on quality and safety. For more information about quality measurement efforts for rural health settings, we refer readers to the MAP Rural Health Workgroup at: *http://www.qualityforum.org/MAP_Rural_Health_Workgroup.aspx*.

Comment: One commenter recommended that before a significant number of measures are eliminated or there is an increase of measures that are required to be reported to CMS, CMS provide an offering of measures that allows organizations to be able to select the measures that are aligned with the care given without increasing implementation and adoption burden. The commenter stated that one option would be to have a listing of all chart-abstracted measures, claims-based measures, hybrid measures, and eCQMs available for the organization to select from and all reporting agencies would accept a combination of any of these measures (without regard to collection method) for providers to achieve minimum quality compliance.

Alternatively, similar to the Promoting Interoperability Program's

[294] We note that under section 1886(b)(3)(B)(viii) of the Act, only subsection (d) hospitals are required to submit data to the Hospital IQR Program. CAHs participate in the electronic reporting of CQMs under the Promoting Interoperability Programs.

Objectives and Measures, the commenter suggested that CMS could implement a 'point system' in which reporting of each quality measure is granted 3 points for chart-abstracted or claims-based measures, 4 points for hybrid measures, and 5 points for eCQMs. Bonus points could be given (up to 5 points) for voluntary measures that are being considered for inclusion. With a selection choice of 20 total measures, a minimum of 30 points could be required to meet the quality reporting requirement. This could satisfy all reporting programs, including but not limited to, CMS' Promoting Interoperability, Hospital IQR, and Hospital VBP Programs, etc., as well as The Joint Commission. Overall, the idea would be to have the ability to choose measures that are best suited for each organization's quality needs, reduce the requirements for complex chart-abstracted and electronic measures across various programs if eCQMs are easily available, and allow measures to satisfy multiple programs with single data submissions.

Response: We appreciate the commenter's suggestions and will take them into consideration as we continually refine the measure sets for our quality programs, as well as to improve alignment of requirements across our programs whenever possible.

Comment: One commenter specifically did not support CMS' proposal to remove the CAC–3 eCQM because it believed that plan-of-care documents are critical for the continuity of care and outcomes once a patient is discharged from the hospital. The commenter requested additional clarification about how removing the plan of care document reduces costs associated with the policy of Meaningful Measures without affecting patient outcomes.

Response: We agree that continuity of care and outcomes once a patient is discharged are important priorities; however, we disagree that the CAC–3 eCQM accomplishes these priorities. The CAC–3 eCQM assesses the proportion of pediatric asthma patients discharged from an inpatient hospital stay with a Home Management Plan of Care document given to the pediatric asthma patient/caregiver (83 FR 20482). We have previously issued guidance that measure developers should avoid selecting or constructing measures that can be met primarily through documentation without evaluating the clinical quality of the activity—often satisfied with a checkbox, date, or code—for example, the delivery-of-the-care-plan document for the CAC–3 measure.[295] In our effort to create a more parsimonious measure set, we assessed which measures were least costly to report and most effective in particular priority areas. We believe that the CAC–3 eCQM is among the measures that provide less benefit to providers and beneficiaries, relative to the costs of implementing, maintaining, and reporting on this measure.

Comment: A few commenters did not support CMS' proposal to remove the ED–1 eCQM because they believed the measure has significant value and organizations have spent the time and effort to map and use this eCQM.

Response: We appreciate the commenters' position; however, we believe that it is appropriate to remove the ED–1 eCQM because the ED–2 eCQM is more effective at driving quality improvements. Removing the ED–1 eCQM is in keeping with our goal of moving the Hospital IQR Program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We refer readers to section I.A.2. of the preamble of this final rule for a detailed description of those goals.

Comment: A few commenters requested that CMS provide at least 2 years notice prior to proposing to remove an eCQM due to the time and effort it takes to map an eCQM.

Response: We specifically crafted our proposed removal of the eCQMs to reflect stakeholder feedback to have more time to prepare for changes to eCQM reporting requirements, including changes to the eCQM measure set. We believe removal of the seven eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination, with a data submission deadline of February 28, 2021, provides sufficient notice of eCQMs that will and will not be available for future reporting and allows hospitals enough time to implement changes associated with mapping new eCQMs. We will take the commenters' feedback about the timing of eCQM changes into consideration for future program years.

Comment: A few commenters believed it is difficult to interpret boarding time (ED–2) without measuring total length of stay for admitted patients (ED–1); the time stamp of ''admit decision time'' varies by hospital, and therefore comparing ED–2 between hospitals has little meaning without measuring ED–1. The commenters cautioned there may be potential for gaming by hospitals if just the ED–2 measure is used because hospitals hoping to reduce their ED–2 time might pressure emergency physicians to not indicate a decision to admit until an inpatient bed is available. If the ED–1 measure is retained, CMS may be able to monitor this practice by assessing how ED–1 increases relative to ED–2. Therefore, the commenters believed that both measures are necessary to ensure that patients receive high-quality care and that ED boarding times are appropriate. Finally, the commenters believed that keeping both measures in the program should not add any burden since hospitals do not have to invest additional financial resources reporting ED–1 and both measures are useful for research purposes.

Response: We understand that hospitals may need to collect the total length of stay for admitted patients to interpret boarding time, but we believe that in order to maintain a parsimonious set of the most meaningful measures, it is appropriate at this time to remove the ED–1 eCQM. We note the commenter's concern about potential for gaming the ED–2 eCQM and we encourage stakeholders to share these concerns and any evidence of such instances with us.

We respectfully disagree that removing the ED–1 eCQM would not reduce some burden on providers and their health IT vendors. Focusing on a more streamlined measure set gives hospitals and their health IT vendors more time and resources to accommodate new reporting requirements by reducing measure maintenance and specification requirements. As we have stated above, the ED–2 eCQM captures more actionable information and hospitals have greater control over allocating resources and aligning inter-departmental communication to consistently reduce the time between the decision to admit and the time of admission. In addition, the Hospital OQR Program includes an ED throughput measure which publicly reports similar data as is captured by ED–1.

Comment: One commenter supported retaining the ED–1 eCQM but suggested refining it by adding the Emergency Severity Index to the measure to allow a better review of the length of time the patient is in the ED and to incorporate the acuity of the patient into the measure result.

Response: We thank the commenter for their suggestion to add the

[295] CMS Measures Management System Blueprint (Blueprint v 13.0). CMS. 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf.*

Emergency Severity Index, a five-level triage algorithm,[296] to refine the ED–1 eCQM, and will take it into consideration as we continually refine the measure sets for our quality programs.

Comment: One commenter did not support removal of the ED–1 eCQM because it is one of few eCQMs available for CAHs to meaningfully report on.

Response: We acknowledge the commenter's concern about the sufficient availability of eCQMs, like the ED–1 eCQM, for reporting by CAHs. We note that under section 1886(b)(3)(B)(vii) of the Act, only subsection (d) hospitals are required to submit data to the Hospital IQR Program. CAHs are neither required to submit eCQM measure data to the Hospital IQR Program, nor subject to any payment reduction. However, CAHs participating in the Promoting Interoperability Programs have eCQM reporting requirements with respect to those programs using the same eCQM measure set, and we acknowledge that facilitating quality improvement for rural hospitals, small hospitals, and CAHs can present unique challenges and is a high priority under the Meaningful Measures Initiative. We are exploring opportunities to develop more relevant measures and less burdensome methods to collect quality measure data for use by small and rural hospitals. For more information about quality measurement efforts for rural health settings, we refer readers to the MAP Rural Health Workgroup at: *http://www.qualityforum.org/MAP_Rural_Health_Workgroup.aspx*.

Comment: One commenter did not support CMS' proposal to remove the EHDI–1a and PC–01 eCQMs because the commenter represents a small community hospital that has already expended resources to implement these measures and because they are one of the few available eCQMs for which the hospital has a sufficient number of patients in the initial patient population to allow them to evaluate and maintain quality care and documentation.

Response: As noted above, we acknowledge that facilitating quality improvement for rural hospitals, small hospitals, and CAHs presents unique challenges and is a high priority under the Meaningful Measures Initiative. We further appreciate the commenter's frustration that they have expended resources to implement measures that are being removed. It is one of our goals to expand EHR-based quality reporting in the Hospital IQR Program using more meaningful measures, which we believe will ultimately reduce burden on hospitals as compared with chart-abstracted data reporting and improve patient outcomes by providing more robust data to support quality improvement efforts. We intend to introduce additional eCQMs into the program as eCQMs that support our program goals become available.

Comment: A few commenters did not support CMS' proposal to remove the PC–01 eCQM because they would prefer to report the eCQM version of the measure rather than the chart-abstracted version. One commenter recommended that CMS begin requiring eCQMs rather than chart-abstracted measures as they are seeing significant cost-reductions associated with not having to chart-abstract, and instead be allowed to submit eCQMs. Another commenter observed that retaining the chart-abstracted version of this measure continues the burden of having to manually collect the data, in order to obtain the numerator and denominator to enter into the QualityNet Secure Portal and argued that retaining the PC–01 eCQM while removing the PC–01 chart-abstracted measure would result in reduced burden as healthcare systems have already mapped the PC–01 eCQM. A third commenter noted that data collection for the PC–01 eCQM may reflect better performance on the measure as compared to the chart-abstracted version due to the discrete data requirement and all patient reporting for the eCQM versus the sample method of using any data (discrete and non-discrete) for reporting the chart-abstracted version.

One commenter did not support CMS' proposal to remove the PC–01 eCQM because the commenter believed it could be useful to retain both the eCQM and chart-abstracted versions of the measure to allow for comparison of the data. The commenter recommended CMS work to improve the PC–01 eCQM so that it can replace the chart-abstracted measure in the future. The PC–01 eCQM could collect all the cases in the population rather than sampling of cases as is done with the chart-abstracted measure. In addition, the electronic version of the measure would reduce the burden to the hospitals having to abstract, aggregate, and submit the measure data elements via the CMS web-based tool.

Response: We acknowledge commenters' feedback regarding a preference to use eCQMs rather than chart-abstracted measures in the Hospital IQR Program. We will take these suggestions into consideration for future program years. We are retaining the chart-abstracted version of the PC–01 measure rather than the PC–01 eCQM, because due to the importance of child and maternal health, we believe all hospitals with a sufficient number of cases should be required to report data on this measure. We reiterate our concern that if the eCQM version were retained and the chart-abstracted version removed, we believe that due to the low volume of patients relative to total adult hospital population and the ability of hospitals to select other eCQMs to report other than the PC–01 eCQM, we would not receive enough data to produce meaningful analyses.

Further, hospitals are only required to submit several aggregate counts for the chart-abstracted version of this measure,[297] instead of the potentially numerous patient-level charts, such that submission of this measure places less information collection burden on hospitals than other chart-abstracted measures. Hospitals are able to submit their aggregate counts using our Web-Based Measure Tool through the QualityNet website. In addition, PC–01 is one of only two measures of child and maternal health in the Hospital IQR Program measure set, and is the only publicly reported measure of child and maternal health in the Program. As to the commenter's belief that the PC–01 eCQM may reflect better measure performance as compared to the chart-abstracted version, we note that since eCQM data are not currently publicly reported, the chart-abstracted version of PC–01 is currently the only pathway for publicly reporting these data and is therefore important to retain. We believe it is important to continue to provide publicly reported information on this important topic, but that it would be costly and duplicative to retain both the chart-abstracted version and the eCQM. As discussed in section VIII.A.4.b. of the preamble of this final rule, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We believe retaining the chart-abstracted version and removing the eCQM version best aligns with that goal. We appreciate commenter's recommendation to improve the PC–01 eCQM version to replace the chart-abstracted version and

[296] For more information on the Emergency Severity Index, we refer readers to: *https://www.ahrq.gov/professionals/systems/hospital/esi/index.html*.

[297] FY 2013 IPPS/LTCH PPS final rule (77 FR 53528 through 53530).

will take that into consideration for future program years.

Comment: Many commenters supported CMS' proposals to remove the seven eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination as proposed, because they stated that hospitals need extensive time and resources to install software, map updates appropriately, and to successfully submit the data to CMS. In particular, commenters noted that the proposed eCQM removal timeline would ensure hospitals currently preparing to report any of the removed measures in 2019 would not be forced to choose new measures with a reduced implementation timeline.

Response: We thank commenters for their support.

Comment: Many commenters supported the alternative considered, for CMS to remove the seven eCQMs sooner beginning with the CY 2019 reporting period/FY 2021 payment determination because they believe earlier removal would alleviate burden from hospitals to report and for health IT vendors to update and certify measures that will not be available to report in the future. Commenters also suggested that measures for which CMS determines that the costs outweigh the benefits should be removed as soon as possible. Several commenters noted that EHR vendors must rewrite all measures in CQL for this reporting period, which would have very limited utility before being phased out. Commenters added that earlier removal would prevent additional work for health IT vendors and hospitals to update internal reporting to the new measure specifications and value sets anticipated in late calendar year 2018.

A few commenters recommended CMS allow hospitals to use the eCQM Extraordinary Circumstances Exception to apply for an exception from the eCQM reporting requirements for the CY 2019 reporting period/FY 2021 payment determination if the hospital cannot use four of the remaining eight eCQMs. One commenter believed that the request to lengthen the time period between changes applies to the updating of specifications or introduction of new eCQMs, not to the complete removal as there is minimal work associated with removing an eCQM compared to updating or implementing an eCQM.

Response: We appreciate commenters' recommendation that we remove the eCQMs sooner than proposed. However, we continue to believe removing these eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination is the least burdensome choice for the largest number of hospitals participating in the Hospital IQR Program. We note that since hospitals will have the same requirement of reporting 4 eCQMs and one quarter of data as in previous years for the CY 2019 reporting period/FY 2021 payment determination, as finalized in section VIII.A.11.d.(2) of the preamble of this final rule, there will be no increase in reporting burden by removing the seven eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination, while preserving greater availability of eCQMs to choose from for an additional year, especially for small and rural hospitals and any other hospitals that may benefit from the additional year to plan time and resources for when the eCQMs are ultimately removed from the program. We have previously received feedback from hospitals indicating they would benefit from longer timelines for implementing changes to eCQM requirements because hospitals may need time to adjust workflows and work with health IT vendors to modify support for eCQM implementation, data collection, and reporting. This lead time is particularly important for hospitals that have already developed the necessary IT and workflow plans to report data on the eCQMs being removed from the Hospital IQR Program, as retaining the measures for an additional year will allow those hospitals to submit data as planned for the CY 2019 reporting period that begins January 1, 2019 and begin any necessary updates for subsequent years' reporting well ahead of time. Therefore, in consideration of the time, effort, and resources already expended to report these measures that we are finalizing for removal and the time and resources necessary to update hospital EHR systems to report on different measures in future program years, we believe retaining these eCQMs measures in the Hospital IQR Program until the CY 2020 reporting period/FY 2022 payment determination is the most appropriate timeline for the greatest number of hospitals.

Under the Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy, hospitals may request an exception when they are unable to submit required data due to extraordinary circumstances not within their control. We note that ECE requests for the Hospital IQR Program are considered on a case-by-case basis (81 FR 57182). We will assess the hospital's request on a case-by-case basis to determine if an exception is merited. Therefore, our decision whether or not to grant an ECE will be based on the specific circumstances of the hospital. For additional information about eCQM-related ECE requests, we refer readers to section VIII.A.16 of the preamble of this final rule.

After consideration of the public comments we received, we are finalizing our proposal to remove the AMI–8a, CAC–3, ED–1, EHDI–1a, PC–01, STK–08, and STK–10 eCQMs from the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years as proposed. We refer readers to section VIII.D.9 of the preamble of this final rule where we also remove these seven eCQMs from the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs.

c. Summary of Hospital IQR Program Measures Newly Finalized for Removal

In the proposed rule, we proposed to remove a total of 39 measures from the program, as summarized in the table in section VIII.A.5.c. of the preamble of the proposed rule (83 FR 20484 through 20485). We are finalizing the removal of those 39 measures as they are summarized in the table below:

SUMMARY OF HOSPITAL IQR PROGRAM MEASURES NEWLY FINALIZED FOR REMOVAL

Short name	Measure name	First payment determination year for removal	NQF #
Structural Patient Safety Measures			
Safe Surgery Checklist	Safe Surgery Checklist Use	FY 2020	N/A
Patient Safety Culture	Hospital Survey on Patient Safety Culture	FY 2020	N/A

SUMMARY OF HOSPITAL IQR PROGRAM MEASURES NEWLY FINALIZED FOR REMOVAL—Continued

Short name	Measure name	First payment determination year for removal	NQF #
Patient Safety Measures			
PSI 90	Patient Safety and Adverse Events Composite	FY 2020	0531
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	FY 2022	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	FY 2022	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	FY 2022	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	FY 2022	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	FY 2022	1716
Claims-Based Coordination of Care Measures			
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	FY 2020	0505
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	FY 2020	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	FY 2020	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Heart Failure (HF) Hospitalization.	FY 2020	0330
READM–30–PNA	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization.	FY 2020	0506
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	FY 2020	1551
READM–30–STK	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization.	FY 2020	N/A
Claims-Based Mortality Measures			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	FY 2020	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	FY 2020	0229
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	FY 2021	1893
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	FY 2021	0468
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	FY 2022	2558
Claims-Based Patient Safety Measure			
Hip/Knee Complications	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	FY 2023	1550
Claims-Based Payment Measures			
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital Measure	FY 2020	2158
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment Measure	FY 2020	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure	FY 2020	N/A
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure.	FY 2020	N/A
AA Payment	Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure	FY 2020	N/A
Chole and CDE Payment	Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure.	FY 2020	N/A
SFusion Payment	Spinal Fusion Clinical Episode-Based Payment Measure	FY 2020	N/A
Chart-Abstracted Clinical Process of Care Measures			
IMM–2	Influenza Immunization	FY 2021	1659
VTE–6	Incidence of Potentially Preventable VTE [Venous Thromboembolism] ..	FY 2021	+

SUMMARY OF HOSPITAL IQR PROGRAM MEASURES NEWLY FINALIZED FOR REMOVAL—Continued

Short name	Measure name	First payment determination year for removal	NQF #
ED–1	Median Time from ED Arrival to ED Departure for Admitted ED Patients	FY 2021	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	FY 2022	0497
EHR-Based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))			
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	FY 2022	+
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	FY 2022	+
ED–1	Median Time from ED Arrival to ED Departure for Admitted ED Patients	FY 2022	0495
EHDI–1a	Hearing Screening Prior to Hospital Discharge	FY 2022	1354
PC–01	Elective Delivery	FY 2022	0469
STK–08	Stroke Education	FY 2022	+
STK–10	Assessed for Rehabilitation	FY 2022	0441

* Measure is finalized for removal in chart-abstracted form, but will be retained in eCQM form.
+ NQF endorsement removed.

6. Summary of Hospital IQR Program Measures for the FY 2020 Payment Determination

The table below summarizes the Hospital IQR Program measure set for the FY 2020 payment determination (including previously adopted measures, but not including measures finalized for removal beginning with the FY 2020 payment determination in this final rule):

MEASURES FOR THE FY 2020 PAYMENT DETERMINATION *

Short name	Measure name	NQF #
Healthcare-Associated Infection Measures		
CAUTI	National Healthcare Safety Network Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
Claims-Based Patient Safety Measures		
Hip/Knee Complications	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications [298]	0351
Claims-Based Mortality Measures		
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–PN	Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Acute Ischemic Stroke.	N/A
Claims-Based Coordination of Care Measures		
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882

MEASURES FOR THE FY 2020 PAYMENT DETERMINATION *—Continued

Short name	Measure name	NQF #
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
Chart-Abstracted Clinical Process of Care Measures		
ED–1 **	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 **	Admit Decision Time to ED Departure Time for Admitted Patients	0497
IMM–2	Influenza Immunization	1659
PC–01 **	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
VTE–6	Incidence of Potentially Preventable Venous Thromboembolism	+
EHR-Based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	+
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
ED–1 **	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 **	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01 **	Elective Delivery	0469
PC–05	Exclusive Breast Milk Feeding	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS ***	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure).	0166 (0228)

* As discussed in section VIII.A.5. of the preamble of this final rule, we are finalizing our proposals to remove 19 measures—17 claims-based measures and two structural measures—beginning with the FY 2020 payment determination. These measures, which had previously been finalized for the FY 2020 payment determination are not included in this summary table.

** Measure listed twice, as both chart-abstracted and eCQM versions.

*** We have proposed to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. We refer readers to the CY 2019 OPPS/ASC proposed rule (available at: *https://www.regulations.gov/document?D=CMS-2018-0078-0001*).

+ NQF endorsement has been removed.

7. Summary of Hospital IQR Program Measures for the FY 2021 Payment Determination

The table below summarizes the Hospital IQR Program measure set for the FY 2021 payment determination (including previously adopted measures, but not including measures finalized for removal beginning with the FY 2021 payment determination in this final rule):

[298] We note that measure stewardship of the recalibrated version of the Death Rate among Surgical Inpatients with Serious Treatable Complications measure is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) when it is used in CMS quality programs.

MEASURES FOR THE FY 2021 PAYMENT DETERMINATION

Short name	Measure name	NQF #
Healthcare-Associated Infection Measures		
CAUTI	National Healthcare Safety Network Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
Hip/Knee Complications	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	+
Claims-Based Mortality Measures		
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke *.	N/A
Claims-Based Coordination of Care Measures		
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
Chart-Abstracted Clinical Process of Care Measures		
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC–01 *	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
EHR-Based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
AMI–8a	Primary Percutaneous Coronary Intervention Received within 90 minutes of Hospital Arrival.	+
CAC–3	Home Management and Plan of Care Document Given to Patient/Caregiver	+
ED–1	Median Time From ED Arrival to ED Departure for Admitted ED Patients (ED–1)	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients (ED–2)	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01*	Elective Delivery	0469
PC–05	Exclusive Breast Milk Feeding	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0438
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Thromboembolism Prophylaxis	0372

MEASURES FOR THE FY 2021 PAYMENT DETERMINATION—Continued

Short name	Measure name	NQF #
Patient Experience of Care Survey Measures		
HCAHPS**	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

*Measure listed twice, as both chart-abstracted and eCQM versions.
**We have proposed to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. We refer readers to the CY 2019 OPPS/ASC proposed rule (available at: *https://www.regulations.gov/document?D=CMS-2018-0078-0001*).
+ NQF endorsement has been removed.

8. Summary of Hospital IQR Program Measures for the FY 2022 Payment Determination and Subsequent Years

The table below summarizes the Hospital IQR Program measure set for the FY 2022 payment determination (including previously adopted measures, but not including measures finalized for removal beginning with the FY 2022 payment determination in this final rule) and subsequent years:

MEASURES FOR THE FY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
Healthcare-Associated Infection Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
Hip/Knee Complications*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
Claims-Based Mortality Measures		
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke.	N/A
Claims-Based Coordination of Care Measures		
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC–01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED–2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC–05	Exclusive Breast Milk Feeding	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

MEASURES FOR THE FY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
Patient Experience of Care Survey Measures		
HCAHPS**	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

*Finalized for removal from the Hospital IQR Program beginning with the FY 2023 payment determination, as discussed in section VIII.A.5.b.(5) of the preamble of this final rule.

**We have proposed to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. We refer readers to the CY 2019 OPPS/ASC proposed rule (available at: *https://www.regulations.gov/document?D=CMS-2018-0078-0001*).

9. Possible New Quality Measures, Measure Topics, and Other Future Considerations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512), we outlined considerations to guide us in selecting new quality measures to adopt into the Hospital IQR Program. We also refer readers to section I.A.2. of the preamble of this final rule where we describe the Meaningful Measures Initiative—quality priorities that we have identified as high impact measurement areas that are relevant and meaningful to both patients and providers.

In keeping with these considerations, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20489 through 20495), we invited public comment on the potential future inclusion of a hospital-wide mortality measure in the Hospital IQR Program, specifically whether to propose to adopt a Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure or a Hybrid Hospital-Wide, All-Cause, Risk-Standardized Mortality measure. We are also considering a newly specified eCQM for possible concurrent inclusion in future years of the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), the Opioid Harm Electronic Clinical Quality Measure (eCQM). We also sought public input on the future development and adoption of eCQMs more generally (for example, burdens, incentives). These topics are discussed in more detail below.

a. Potential Inclusion of Claims-Only Hospital-Wide Mortality Measure and/or Hybrid Hospital-Wide Mortality Measure With Electronic Health Record Data

(1) Background

Mortality is an important health outcome that is meaningful to patients and providers, and the vast majority of patients admitted to the hospital have survival as a primary goal. However, estimates using data from 2002 to 2008 suggest that more than 400,000 patients die each year from preventable harm in hospitals.[299] While we do not expect mortality rates to be zero, studies have shown that mortality within 30 days of hospital admission is related to quality of care, and that high and variable mortality rates across hospitals indicate opportunities for improvement.[300] [301] In addition to the harm to individuals, their families, and caregivers resulting from preventable death, there are also significant financial costs to the healthcare system associated with high and variable mortality rates. While capturing monetary savings for preventable mortality events is challenging, using two recent estimates of the number of deaths due to preventable medical errors and assuming an average of ten lost years of life per death (valued at $75,000 per year in lost quality adjusted life years), the annual direct and indirect cost of potentially preventable deaths could be as much as $73.5 to $735 billion.[302] [303] [304]

Existing condition-specific mortality measures adopted into the Hospital IQR Program support quality improvement work targeted toward patients with a set of common medical conditions, such as heart failure, acute myocardial infarction, or pneumonia. The use of these measures may have contributed to national declines in hospital mortality rates for the measured conditions and/or procedures.[305] However, a measure of hospital-wide mortality captures a hospital's performance across a broader set of patients and across more areas of the hospital. Because more patients are included in the measure, a hospital-wide mortality measure also captures the performance for smaller volume hospitals that would otherwise not have sufficient cases to calculate condition- or procedure-specific mortality measures.

We developed two versions of a hospital-wide, all-cause, risk-standardized mortality measure: One that is calculated using only claims data (the Claims-Only Hospital-Wide All-Cause Risk Standardized Mortality Measure (hereinafter referred to as the ''Claims-Only HWM measure'')); and a hybrid version that uses claims data to define the measure cohort and a combination of data from electronic health records (EHRs) and claims for risk adjustment (Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (hereinafter referred to as the ''Hybrid HWM measure'')). The goal of developing hospital-wide mortality measures is to assess hospital performance on patient outcomes among patients for whom mortality is likely to present an important quality signal and those where the hospital can positively influence the outcome for the patient. Both versions of the measure address the Meaningful Measures Initiative quality priority of promoting effective treatment to reduce risk-adjusted mortality.

[299] James JT. A new, evidence-based estimate of patient harms associated with hospital care. *Journal of patient safety.* 2013;9(3):122–128.

[300] Peterson ED, Roe MT, Mulgund J, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. *JAMA.* 2006;295(16):1912–1920.

[301] Writing Group for the Checklist- I.C.U. Investigators, Brazilian Research in Intensive Care Network. Effect of a quality improvement intervention with daily round checklists, goal setting, and clinician prompting on mortality of critically ill patients: A randomized clinical trial. *JAMA.* 2016;315(14):1480–1490.

[302] Institute of Medicine. To Err is Human: Building a Safer Health System. 1999; Available at: *https://iom.nationalacademies.org/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf.*

[303] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs. 2011;30(4):581–589.

[304] Andel C, Davidow SL, Hollander M, Moreno DA. The economics of health care quality and medical errors. *Journal of health care finance.* 2012;39(1):39–50.

[305] Suter LG, Li SX, Grady JN, et al. National patterns of risk-standardized mortality and readmission after hospitalization for acute myocardial infarction, heart failure, and pneumonia: Update on publicly reported outcomes measures based on the 2013 release. *Journal of general internal medicine.* 2014;29(10):1333–1340.

Several stakeholder groups were engaged throughout the development process, including a Technical Work Group and a Patient and Family Work Group, as well as a national, multi-stakeholder Technical Expert Panel (TEP) consisting of a diverse set of stakeholders, including providers and patients. These groups were convened by the measure developer under contract with us and provided feedback on the measure concept, outcome, cohort, risk model variables, and reporting results. The measure developer also solicited stakeholder feedback during measure development as required in the Measures Management System (MMS) Blueprint.[306]

We developed a Hybrid HWM measure in addition to a Claims-Only HWM measure in order to move toward greater use of EHR data for quality measurement, and in response to stakeholder feedback that is important to include clinical data in outcome measures (80 FR 49702 through 49703). The Hybrid HWM measure is harmonized with the Claims-Only HWM measure. Both measures use the same cohort definition, outcome assessment, and claims-based risk variables (discussed in more detail below). The Hybrid HWM measure builds upon prior efforts to use of a set of core clinical data elements extracted from hospital EHRs for each hospitalized Medicare FFS beneficiary over the age of 65 years, as outlined in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698). The core clinical data elements are data which are routinely collected on hospitalized adults, extraction from hospital EHRs is feasible, and the data can be utilized as part of specific quality outcome measures. The Hybrid HWM measure's core clinical data elements are very similar to, but not precisely that same as, those used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data measure (NQF #2879), for which we are currently collecting data from hospitals on a voluntary basis and are considering proposing as a required measure as early as the FY 2023 payment determination (82 FR 38350 through 38355). For more detail about the core clinical data elements used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data measure (NQF #2879), we refer readers to our discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698 through 49704) and the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors report (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*).

The Claims-Only Hospital-Wide All-Cause Risk Standardized Mortality Measure (MUC17–195) and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (MUC17–196) were included in a publicly available document entitled ''2017 Measures Under Consideration List'' (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and have been reviewed by the NQF MAP Hospital Workgroup. The MAP conditionally supported both measures pending NQF review and endorsement, as referenced in the 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS (available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*). The MAP also recommended the Hybrid HWM measure have a voluntary reporting period before mandatory implementation.[307]

The MAP noted both measures are important measures for patient safety, and that these measures could help reduce deaths due to medical errors.[308] We agree with MAP stakeholder concerns regarding the need for the NQF endorsement process to ensure the measures have appropriate clinical and social risk factors in the risk adjustment models and address necessary exclusions to ensure the measure does not disproportionately penalize facilities that may treat more complex patients.[309] The MAP also expressed concern regarding the potential unintended consequences of unnecessary interventions for patients at the end of life; [310] however, this issue was carefully addressed during measure development by excluding patients at the end of life and for whom survival is unlikely to be the goal of care from the measure cohort based upon the TEP and patient work group input. Specifically, the measure does not include patients enrolled in hospice in the 12 months prior to admission, on admission, or within 2 days of admission; the measure also does not include patients admitted primarily for cancer that are enrolled in hospice at any time during the admission, those admitted primarily for metastatic cancer, and those admitted for specific diagnoses with limited chances of survival.

The MAP further suggested that condition-specific mortality measures may be more actionable for providers and informative for consumers.[311] While service-line divisions may not be as granular as condition-specific measures, we believe a single comprehensive marker of hospital quality encourages organization-wide improvement, allows more hospitals to meet volume requirements for inclusion, offers more rapid detection of changes in performance due to performance being based on the most recent year of data available, and aligns with the Meaningful Measures Initiative by creating the framework for stakeholders to have fewer measures to track and a single score to reference. We plan to submit both measures to NQF for endorsement proceedings as part of the Patient Safety Committee as early as FY 2019, after the measures have been fully specified for use with ICD–10 data.

(2) Overview of Measures

Both the Claims-Only HWM measure and the Hybrid HWM measure capture hospital-level, risk-standardized mortality within 30 days of hospital admission for most conditions or procedures. The measures are reported as a single summary score, derived from the results of risk-adjustment models for 13 mutually exclusive service-line divisions (categories of admissions grouped based on discharge diagnoses or procedures), with a separate risk model for each of the 13 service-line divisions. The 13 service-line divisions include: 8 non-surgical divisions and 5 surgical divisions. The non-surgical divisions are: Cancer; cardiac; gastrointestinal; infectious disease; neurology; orthopedics; pulmonary; and renal. The surgical divisions are: Cancer; cardiothoracic; general; neurosurgery; and orthopedics. Hospitalizations are eligible for inclusion in the measure if the patient was hospitalized at a non-Federal, short-stay acute care hospital. To compare mortality performance across hospitals, the measure accounts for differences in patient characteristics (patient case mix) as well as differences in the medical services provided and procedures performed by hospitals (hospital service

[306] CMS Measures Management System Blueprint (Blueprint v 13.0). CMS. 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf*.

[307] Measure Application Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[308] Ibid.

[309] Ibid.

[310] Ibid.

[311] Ibid.

mix). In addition, the Hybrid HWM Measure employs a combination of administrative claims data and clinical EHR data to enhance clinical case mix adjustment with additional clinical data.

Our goal is to more comprehensively measure the mortality rates of hospitals, including to improve the ability to measure mortality rates in smaller volume hospitals. The cohort definition attempts to capture as many admissions as possible for which survival would be a reasonable indicator of quality and for which adequate risk adjustment is possible. We assume survival would be a reasonable indicator of quality for admissions fulfilling two criteria: (1) Survival is most likely the primary goal of the patient when they enter the hospital; and (2) the hospital can reasonably influence the patient's chance of survival through quality of care. These measures would provide information to hospitals that can facilitate quality improvement efforts for hospital settings, types of care, and types of patients not included in currently available condition-and procedure-specific mortality measures. Also, these measures would provide more transparency about the quality of care in clinical areas not captured in the current condition- and procedure-specific measures.

Additional information on the development of both the Claims-Only and Hybrid versions of the HWM measure can be found on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(3) Data Sources

Both the Claims-Only and Hybrid versions of the HWM measure use Part A Medicare administrative claims data from Medicare FFS beneficiaries aged between 65 and 94 years, and use one year of data. Part A data from the 12 months prior to the index admission are used for risk adjustment.

The Hybrid HWM measure uses two sources of data for the calculation of the measure: Medicare Part A claims and a set of core clinical data elements from hospitals' EHRs. Claims and enrollment data are used to identify index admissions included in the measure cohort, in the risk-adjustment model, and to assess the 30-day mortality outcome. These data are merged with the core clinical data elements for eligible patient admissions from each hospital's EHR. The data elements are the values for a set of vital signs and common laboratory tests collected at presentation and used for risk-adjustment of patients' severity of illness (for Medicare FFS beneficiaries who are aged between 65 and 94 years), in addition to data from claims.

(4) Outcome

The outcome of interest for both the Claims-Only and Hybrid versions of the HWM measure is the same, all-cause 30-day mortality. We define all-cause mortality as death from any cause within 30 days of the index hospital admission date.

(5) Cohort

The cohorts for both the Claims-Only HWM and Hybrid versions of the HWM measure are the same. The measure cohorts consist of Medicare FFS beneficiaries, aged between 65 and 94 years, discharged from non-federal acute care hospitals.

The Claims-Only HWM measure and Hybrid HWM measure were developed using ICD–9 codes. The measures are currently being updated for use with ICD–10 codes; ICD–10 updates will be completed prior to NQF submission and potential future implementation. Similar to the existing Hospital-Wide All-Cause Unplanned Readmission measure (NQF #1789), which was adopted into the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule beginning with the FY 2015 payment determination (77 FR 53521 through 53528), the Claims-Only HWM measure and Hybrid HWM measure include a large and diverse number of admissions represented by thousands of included ICD–9 codes. During measure development, we used the AHRQ Clinical Classification Software (CCS) [312] to group diagnostic and procedural ICD–9 codes into the clinically meaningful categories defined by the AHRQ grouper. The transition of the ICD–9 CCS-based measure specifications to the ICD–10–CM version of the CCS is underway. The ICD–10 to CCS map and tools for its use are currently available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs10/ccs10.jsp*. Both the Claims-Only and Hybrid versions of the HWM measure use those CCS categories as part of cohort specification and risk-adjustment, including the 13 service-line risk models.

For the AHRQ CCSs and individual ICD–9–CM codes that define the measure development cohort, we refer readers to the measure methodology reports on our website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(6) Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for both the Claims-Only and Hybrid versions of the HWM measure are the same. For both versions of the HWM measure, the cohort currently includes Medicare FFS patients who: (1) Were enrolled in Medicare FFS Part A for the 12 months prior to the date of admission and during the index admission; (2) have not been transferred from another inpatient facility; (3) were admitted for acute care (do not have a principal discharge diagnosis of a psychiatric disease or do not have a principal discharge diagnosis of ''rehabilitation care; fitting of prostheses and adjustment devices''); (4) are aged between 65 and 94 years; (5) are not enrolled in hospice at the time of or in the 12 months prior to their index admission; (6) are not enrolled in hospice within two days of admission; (7) are without a principal diagnosis of cancer and enrolled in hospice during their index admission; (8) are without any diagnosis of metastatic cancer; and (9) are without a principal discharge diagnosis of a condition which hospitals have limited ability to influence survival, including: Anoxic brain damage; persistent vegetative state; prion diseases such as Creutzfeldt-Jakob disease, Cheyne-Stokes respiration; brain death; respiratory arrest; or cardiac arrest without a secondary diagnosis of acute myocardial infarction.

Both the Claims-Only and Hybrid versions of the HWM measure currently exclude the following index admissions for patients: (1) With inconsistent or unknown vital status; (2) discharged against medical advice; (3) with an admission for crush injury, burn, intracranial injury, or spinal cord injury; (4) with specific principal discharge diagnosis codes for which mortality may not be a quality signal; (5) with an admission in a CCS condition or procedure categorized as in the service-line divisions: Other Surgical Procedures or Other Non-Surgical Conditions (this exclusion is being reassessed to include these patients in the final measure); and (6) with an admission in a low-volume CCS (within a particular service-line division), defined as equal to or less than 100 patients with that principle diagnosis across all hospitals.

For both the Claims-Only and Hybrid versions of the HWM measure, each index admission is assigned to one of 13

[312] Clinical Classifications Software (CCS) for ICD–9–CM Fact Sheet. Accessed at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp*.

mutually exclusive service-line divisions. For details on how each admission is assigned to a specific service-line division, and for a complete description and rationale of the inclusion and exclusion criteria, we refer readers to the methodology reports found on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(7) Risk-Adjustment

Both the Claims-Only and Hybrid versions of the HWM measure adjust for both case mix differences (clinical status of the patient, accounted for by adjusting for age and comorbidities) and service-mix differences (the types of conditions and procedures cared for and procedures conducted by the hospital, accounted for by the discharge condition category), and use the same patient comorbidities in the risk models. Patient comorbidities are based on inpatient hospital administrative claims during the 12 months prior to and including the index admission derived from ICD–9 codes grouped into the CMS condition categories (CMS–CCs). The measures are currently being updated for use with ICD–10 codes; ICD–10 updates will be completed prior to NQF submission and potential future adoption.

The Hybrid HWM measure also includes the core clinical data elements from patients' EHRs in the case mix adjustment. The core clinical data elements are derived from information captured in the EHR during the index admission only, and are listed below.

CURRENTLY SPECIFIED CORE CLINICAL DATA ELEMENT VARIABLES

Data elements	Units of measurement	Time window for first captured values (hours)
Heart Rate	Beats per minute	0–2
Systolic Blood Pressure	mmHg	0–2
Temperature	Degrees (Fahrenheit or Celsius)	0–2
Oxygen Saturation	Percent	0–2
Hemoglobin	g/dL	0–24
Platelet	Count	0–24
White Blood Cell Count	Cells/mL	0–24
Sodium	mEq/L	0–24
Bicarbonate	mmol/L	0–24
Creatinine	mg/dL	0–24

The core clinical data elements are clinical information meant to reflect a patient's clinical status upon arrival to the hospital. For more details on how the risk variables in each measure were chosen, we refer readers to the methodology reports found on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(8) Calculating the Risk-Standardized Mortality Rate (RSMR)

The method for calculating the RSMR for both the Claims-Only and the Hybrid versions of the HWM measure is the same. Index admissions are assigned to one of 13 mutually exclusive service-line divisions consisting of related conditions or procedures. For each service-line division, the standardized mortality ratio (SMR) is calculated as the ratio of the number of ''predicted'' deaths to the number of ''expected'' deaths at a given hospital. For each hospital, the numerator of the ratio is the number of deaths within 30 days predicted based on the hospital's performance with its observed case mix and service mix, and the denominator is the number of deaths expected based on the nation's performance with that hospital's case mix and service mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses.

The service-line SMRs are then pooled for each hospital using an inverse variance-weighted mean to create a hospital-wide composite SMR. The inverse variance-weighted mean can be interpreted as a weighted average of all SMRs that takes into account the precision of SMRs. The composite SMR is multiplied by the national observed mortality rate to produce the RSMR. For additional details regarding the measure specifications to calculate the RSMR, we refer readers to the Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure: Measure Methodology for Public Comment report and Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors: Measure Methodology for Public Comment report, which are posted on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

We invited public comment on the possible future inclusion of one or both hospital-wide mortality measures in the Hospital IQR Program simultaneously. We are also considering possible future inclusion of the Hybrid HWM measure in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for Clinical Quality Measures (CQM) electronic reporting by eligible hospitals and CAHs. We also invited public comment on other aspects of the measure. Specifically, we sought public comment on the following: (1) Feedback about the service-line division structure of the measure; (2) input on the measure testing approach, particularly if there is any additional validity testing that would be meaningful; and (3) how the measure results might be presented to the public, including ways that we could present supplemental hospital performance information in public reporting, such as service-line division-level results, to create a more meaningful and usable measure and ways that we could report more information about hospitals in a No Different From National Average group (defined using 95 percent confidence intervals) to help clinicians and patients use the measure results to improve patient care and make informed choices.

Comment: Several commenters supported future implementation of the hybrid version of the Hospital-Wide Mortality Measure over the claims-only version of the measure. Many commenters commended use of EHR data in the hybrid version of the measure.

Response: We thank commenters for their support of the hybrid version of the measure.

Comment: One commenter supported future implementation of the claims-only version of the measure, expressing concern that hybrid measures have not been sufficiently validated. Another commenter supported the claims-only version, citing the need for improvements to the process of submitting EHR data elements using the Quality Reporting Data Architecture (QRDA) I file format prior to implementation of hybrid measures.

Response: We thank commenters for their support of the claims-only version of the measure. However, in response to concerns that the hybrid measures have not been sufficiently validated, we note that several condition-specific hybrid measures (Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke with Risk Adjustment for Stroke Severity (NQF #2877) and Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) (NQF #2473)), and the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879), have all been tested and validated. Their validity and reliability have been reviewed by the NQF and the measures have been endorsed. The Hybrid Hospital-Wide Readmission Measure was implemented in the Hospital IQR Program as a voluntary measure for the CY 2018 reporting period. Hospitals that voluntarily participate will submit 13 EHR data elements for adult inpatients discharged between January and June of 2018. These data elements are nearly identical to those required for the Hybrid Hospital-Wide Mortality Measure. The results from the voluntary reporting will assist in confirming the feasibility of submitting the required data elements. In addition, we continue to work to improve the process of EHR data submission using the QRDA I file format, including the availability of the Pre-Submission Validation Application (PSVA) tool to perform test and production QRDA I file conformance checks.

Comment: Several commenters supported the proposed voluntary reporting of the Hybrid HWM measure following endorsement by the NQF.

Response: We thank commenters for their support. As stated in the proposed rule (83 FR 20490) and above, we plan to submit both versions of the measure to NQF for endorsement proceedings as part of the Patient Safety Committee as early as FY 2019, after the measures have been fully specified for use with ICD–10 data. We have not yet determined the implementation pathway or timeline for these measures. We will consider these suggestions if we move forward with proposing to include either or both of these measures in the Hospital IQR Program in the future through rulemaking.

Comment: Several commenters proposed revisions to the measure methodology, including merging surgical and non-surgical cancer service-line divisions and surgical and non-surgical orthopedic divisions.

Response: We thank commenters for their feedback. By design, the measure separates surgical and non-surgical admissions in order to account for differences in mortality risk between surgical and non-surgical patients. Analyses performed during measure development showed that even for patients with the same discharge condition, patient risk of death was strongly affected by whether a major surgical procedure was performed during hospitalization. Patients undergoing major surgical procedures typically have different risk of mortality than patients admitted with the same discharge condition but who do not undergo a major surgical procedure. For example, a patient admitted for a hip fracture (CCS 226) who undergoes a major surgical procedure such as hip replacement to treat their fracture is likely healthy enough to have the surgery, as compared to patients who are so ill that they either would not survive or choose not to risk undergoing surgery. In this example, surgery is associated with a lower observed mortality rate. The measure has more accurate risk adjustment, and thereby is better at accounting for the underlying risk of the population that the hospital serves, when the surgical and non-surgical patients are separated into distinct risk models.

To demonstrate this further, we note that in the case of surgical and non-surgical orthopedics, as well as surgical and non-surgical cancer, the hospital-level risk-standardized mortality rates (RSMR) are quite different. For example, for non-surgical cancer, the median RSMR in the development sample was 2.5 percent (range 1.3 percent–6.0 percent) for surgical cancer, compared to 19.3 percent (range 9.3 percent–33.7 percent) for non-surgical cancer. Furthermore, prior experience with other quality measures suggests that hospitals do not perform equally well across different service lines, thus it benefits hospitals and consumers to provide quality information on more narrow cohorts. Therefore, in order to make this measure useful in terms of quality improvement and patient choice, we designed the measure to report the surgical and non-surgical divisions separately.

Further, we note that some commenters observed that cancer care is complex and often includes surgical procedures, and advocated for both surgical and non-surgical cancer divisions to better capture cancer patients and allow providers, and possibly consumers, to view more detailed quality information related to cancer.

Comment: Multiple commenters expressed concern about the limitations of claims data including effectiveness in quality measurement. One commenter suggested that the measure should not include claims data and instead be specified entirely using EHR data. One commenter recommended that CMS use specialty specific registry data in the measure.

Response: We thank commenters for their feedback. Administrative claims data are routinely submitted by hospitals for quality measurement and are frequently audited by CMS. This allows for relatively accurate data about patients' acute and chronic conditions while also preventing undue burden on providers to submit additional clinical information. In addition, claims-based measures continue to provide important quality information that cannot currently be captured using EHR data alone. For example, claims data can be linked across care settings to gather complete risk factors for patients. Claims data also enable tracking patient outcomes such as deaths that occur outside of a single care setting, and provide a reliable and valid source of information that supports the development of measures not currently feasible using EHR data alone. For these reasons, we believe that claims-based measures will continue to play a vital role in quality assessment. In addition, for claims-based outcome measures (procedure-specific mortality and readmission measures) we have previously developed, we have found measure scores calculated from data derived from medical records correlate highly with measure scores calculated

with claims.[313] [314] [315] [316] These studies support the use of claims for outcomes such as mortality.

At this time it is not feasible to develop and implement an eCQM measuring the outcome of mortality 30-days after admission to an acute care hospital. Deaths recorded as outcomes in CMS' claims-based mortality measures are derived from the Medicare Enrollment Database which provides information about deaths among Medicare beneficiaries.[317] Hospitals' EHRs do not include information about deaths that occur outside of the hospital and therefore cannot be used in place of Medicare enrollment data. In addition, hospital claims provide a standardized and audited assessment of patients' principal discharge diagnoses, which are the basis for the service-line division assignment in the HWM measures. Therefore, claims and administrative data continue to provide critical information to support these quality measures.

Regarding the use of specialty registry data, we agree that registry data are a useful source of data to consider, in particular because registry data address care for all patients (not limited to Medicare fee-for-service patients). Registry data, however, are generally reported on a voluntary basis among registry participants only, and accordingly are not currently an available source of measurement data from all hospitals. However, we will continue to consider the potential use, feasibility, and availability of registry data for future measures.

Comment: Several commenters expressed concern about risk adjustment, including how the measure accounts for various mortality risks associated with different procedures performed at a hospital. In addition, commenters noted that the measure includes a broad range of conditions and procedures associated with widely varying mortality risk. Commenters expressed concern that these shortcomings could mask preventable hospital harms and lead to inaccurate performance comparisons. One commenter requested a better explanation of the risk adjustment utilized within each of the service line divisions.

Response: We thank commenters for their feedback. We agree that one of the key challenges in developing a hospital-wide mortality measure is to adequately account for the varying risk of mortality for the different populations of patients admitted to hospitals and to adequately adjust for these differences when comparing performance across hospitals. However, we feel our risk adjustment approach appropriately accounts for these differences.

The measure addresses risk adjustment in several ways. First, since the risk of death differs between surgical and non-surgical patients, the measure separates patients who underwent major surgical procedures from those who did not. The measure then further divides the surgical and non-surgical groups into a total of 13 service-line divisions (Surgical divisions: General, Orthopedics, Cardiac, Cancer, and Neurosurgery; Non-surgical divisions: Cardiac, Infectious Disease, Pulmonary, Gastrointestinal, Renal, Orthopedic, Neurology, and Cancer). The surgical divisions are created by combining clinically related groups of procedures, considering the risk of death and the reason for admission (the principal discharge diagnosis) during the combination step. For the non-surgical division, the measure categorizes patients based on medical conditions that would typically be cared for by the same group of clinicians, as well as based on the risk of death.

To further account for differences in risk among patients, the measure adjusts for both patient-level factors (the medical condition of the patient when admitted to the hospital, accounted for by adjusting for illnesses and diagnoses the patient has when admitted) and hospital service mix differences (the types of conditions/procedures cared for by the hospital). Each of the 13 service-line divisions is risk-adjusted independently of the others, which helps account for differences in the mortality risks of procedures in the separate divisions. The hybrid version of the measure uses the same service-line division risk models, patient case mix, and hospital service mix, but adds an additional 10 clinical risk variables extracted from the EHR. Although no measure is perfectly able to assess each harm or death, the detailed approach to risk adjustment of individual groups of procedures and conditions is intended to prevent inaccurate performance assessment by this measure.

The work described above was done with the careful and systematic input of clinicians. In addition, the steps described above were presented to the measure developer's Patient & Family Caregiver workgroup, technical and clinical workgroup, and the TEP, all of whom generally supported the approach. For more details about the risk-adjustment approach, we refer readers to the measure methodology report on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html.*

Comment: Several commenters expressed concern that the measure does not adjust for social risk factors and that no analysis of their impact on the measures was provided. In addition, some commenters recommended additional research on the community-level factors described in the report by the Office of the Assistant Secretary for Planning and Evaluation (ASPE).[318]

Response: We thank commenters for their feedback. As part of our plans to submit this measure to the NQF for endorsement, we intend to provide the results of measure testing that includes assessing the impact of social risk factors on the measure results, as required for all measures seeking NQF endorsement. Specifically, NQF requires developers to present the results of analyses examining the impact of social risk factors on the measure outcome, as well as the degree to which any association is occurring at the patient-level or hospital-level.[319] We understand that the relevant NQF committees will examine the evidence and determine whether the measure is suitable for endorsement with or without adjustment for social risk

[313] Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with an acute myocardial infarction. *Circulation.* 2006 Apr 4;113(13):1683–701.

[314] Krumholz HM, Lin Z, Drye EE, et al. An administrative claims measure suitable for profiling hospital performance based on 30-day all-cause readmission rates among patients with acute myocardial infarction. *Circ Cardiovasc Qual Outcomes.* 2011 Mar 1;4(2):243–52.

[315] Keenan PS, Normand S–LT, Lin Z, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. *Circ Cardiovasc Qual Outcomes.* 2008 Sep;1(1):29–37.

[316] Bratzler DW, Normand S–LT, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. *PLoS One.* 2011 Apr 12;6(4):e17401.

[317] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), Centers for Medicare & Medicaid Services: Enrollment Database. Available at: *https://aspe.hhs.gov/centers-medicare-medicaid-services.*

[318] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[319] National Quality Forum (NQF). ''A Roadmap for Promoting Health Equity and Eliminating Disparities: The Four I's for Health Equity.'' Available at: *https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

factors, including consideration of potential community-level factors. This NQF analysis would be taken into consideration before we move forward with proposing either or both of these measures for inclusion in the Hospital IQR Program in future rulemaking.

Comment: One commenter recommended educating the public about where to obtain information about hospital performance on the measure in order to ensure that the measure is useful once results are made public.

Response: We thank the commenter for the suggestion. Should we decide to move forward with proposing either or both of these measures for inclusion in the Hospital IQR Program in future rulemaking, the results will be publicly reported on the *Hospital Compare* website.

Comment: One commenter requested clarification on how the term ''average'' is derived and the usage of the term by the measure developer.

Response: The term ''average'' is employed in three different circumstances. First, when identifying outlier hospitals, we use the unadjusted national average mortality rate, which is calculated as the total number of deaths divided by the total number of patients; hospitals' risk-standardized mortality rates are considered outliers if they are statistically significantly different from the unadjusted national average mortality rate. Secondly, in calculating the hospital risk-standardized mortality rate, we multiply the standardized mortality ratio (predicted mortality/expected mortality) by the same unadjusted national average mortality rate, which is calculated as the total number of deaths divided by the total number of patients. Lastly, to calculate the denominator of the standardized mortality ratio (expected mortality), we determine the number of deaths among that hospital's patients given the patients' risk factors and the average of all hospital-specific effects in the nation. Specifically, for each patient in the data-set, the estimated regression coefficients are multiplied by the observed characteristics and the average of the hospital-specific intercepts is added to this quantity. In the hierarchal logistic regression model, we modelled hospital specific intercept as deviation from the average which is set to 0, therefore some hospital specific intercepts will be above 0 while some hospital specific intercepts will be below 0. For more details, we refer readers to the measure methodology report on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

Comment: Multiple commenters submitted suggestions about how CMS should implement the hybrid version of the HWM measure, including: (1) Conducting a pilot run of data submission prior to implementation; (2) testing the use of EHR data to risk-adjust the current condition-specific mortality measures; (3) implementing a voluntary reporting period; and (4) publicly reporting service line data.

Response: We thank commenters for their suggestions. We will take all feedback under consideration as we determine future use of these measures in the Hospital IQR Program.

Comment: Some commenters expressed concern about potential unintended consequences of the measure, including incentivizing hospitals to withhold appropriate end-of-life care and penalizing hospitals for mortality that is not related to quality. Several commenters believed that the exclusions, as currently specified, could mask preventable hospital harms and could be improved. One commenter suggested a four-day hospice enrollment window instead of the 2-day window currently specified.

Response: We thank commenters for their feedback. We are committed to examining and avoiding unintended consequences in relation to patient perspectives, and we agree that mortality is not an appropriate assessment of quality for patients or families who have elected to enroll in hospice and are at the end of life.

During measure development, we sought to identify and exclude cases in which survival was not the primary goal and in which hospitals cannot influence survival through quality of care. This was achieved by excluding patients who had enrolled in hospice within the past 12 months of the index hospitalization, upon admission, or within two days after admission to the hospital. Most patients who have enrolled in hospice do not have the same goals of care as those who are not enrolled. In addition, based on feedback from stakeholders and experts consulted during measure development, it is likely that for most patients and/or families who discussed and agreed to enroll in hospice within two days of admission, survival is not the primary goal due to a condition that was present on admission and therefore, mortality should not be used as a marker of quality care. Longer enrollment windows were considered in our discussions with experts, patients, and families. However, the TEP felt that the risk of excluding patients who enrolled in hospice care due to the outcome of poor quality of care provided by a hospital outweighed the potential benefit of extending the window for the exclusion of these patients. We recognize that there is no single, correct approach to identifying patients at the end-of-life and the use of hospice enrollment does not perfectly differentiate between patients who have a goal of survival from those who do not. Similarly, we cannot perfectly distinguish every preventable harm. However, we feel the current approach accurately identifies most patients we intend to assess through the HWM measure and errs on the side of protecting a patient's choice to defer aggressive treatment at the end of life.

Comment: Several commenters expressed concerns that this measure was developed using ICD–9 codes that are not indicative of the current healthcare environment which utilizes ICD–10 codes. One commenter noted there is no longer a specific diagnosis code for ''admission for rehab'' in the ICD–10 codes.

Response: We thank commenters for their feedback. The measures are currently being respecified with ICD–10 data, prior to submission to NQF for endorsement. Identification of admissions for rehabilitation and other exclusion criteria, surgical and non-surgical service-line division placement, and risk adjustment will be updated using ICD–10 data.

Comment: One commenter sought clarification in the cross-over of CEHRT to submit information for hybrid measures.

Response: We have not yet determined any future implementation pathway or timeline for this measure. Any proposal to adopt the Hybrid HWM measure into the Hospital IQR Program measure set would be made through future rulemaking. Should we decide to move forward with proposing to include the Hybrid HWM measure into the Hospital IQR Program in the future, we will consider the certification requirements applicable to hybrid measures at that time.

Comment: Some commenters had concerns about the validity of the hybrid version of the measure given the small sample size it would have as a voluntary measure should only a fraction of the nation's acute care hospitals participate.

Response: We thank the commenters for their feedback. The Hybrid Hospital-Wide Readmission measure, which uses a nearly identical set of EHR data elements, was implemented as a voluntary measure in the Hospital IQR Program for the reporting period from January 2018 through June 2018. We are

actively compiling stakeholder feedback on the electronic specifications for the EHR data elements, their extraction, and on the data submission process. Because the Hybrid HWM measure uses a nearly identical set of data elements, we believe the experience gained through the voluntary reporting of the Hybrid HWR measure would potentially facilitate implementation of the Hybrid HWM measure should we move forward with proposing to include the measure in the Hospital IQR Program through future rulemaking.

Comment: Several commenters did not believe the HWM measure is sensitive enough to accurately capture hospital quality. They noted that there are few performance outliers identified and questioned whether this measure would provide actionable data to inform quality improvement for hospitals or meaningful information to patients about the quality of hospitals. One commenter suggested that preventable mortality represents only a fraction of the overall mortality rates and that the simple variation in rates might be due to non-modifiable factors rather than quality of care. To address this variation, they suggested that the measure score improvement should be reported rather than the measure rate alone.

Response: Although there are not many statistical performance outliers, we believe that the measure can still convey meaningful performance information. Using 95 percent confidence interval (uncertainty) estimates to categorize hospital outliers is conservative by design, meaning that the measure is designed to only declare a hospital as an outlier with a very high degree of certainty. But the overall distribution of mortality rates show meaningful variation. We found that the claims-only overall hospital risk-standardized mortality rates ranged from 5.0 percent to 9.8 percent with a median risk-standardized mortality rate of 7.4 percent.[320] This variation provides information about the range of quality among hospitals and will allow hospitals and consumers to see if a hospital is at the high end or the low end of the range. We believe reporting hospital mortality scores will improve transparency and promote quality improvement efforts. This measure identified 2.6 percent of hospitals as outliers, which is consistent with other CMS condition- and procedure-specific measures that display a range of 2.5 percent to 11.2 percent of hospitals as outliers.

Should we move forward with proposing to include either of these measures for inclusion in the Hospital IQR Program in the future, in advance of public reporting, hospitals would receive confidential, service-line division and patient-level data to support quality improvement. This information would allow for thorough investigation of patient scenarios that resulted in mortality and, therefore, that contributed to each division-level standardized mortality ratios, which are rolled up into the overall risk-standardized mortality rate. We will continue to consider the best approach for communicating meaningful variation in performance and optimizing the usefulness of this measure for the public. This includes consideration of reporting improvement in scores in addition to hospitals' performance in a single measurement period.

Comment: Several commenters did not support the inclusion of either version of the HWM measure in the Hospital IQR Program because they felt these measures are very broad and require more testing. Some commenters felt this measure would fail to enhance quality improvement efforts and noted that the condition-specific measures in the Hospital VBP Program are more actionable.

Response: We appreciate commenters' interest in the information provided by the narrower condition-specific measures, but believe that while the Hospital-Wide Mortality measure assesses a broad population, it serves an important complementary purpose. In contrast to the condition-specific measures, a hospital-wide measure provides a picture of a hospital's overall quality and thereby complements the condition-specific mortality measures. The measure underwent significant testing of the risk variables, performance of the risk models for each service-line division, and the overall measure score. In addition, we compared hospital-level results from the claims-only measure with the Hybrid Hospital-Wide Mortality measure to establish the validity of the claims-only risk model. All testing results support the reliability and validity of the measure construct and methodology.

In addition, the Hospital-Wide Mortality measure was developed to broadly measure the quality of care across hospitals, including the quality of care in smaller volume hospitals that might lack sufficient numbers of patients to be included in condition-specific mortality measures. Mortality is an important health outcome that is meaningful to patients and providers, and updated estimates suggest that more than 400,000 patients die each year from preventable harm in hospitals.[321] In addition, this measure captures a broader group of patients than those included in condition- and procedure-specific mortality measures.

The Hospital-Wide Mortality Measure was also designed to support quality improvement efforts. By giving a hospital-wide quality score, the measure provides hospitals and the public with an overall evaluation of a hospital's performance on an important outcome. The Hospital-Wide Mortality measure, both with respect to the overall score as well as the division-level results, provides actionable information to hospitals that can support important quality improvements. Should we move forward with proposing to include either or both the hybrid or claims-based version of these measures for inclusion in the Hospital IQR Program, hospitals would receive detailed service-line and patient-level data along with their hospital-wide mortality performance scores. This patient-level detail can help a hospital decide where to focus its quality improvement efforts.

We thank the commenters and we will consider their views as we develop future policy regarding the potential inclusion of claims-only hospital-wide mortality measure and hybrid hospital-wide mortality measure with electronic health record data in the Hospital IQR Program.

b. Potential Future Inclusion of the Hospital Harm—Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM)

(1) Background

Opioids are among the most frequently implicated medications in adverse drug events among hospitalized patients. The most serious opioid-related adverse events include those with respiratory depression, which can lead to brain damage and death. Opioid-related adverse events have both negative patient impacts and financial implications. These patients have been noted to have 55 percent longer lengths of stay, 47 percent higher costs, 36 percent higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events.[322] While noting that

[320] Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure: Measure Methodology for Public Comment. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html.*

[321] James JT. A new, evidence-based estimate of patient harms associated with hospital care. *Journal of Patient Safety.* 2013;9(3):122–128.

[322] Kessler ER, Shah M, Gruschkkus SK, et al. Cost and quality implications of opioid-based

data are limited, The Joint Commission suggested that opioid-induced respiratory arrest may contribute substantially to the 350,000–750,000 in-hospital cardiac arrests annually.[323]

Most opioid-related adverse events are preventable. Of the opioid-related adverse drug events reported to The Joint Commission's Sentinel Event database,[324] 47 percent were due to a wrong medication dose, 29 percent to improper monitoring, and 11 percent to other causes (for example, medication interactions and/or drug reactions). In addition, in an analysis of a malpractice claims database, a review of cases in which there was opioid-induced respiratory depression among post-operative surgical patients, 97 percent of these adverse events were judged preventable with better monitoring and response.[325] While hospital quality interventions such as, proper dosing, adequate monitoring, and attention to potential drug interactions that can lead to overdose are key to prevention of opioid-related respiratory events, the use of these practices can vary substantially across hospitals.

Administration of opioids also varies widely by hospital, ranging from 5 percent in the lowest-use hospital to 72 percent in the highest-use hospital.[326] Notably, hospitals that use opioids most frequently have increased adjusted risk of severe opioid-related adverse events.[327] Surgical patients are at particular risk of these adverse events because opioid administration is common in this population. For example, among a diverse group of surgical patients undergoing common surgical procedures at a large medical center, 98.6 percent received opioids and 13.6 percent of those patients experienced an opioid-related adverse drug event.[328] Reduction of adverse events in surgical and non-surgical patients receiving opioids, may be enhanced by measuring the rates of these events at each hospital in a systematic, comparable way. We have developed the Hospital Harm—Opioid-Related Adverse Events eCQM to assess the rates of these adverse events as well as the variation in rates among hospitals.

(2) Overview of Measure

The Hospital Harm—Opioid-Related Adverse Events eCQM outcome measure assesses, by hospital, the proportion of patients who had an opioid-related adverse event. This measure addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. The measure uses the administration of naloxone, an opioid reversal agent that has been used in a number of studies as an indicator of opioid-related adverse respiratory events, to indicate a harm to a patient.[329] [330] The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. This measure focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and may bring a patient into the emergency department. We acknowledge that some stakeholders have expressed concern that some providers could withhold the use of naloxone, believing that may help those providers avoid poor performance on this quality measure. This measure is not intended to incentivize hospitals to not administer naloxone to patients who are in respiratory depression, but rather incentivize hospitals to closely monitor patients who receive opioids during their hospitalization to prevent respiratory depression or other symptoms of opioid overdose. In addition, the aim of this measure is not to identify preventability of an individual harm instance or whether each instance of harm was an error, but rather to assess the overall rate of the harm within a hospital incorporating a definition of harm that is likely to be reduced as a result of hospital best practice.

As with all quality measures we develop, testing was performed to establish the feasibility of the measure, data elements, and validity of the numerator. Clinical adjudicators reviewed medical records on each instance of a harm identified through query of the EHR data to confirm naloxone was in fact administered to reverse symptoms of opioid overdose. Additional testing is currently being performed to establish the data element validity using output from the Measure Authoring Tool (MAT) [331] in multiple hospitals, using multiple EHR systems. The MAT is a web-based tool used to develop the electronic measure specifications, which expresses complicated measure logic in several formats including a human-readable document. The electronically extracted data would be validated by comparison to medical chart abstracted data.

This measure addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care discussed in section I.A.2. of the preamble of the proposed rule. The Hospital Harm—Opioid-related Adverse Events (MUC17–210) was included in a publicly available document entitled ''2017 Measures Under Consideration List'' (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*). This measure was reviewed by the NQF MAP Hospital Workgroup in December 2017 and received the recommendation to refine and resubmit for consideration for programmatic inclusion, as referenced in the 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS (available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*). For additional information and discussion of concerns and considerations raised by the MAP related to this measure, we refer readers to the December 2017 NQF MAP Hospital Workgroup meeting transcript (available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87148*).

postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. *Pharmacotherapy.* 2013; 33(4):383–391.

[323] Overdyk FJ. Postoperative respiratory depression and opioids. Initiatives in Safe Patient Care. 2009. Available at: *http://files.sld.cu/anestesiologia/files/2012/01/postoperative-respiratory-depression-opioids.pdf.*

[324] The Joint Commission. Safe use of opioids in hospitals. *The Joint Commission Sentinel Event Alert.* 2012; 49:1–5. *https://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf.*

[325] Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: a closed claims analysis. *Anesthesiology.* 2015; 122(3):659–665.

[326] Herzig SJ, Rothberg MB, Cheung M, et al. Opioid utilization and opioid-related adverse events in nonsurgical patients in US hospitals. *J Hosp Med.* 2014; 9(2):73–81.

[327] Ibid.

[328] Kessler ER, Shah M, Gruschkkus SK, et al. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. *Pharmacotherapy.* 2013; 33(4):383–391.

[329] Eckstrand JA, Habib AS, Williamson A, et al. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009; 3:18.

[330] Nwulu U, Nirantharakumar K, Odesanya R, et al. Improvement in the detections of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. *Eur J Clin Pharmacol.* 2013; 69(2):255–259.

[331] The Measure Authoring Tool (MAT) is a web-based tool used by measure developers in the creation of eMeasures. For additional information, we refer readers to: *https://www.emeasuretool.cms.gov/.*

MAP stakeholders acknowledged the significant health risks associated with opioid-related adverse events, but recommended adjusting the numerator to consider the impact on chronic opioid users.[332] Accordingly, we will address this issue in upcoming testing and NQF review. Regarding MAP stakeholder concern that the measure needs to be tested in more facilities to demonstrate reliability and validity, as stated previously, we are currently testing the MAT output for this measure in multiple hospitals that use a variety of EHR systems.[333] We plan to submit this measure for NQF endorsement as part of the Patient Safety Committee in November 2018.

(3) Cohort

The measure denominator includes all patients 18 years or older discharged from an inpatient hospital encounter during the 1-year measurement period. The measure includes inpatient admissions that were initially seen in the emergency department or in observational status and then admitted to the hospital.

(4) Outcome

The numerator for this electronic outcome measure is the number of patients who received naloxone outside of the operating room either: (1) After 24 hours from hospital arrival; or (2) during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to the naloxone administration. We narrowed cases to exclude naloxone use in the operating room where it could be part of the sedation plan as administered by an anesthesiologist. Use of naloxone for procedures outside of the operating room (such as bone marrow biopsy) are counted in the numerator as it would indicate the patient was over sedated. These criteria exist to ensure patients are not considered to have experienced harm if they receive naloxone in the first 24 hours due to an opioid overdose that occurred in the community prior to hospital arrival. We do not require the administration of an opioid prior to naloxone after 24 hours from hospital arrival because an event occurring 24 hours after admission is most likely due to hospitals' administration of opioids. By limiting the requirement of documented opioid administration to the first 24 hours of the encounter, we are reducing the complexity of the measure logic and therefore the burden of implementation for hospitals. For more information about the measure specifications, we refer readers to our MAT Header (measure specs) and framing document (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Public-Comments.html*).

We invited public comment on the possible future inclusion of the Hospital Harm—Opioid-related Adverse Events eCQM in the Hospital IQR Program. Specifically, we sought public comment on whether to: (1) Initially introduce this measure as voluntary; (2) adopt the measure into the existing eCQM measure set from which hospitals currently select four to report; or (3) adopt the measure as mandatory for all hospitals to report. In addition, we sought public comment on ways to address any potential unintended consequences resulting from future implementation of this measure. We are also considering future adoption of this measure in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for Clinical Quality Measures (CQM) electronic reporting by eligible hospitals and CAHs.

Comment: Several commenters expressed either outright or conditional support for the Hospital Harm—Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM). Several commenters believed this measure would be useful and important.

Response: We thank the commenters for their support.

Comment: A number of commenters recommended various implementation pathways for the measure. Many commenters recommended that reporting on the Hospital Harm—Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM) be made voluntary prior to mandatory reporting in either the Hospital IQR or Promoting Interoperability Programs, specifically until validity and feasibility of the measure has been proven, and the NQF has endorsed it. Several commenters recommended that CMS incorporate this measure into the eCQM measure set from which hospitals select four eCQMs to report, while one commenter specifically supported its inclusion in the Hospital IQR and PI Programs as a mandatory measure. A few commenters noted that if this measure is implemented, measure submission should count toward one of eCQMs required for the PI Program.

One commenter suggested that CMS limit the use of this measure to public reporting and quality improvement programs, rather than value-based purchasing programs. A few commenters recommended that CMS complete measure specification and testing prior to implementation and consider implementation only after the 2018 eCQM annual updates. Several commenters suggested that CMS provide education to hospitals on how to utilize this measure to improve patient safety. A few commenters asked for clarification on whether health IT developers will be required to support or certify the measure if it is introduced on a voluntary basis.

Response: We thank commenters for their feedback and we will consider all suggestions for measure implementation and stakeholder outreach for future program years. We will complete specifications for the measure and measure validity and reliability testing prior to proposing this measure for future inclusion in the Hospital IQR Program. We have performed measure testing in multiple hospitals with various EHR systems to establish the feasibility of this measure as well as the validity of the data elements and the numerator. Additional testing is currently being performed to provide information about the feasibility and data element validity based on output from the Measure Authoring Tool (MAT) in multiple hospitals, using multiple EHR systems. We reiterate that we intend to submit this measure to the NQF for endorsement as part of the Patient Safety Committee as early as FY 2019. We will continue to engage stakeholders in the development of this measure. Any proposals for future adoption of this measure will be announced through rule-making.

Comment: Commenters raised concerns that the measure does not capture opioid-related adverse events that occur outside of the hospital. One commenter expressed concern that including naloxone administered in the hospital to reverse a narcotic overdose that occurred outside of the hospitals would place unwarranted blame on hospitals.

Response: We thank commenters for sharing their concerns. This measure is not intended to measure opioid-related adverse events that occur outside of the hospital. This Hospital Harm eCQM focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community. For naloxone administration to be considered a harm, the measure requires documentation of hospital-administered opioids in the

[332] Measure Application Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[333] Ibid.

first 24 hours of a hospitalization (including patients treated in the emergency department or who are in observational status who become inpatient), with the intent to capture only naloxone administrated due to overuse of narcotics that were given in the hospital and to exclude naloxone administered to reverse community-acquired opioid overdoses. The measure is designed to focus on the quality of care and to capture a specific harm: Naloxone given due to opioid administration that occurred within the hospital.

Comment: Commenters suggested several changes to the measure specifications, including excluding instances in which naloxone is administered by an anesthesiologist, or to patients with opioid sensitivity. Two commenters suggested including only patients with documented respiratory failure in presence of narcotic administration. Commenters also advised considering stratification rather than risk adjustment, particularly for chronic opioid users.

Response: We thank commenters for their recommendations regarding potential measure exclusions and stratification. We aim to be as inclusive as possible in defining a measure cohort to ensure the measure will have an impact on the broadest possible group of patients at risk of the outcome. We also intend to minimize the complexity of the measure specifications to reduce burden to hospitals when implementing the measure. The measure does exclude instances in which naloxone is administered in the operating room where it could be part of the sedation plan administered by an anesthesiologist. Regarding the comments on including only patients with documented respiratory failure in presence of narcotic administration, we believe that using EHR data to capture respiratory failure may not be consistently feasible or consistent across different hospital systems. Given that naloxone is primarily administered when a patient has severe responses to an opioid overdose, it has been used as a surrogate for important adverse reactions and is more feasible to capture.[334] We will continue to consider the suggested modifications to the cohort during measure testing.

Regarding commenters' suggestions about measure stratification and risk adjustment, this measure does not require a data element for chronic opioid users. We do not anticipate risk adjusting this measure for chronic opioid use, as most instances of opioid-related adverse events should be preventable for all patients regardless of prior exposure to opioids or chronic opioid use. In addition, there are several risk factors that affect sensitivity to opioids that physicians should consider when dosing opioids. Risk adjustment would only be needed if certain hospitals have patients with distinctly different risk profiles that cannot be mitigated by providing high-quality care. Similarly, the current measure specification does not include stratification of patients for chronic opioid use for three reasons: (1) This is a challenging data element to capture consistently in the EHR; (2) chronic opioid use should be taken into consideration by clinicians in determining dosing in the hospital and theoretically should not be considered a different risk level for patients; and (3) stratification can reduce the effective sample size of a measure and make it less useable.

Comment: Multiple commenters discussed the potential burden of the measure on hospitals, and the feasibility of the required EHR data elements. Several commenters believed all required data elements are readily available in the EHR, while several other commenters disagreed, and noted challenges in mapping the required data elements and the complex measure logic. One commenter questioned whether manual abstraction would be necessary to report this measure. Another commenter noted that some hospitals lack EHRs in procedural or surgical areas, which might bias their results. One commenter noted that the costs associated with this measure outweigh the benefits, which is contrary to the Meaningful Measures Initiative. One commenter noted that many providers will not have enough time to update their reporting systems if detailed specifications are not provided far enough in advance.

Response: We appreciate commenters' concerns. The measure specifications were developed with the end-user in mind and with the goal of minimizing the burden on hospitals. Testing has demonstrated that the data elements and measure logic are feasible and accurately capture opioid-related adverse events using EHR data. This measure should not require manual chart abstraction. To clarify, currently, the measure specifications capture naloxone administration in post-procedural areas as a harm, but not naloxone administered in procedural areas, such as operating rooms. We recognize that stakeholders would require time to prepare for mandatory reporting and we will consider that need as we make decisions about proposing to add measures to the Hospital IQR Program in future years. We aim to provide measure specifications that are simple, useful, and provide as much information as possible to ease the burden of data collection and reporting.

Comment: Many commenters noted the potential negative unintended consequences of the measure, and disagreed with using naloxone as a proxy for opioid-related adverse events. These commenters asserted that the use of naloxone does not necessarily mean a harm was caused by an opioid. One commenter stated that preliminary results presented to the NQF MAP Hospital Workgroup in December 2017 showed a high ''error rate,'' and expressed concern that these results will only be magnified in broader testing. Another commenter noted the low event rate of this harm. One commenter requested additional evidence, based on the tracking of performance on this measure when implemented, to ensure that the measure does not inappropriately incentivize providers to withhold naloxone before the measure is made mandatory. Several commenters expressed interest in whether there is true performance variation for this measure in care across hospitals.

Response: We thank commenters for their feedback. We acknowledge that naloxone administration alone does not conclusively indicate a harm. For example, in some cases naloxone can be given to reverse severe itching related to opioids.[335] The intent of the measure is not to reduce appropriate use of naloxone or to bring the rate of administration to zero. Rather, the measure is intended to identify hospitals that have particularly high rates of naloxone use relative to others, and thereby incentivize improved clinical practices, such as appropriate dosing of opioids and monitoring of patients to reduce the need for naloxone use in patient care. We do not believe that this measure would deter providers from prescribing opioids or using naloxone for patients who require it. The goal is to incentivize hospitals to avoid over-sedation and to closely monitor patients on opioids.

[334] Agency for Healthcare Research and Quality. (2016). *National Scorecard on Rates of Hospital-Acquired Conditions 2010–2015: Interim Data from National Efforts to Make Health Care Safer.* Retrieved from: *https://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html.*

[335] Eckstrand JA, Habib AS, Williamson A, et al. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009;3(1):18.

Moreover, naloxone administration has been used in a number of studies as an indicator of opioid-related adverse respiratory events.[336] [337] Prior testing in five hospitals showed the measure captured the intended harm, by assessing whether each harm identified in the measure could be confirmed though clinical review of the patients' medical record. In 93.9 percent of events, adjudicators noted that naloxone was administered because of excessive opioid medication administration. To clarify testing results around an ''error rate,'' we believe the commenter is referring to the success rate of capturing the intended harm, which ranged from 87.2 percent to 95.7 percent across five hospitals. We agree that this measure has a low event rate, nonetheless, we believe hospital-caused opioid overdoses are important to measure. Opioids are among the most frequently implicated medications in adverse drug events among hospitalized patients, with the most serious opioid-related adverse events leading to brain damage and death.[338] Further, this measure addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. Regarding commenters' interest in whether there will be true performance variation in care across hospitals, preliminary testing showed variation in event rates across the set of testing hospitals. This measure is undergoing continued testing and we will continue to examine the extent of performance variation captured by the measure. We continue to believe that the measure specifications are appropriate for this measure and if this measure were to be proposed for future inclusion in the Hospital IQR Program, any unintended consequences would be closely monitored during measure reevaluation.

Comment: Commenters voiced additional concerns and sought clarification about the measure specifications. One commenter sought clarification regarding whether patients seen in the emergency department were included in the measure specifications. One commenter noted changes in the measure specifications from what was reviewed by the NQF MAP Hospital Workgroup in December 2017, and the measure specifications outlined in the FY 2019 IPPS/LTCH PPS proposed rule. Two commenters recommended changing the numerator to require documentation of opioid administration prior to naloxone administration in all cases, and noted this would illuminate opportunities for hospital process improvement. One commenter sought clarification on the numerator since this measure only counts one harm per patient, and would not capture multiple harms to the same patient.

Response: We thank the commenters for their feedback. The measure's initial population and denominator includes patients treated in the emergency department or who are in observational status who become inpatients. The Hospital Harm—Opioid-Related Adverse Events eCQM measure specifications were originally submitted to the ''2017 Measures Under Consideration List'' (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*), included documentation on a respiratory stimulant within 24 hours of opioid administration as representative of a harm to a patient, and required documentation of an opioid administration within the hospital within 24-hours of the narcotic antagonist. This measure was simplified after preliminary testing, to not include a respiratory stimulant and only to require documentation of an opioid administration prior to naloxone within the first 24-hours of the hospitalization. Previous testing of the measure indicated that we did not miss harm events when the measure logic was simplified in this manner. These modifications were made to reduce the complexity of the measure specifications while still capturing a signal of hospital quality. The results from hospital testing presented at the NQF MAP Hospital Workgroup meeting in December 2017 represented the final measure specifications as described in this final rule.

The measure does capture only a single harm for each patient and does not capture multiple harms on a single patient during a single inpatient encounter. The numerator captures the number of patients who experience a harm, rather than the number of harms occurring to simplify the measure and limit the reporting burden, while still capturing a signal of hospital quality. For more information on the specifications of this measure, we refer readers to the MAT Header (measure specifications) and framing document (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Public-Comments.html*).

Comment: Some commenters did not support the Hospital Harm—Opioid-Related Adverse Events eCQM, and proposed alternative measures to address the opioid epidemic. One commenter recommended that CMS consider including non-pharmacologic technologies such as medical devices to serve as alternatives to treat acute and chronic pain. Several commenters suggested providing education to patients to help prevent or reduce the risk of addiction.

Response: We thank commenters for their feedback and suggestions on additional potential opioid measures. We appreciate the suggestions and we intend to consider other ways the Hospital IQR Program can address the opioid crisis. While this measure may not address all root causes of opioid overuse, it addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.

We thank the commenters and we will consider their views as we develop future policy regarding the potential inclusion of the Hospital Harm—Opioid-Related Adverse Events Electronic Clinical Quality outcome measure (eCQM) in the Hospital IQR Program.

c. Potential Future Development and Adoption of eCQMs Generally

Stakeholders continue to identify areas for improvement in the implementation of eCQMs under a variety of CMS programs, including the Hospital IQR Program and the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). While effective utilization of eCQMs promises greater efficiency and more timely access to data to support quality improvement activities, various types of costs associated with these measurement approaches detract from these benefits. Moreover, some providers may have low awareness of the resources and tools available to help address issues that arise in utilizing eCQMs.

Program design and operations associated with measurement aspects of these programs can be a significant source of cost for providers. Uncertainty around rapidly shifting timelines and requirements can pose significant financial and operational planning challenges for organizations, while lack of alignment across programs results in further complexity. In addition, the implementation of eCQMs within the

[336] Eckstrand JA, Habib AS, Williamson A, et al. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009; 3:18.

[337] Nwulu U, Nirantharakumar K, Odesanya R, et al. Improvement in the detections of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. Eur J Clin Pharmacol. 2013; 69(2):255–259.

[338] The Joint Commission. (2012). Safe use of opioids in hospitals. *Sentinel Event Alert, 49,* 1–5.

EHR is a significant source of cost. Health IT products vary widely in the eCQMs they offer, and incorporating new measure specifications into a product, along with validation and testing of the updates, can be challenging and time-consuming. Lack of transparency from developers around data sources within the EHR, mapping, measure calculations, and reporting schemas, can hinder providers' ability to implement eCQMs and ensure the accuracy of results. Moreover, challenges in extracting data from the EHR and integrating with other applications can serve as a source of cost for providers seeking to bring together different technology solutions and work with other third party services to complete reporting and quality improvement activities.

Stakeholders have expressed support for increasing the availability of new eCQMs, developing eCQMs that focus on patient outcomes and higher impact measurement areas, and exploring how eCQMs can reduce the costs and information collection burden associated with chart-abstracted measures. However, they have also identified barriers which may contribute to a lack of adequate development of eCQMs and limit their potential, including long development timelines, lack of guidelines/prioritization of and participation in eCQM development, limited field testing, and program policies that limit innovation by focusing on ''least common denominator'' approaches.

We sought stakeholder feedback on ways that we could address these and other challenges related to eCQM use. Specifically, we invited comment on the following questions: (1) What aspects of the use of eCQMs are most costly to hospitals and health IT vendors?; (2) What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM costs?; (3) What are the most significant barriers to the availability and use of new eCQMs today?; (4) What specifically would stakeholders like to see us do to reduce costs and maximize the benefits of eCQMs?; (5) How could we encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?; (6) How could we encourage hospitals and health IT vendors to engage in testing new eCQMs?; (7) Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?; (8) What ways could we incentivize or reward innovative uses of health IT that could reduce costs for hospitals?; and (9) What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?

Comment: Question 1. A number of commenters responded to CMS' request for feedback on question (1)—What aspects of the use of eCQMs are most costly to hospitals and health IT vendors? Many commenters believed the costliest aspect of eCQM use is vendor cost to build, develop, implement, adequately test, and maintain eCQMs. This includes vendor support costs to develop and install code updates following changes to measures and program requirements made through rulemaking. A few commenters noted the significant labor cost associated with validation of eCQM reports, including re-validation of those reports, as they need to be re-validated after every software upgrade or enhancement. One commenter noted that there is considerable burden required to map the necessary data elements from the EHR to the appropriate QRDA format, and some vendors are not properly equipped to collect and transmit such data through the CMS portal.

Many commenters also noted high personnel costs, including the personnel time and cost associated with keeping pace with on-going certification, mandated reporting, and annual program update change requirements, as well as the costs associated with training personnel if changes to eCQM reporting requirements are outside out of the normal workflow. A few commenters added that eCQM implementation requires utilization of resources from multiple disciplines, including IT, data science, quality, analytics, clinicians, laboratory, radiology, coding, and billing.

Many commenters believed that eCQMs are costly because of the uncertainty around the reporting and submission requirements, including the high burden associated with making preparations to report measures that have been identified for removal in the near future. In addition, several commenters noted that the time between the finalization of a new quality measure in the rules and its inclusion in a government incentive or penalty program is too short, resulting in heightened resource use and high burden.

A few commenters expressed concern that there are high costs associated with collecting and reporting data on measures that they believe are fundamentally unusable or not valuable because they include errors or do not appropriately serve clinician needs. Other commenters noted that the manual abstraction and documentation requirements associated with some eCQMs add to the total administrative burden placed on clinicians. One commenter explained that there is high burden associated with alignment following a facility's merger with a larger system.

Question 2. A number of commenters responded to CMS' request for feedback on question (2)—What program and policy changes, such as an improved regulatory alignment, would have the greatest impact on addressing eCQM costs? A number of commenters suggested program and policy changes that might impact the costs associated with eCQM reporting, including: (1) Aligning the regulatory and reporting requirements and timeframes for eCQMs across federal and State programs; (2) adopting nationally standardized eCQMs; (3) streamlining and de-duplicating measure sets across CMS programs; (4) providing more time to implement new measures or measure specification updates and reducing the frequency of changes to the reporting requirements; (5) implementing broader eCQM selections and continuing to offer flexibility for hospitals to self-select and submit data on available measures best suited to their needs that would satisfy multiple reporting programs with a single data submission; (6) focusing on current challenges and not adopting new eCQMs for a period of time, then introducing new eCQMs at a slower pace and in lower volumes; (7) creating a single, facility-based quality reporting program that encompasses inpatient, outpatient, and observation statuses; (8) providing more transparency around program changes, including decision-making criteria geared more toward clinicians, for retaining or removing measures; (9) offering scoring bonuses that incentivize technology utilization; (10) utilizing eCQM data already collected to inform future program requirements and stakeholders about successful practices; (11) requiring reporting only on the eCQM version of measures, and not the chart-abstracted versions, and phasing out claims-only outcomes reporting, or implementing a point system which would assess more points for submission of eCQMs than for chart-abstracted measures to satisfy multiple reporting programs; and (12)

identifying quality reporting requirements in a separate rulemaking process.

Several commenters recommended that CMS regulate the amount charged by health IT vendors for new packages and updates, reimburse hospitals for the cost of software updates needed to meet quality reporting requirements, or provide grants to hospitals for these purposes.

Some commenters provided feedback specifically related to eCQM testing, including: (1) Releasing technical measure specifications earlier; (2) allowing vendors to engage in early testing; (3) making the Pre-Submission Validation Application (PSVA) tool and QualityNet secure portal available before the start of the reporting year; (4) facilitating testing through shared infrastructure; and (5) providing timely answers to questions submitted via the JIRA case system.

A number of commenters focused on improvements that could be made regarding measure development, measure specification, and measure standards, including: (1) Developing eCQMs based on available data and the provision of care; (2) working with the Office of the National Coordinator to develop interoperability and EHR data standards, including defining standards for quality reporting and further aligning existing QRDA standards; (3) working with industry stakeholders in the early stages of measure development; (4) promoting accurate provider attribution; and (5) utilizing eCQMs that pull from common data fields rather than data codes.

Some commenters recommended changes that could be made with regards to measure submission, including: (1) Developing a mechanism to allow facilities to manually correct data once pulled; (2) providing updates to the value set and QRDA I file submission in advance; (3) providing more detailed information on submission errors and providing submission reports earlier; (4) providing avenues for data submission other than hospitals submissions, such as having The Joint Commission obtain eCQM data from QualityNet; and (5) creating a single submission reporting platform for multiple CMS programs and State Medicaid agencies to accept quality data submissions provided to CMS.

Question 3. A number of commenters responded to CMS' request for feedback on question (3)—What are the most significant barriers to the availability and use of new eCQMs today? Many commenters observed significant barriers to the availability and use of new eCQMs. Several commenters expressed their belief that the technology costs, including EHR systems upgrades, adapting workflows, aligning documentation of care to capture required data, shifting timelines, building new specifications, testing and validating new measures, purchasing additional modules for reporting, is a barrier to implementation and reporting on new eCQMs. Other commenters identified lack of alignment across programs as another barrier. One commenter suggested that lack of transparency from developers and the variation in eCQM offerings for reporting new eCQMs also presents a barrier to eCQM reporting. A few commenters expressed their belief that the impact on clinical workflows where eCQMs require documentation that is not part of existing workflows, which actually increases burden on hospitals as compared with reporting on non-eCQM measures, is a significant barrier to reporting on new eCQMs, as is the fact that many EHRs allow for narrative documentation which does not flow into the discrete fields required by eCQMs.

One commenter recommended that CMS limit costs by imposing requirements related to pricing or reimbursement for the purchase of additional reporting modules. Another commenter recommended that CMS consolidate available information on eCQMs into one website that would provide both technical and operational information, and requested additional resources to help standardize and simplify the complexity of codes. A few commenters asserted their belief that measure accuracy and the vague wording of measures causes confusion between developers and providers regarding the intent of the measure, which can present a significant barrier to reporting on new eCQMs. A few commenters remarked on their perceived lack of value or impact on quality improvement associated with eCQM reporting.

Some commenters recommended that CMS provide additional support to vendors, to identify how best to capture required eCQM data, and to offer technical expert teams to organizations that lack the resources to participate in eCQM development or testing. One commenter expressed concern that hospitals and vendors are not ready to fully report on eCQMs and recommended that CMS work with EHR vendors, hospital quality staff, and other affected stakeholders to identify underlying structural problems and barriers to successful eCQM reporting. A few commenters noted that a major hurdle to reporting on new eCQMs is that EHR vendors are unwilling to participate in mapping or supporting voluntary measures, or prioritize certifying to report on existing measures above new measures. One commenter suggested that CMS work with the ONC to advance standards for CEHRT to develop robust interoperability and EHR data standards. Several commenters expressed their belief that more time is needed between the adoption of a new eCQM into the Hospital IQR Program and its required implementation by providers in part to accommodate vendors' need to build and test processes and develop reports. One commenter recommended that CMS identify a date by which the QualityNet Secure Portal will open for 2018 testing. One commenter stated that a barrier to the availability of new eCQMs was the measure development process, and suggested that CMS work to improve the development and approval process. One commenter recommended that CMS explore whether the burden of eCQM reporting could be shifted to billing operations.

Question 4. A number of commenters responded to CMS' request for feedback on question (4)—What specifically would stakeholders like to see CMS do to reduce costs and maximize the benefits of eCQMs? Some commenters suggested removing all the eCQMs. Conversely, a few commenters expressed their preference for eCQM reporting and requested that CMS eliminate all chart-abstracted measures, and require all applicable eCQMs be reported for future program years.

A number of commenters provided feedback on how CMS could reduce costs and maximize the benefits of eCQM development, including: (1) Streamlining the measure development process; (2) developing measures that rely on data elements already present in EHRs and that have direct links to improved outcomes; (3) refining current eCQMs to reflect different settings of care and patient populations; (4) refining measures to add exclusions instead of requiring extra chart documentation; (5) considering moving to improved standards-based eCQM development and reporting; (6) working with health IT vendors to identify and implement ways to present eCQM data to support quality improvements; (7) seeking feedback from other industry stakeholders; (8) connecting novice eCQM measure developers with experts; and (9) establishing a national testing infrastructure for eCQMs.

Several commenters provided feedback on how CMS could reduce costs and maximize the benefits of eCQM reporting, including: (1) Making

eCQM tools and resources available before the start of the reporting year; (2) ensuring there are systems in place to receive data seamlessly; (3) providing timely and accurate feedback reports; (4) supplying additional information on the error messages during the submission process; (5) providing detailed measure specifications to ensure data is collected consistently across providers and communicating about individual indicators and their weights; (6) improving access to QualityNet for analytics personnel; (7) giving adequate, early notice of software updates; (8) improving interoperability of EHR systems; and (9) centralizing the proper resource for questions related to eCQMs.

Some commenters provided feedback on how CMS could reduce costs and maximize the benefits of eCQM through policy changes including: (1) Aligning the eCQM reporting requirements across CMS programs; (2) requiring that vendors support reporting on all eCQMs in the Hospital IQR Program; (3) allowing hospitals to voluntarily report on new eCQMs rather than requiring reporting on new measures; (4) refraining from retroactively applying standards that are updated mid-year; (5) requiring reporting of the eCQM version only for measures also available in chart-abstracted form; (6) utilizing other sources of data rather than having hospitals report the eCQM data directly; (7) constraining the costs of vendor services; (8) sharing a plan for future eCQM use in the Hospital IQR Program; (9) changing the eCQM measure set less often and providing a longer time period to implement program changes (including adding new eCQMs or updating existing eCQMs); and (10) reducing the number of eCQMs available for reporting and only including those that are actionable with the highest return on investment.

A number of commenters recommended that CMS develop new eCQMs for specific chart-abstracted measures, including SEP–1, IMM–2, TOB–1, TOB–2, TOB–3, acute renal failure, ventilator use, and stroke. One commenter suggested refinements to EHDI–1a eCQM. One commenter recommended that CMS require reporting on the PC–01 eCQM.

Question 5. A number of commenters responded to CMS' request for feedback on question (5)—How could CMS encourage hospitals and health IT vendors to engage in improvements to existing eCQMs? A number of commenters suggested that hospitals and health IT vendors would be more willing to engage in improvements to existing eCQMs if CMS provided incentives, such as providing a per diem or honorarium for participation in focus groups and other forums.

A few commenters noted that participation would be enriched if hospitals were able to discuss eCQM improvement in the context of data from prior eCQM data submissions and be given an opportunity to inform future eCQM priorities that reduce reporting burden to advance improvements in the quality of care. One commenter suggested that CMS provide real-time feedback to hospitals on eCQM performance in order to encourage participating in eCQM improvement efforts.

Several commenters observed that successfully meeting mandatory eCQM reporting requirements depends on hospitals using the correct version of specifications, which is generally in the control of the EHR vendors, not the hospitals. Commenters urged CMS to continue outreach to EHR vendors, hospital quality staff, and other affected stakeholders to identify underlying structural problems and barriers to successful eCQM reporting. A number of commenters recommended coordinating efforts between CMS, CMS subcontractors, and measure stewards to solicit feedback from hospitals in order to implement a more efficient feedback loop.

One commenter believed that the introduction of voluntary measures has received increased interest and participation by providers, as it allows for more flexibility without the requirement for mandatory submissions.

Question 6. A number of commenters responded to CMS' request for feedback on question (6)—How could CMS encourage hospitals and health IT vendors to engage in testing new eCQMs? A number of commenters suggested that hospitals and health IT vendors would be more willing to engage in testing new eCQMs if CMS provided incentives, such as: (1) Supplementing or reimbursing the costs to trial eCQMs and provide feedback; (2) providing an upside APU adjustment to the hospitals that participate in testing a new eCQM; (3) providing scoring bonuses, or offering ''bonus'' points similar to those being proposed in the Promoting Interoperability Program; (4) allowing providers to receive credit for meeting the eCQM reporting requirement in the Promoting Interoperability Programs; (5) conducting an ''Implementation-A-Thon;'' and (6) granting providers participating in a defined testing and development program relief from other, mandated reporting, such as creating a ''safe harbor'' status for organizations that utilize their own vetted quality measurement systems or reducing the number of required eCQMs if the hospital is testing a measure.

Many commenters suggested that CMS should vet new eCQMs across a selection of vendors and hospitals prior to considering the measures for inclusion in a CMS quality reporting program for implementation.

A few commenters noted that the data produced by chart-abstracted measures varies significantly from eCQM data, and recommended that CMS adopt a validation process and conduct robust testing to ensure eCQM data are accurate and comparable to chart-abstracted information. One commenter proposed a hybrid approach to eCQM adoption in which hospitals would submit eCQM data, but in the event of a measure failure, the hospital could also supplement the data with manual chart abstraction. The commenter noted that this approach would be mutually beneficial, as CMS would receive more accurate data and hospitals would learn their workflows and documentation gaps for improvement efforts. Moreover, this approach would be less burdensome than manual abstraction, without the fear of penalizing hospitals who are still working through the burden to transition to eCQMs. The commenter also advised that completed testing of eCQMs under development should demonstrate reliability and validity in the acute care setting and should also be submitted to NQF for review and endorsement prior to inclusion in CMS quality programs.

A few commenters noted that providers and vendors likely would be encouraged to engage more in testing if additional time were available by, for example, delaying major program changes to a biennial timeframe.

A number of commenters also recommended that CMS create a public ''playbook'' outlining eCQM development and testing activities available for hospitals, as well as issuing standardized expectations and processes for hospitals engaging in testing, and doing so with more advanced notice. One commenter also noted that the legal concerns with release of patient detail files sometimes limits involvement, and thus encouraged CMS to explicitly clarify policies with regard to sharing PHI in a protected and legal manner for testing and development.

Question 7. A number of commenters responded to CMS' request for feedback on question (7)—Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching

quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches? A number of commenters expressed that hospitals and vendors would be interested in participating in pilots or models of alternative approaches to quality measurement. Several commenters provided suggestions on how to structure pilots, including developing a cross-section of participants, communications, and providing incentives for participants.

A few commenters expressed that hospitals and vendors would not want to participate in pilots because they would not want to divert resources necessary to pilot models that may never be incorporated into quality reporting, or expressed concern about the costs and resource tolls associated with participating.

One commenter specifically did not support research and pilot projects on the use of machine learning and natural language processing.

Question 8. A number of commenters responded to CMS' request for feedback on question (8)—What ways could CMS incentivize or reward innovative uses of health IT that could reduce costs for hospitals? Many commenters shared recommendations about incentives and rewards for innovative uses of health IT, including: (1) Providing an upside adjustment to the hospital APU or a larger increase in the Market Basket Increase for completing certain activities or demonstrating innovative uses of HIT; (2) offering ''bonus points'' for demonstrable innovative uses of health IT; (3) providing scoring bonuses to providers who report more than the required number of measures or who have accurate rates; (4) allowing ''bonus points'' for voluntary or pilot project participation; (5) providing physician providers with credit under the MIPS–QPP Improvement Activities or Advancing Care Information (now called Promoting Interoperability) performance categories for participating in eCQM-related workgroups or development and/or demonstrating innovative uses of HIT; (6) establishing technology 'challenges' to foster innovative developments in health IT; (7) relieving reporting burden; (8) providing hospitals with incentives to recover any IT software costs; (9) excluding measures that are not applicable for CAHs or offering other reporting options for hospitals with low patient volumes; and (10) providing free software to submit the eCQMs and future required measures.

Other commenters suggested that CMS provide standards, and perhaps incentives, for health IT vendors to standardize their practices, particularly with respect to the standardized reports commonly used for quality data and internal quality review. One commenter noted that currently, providers must pay extra and wait for reports to be developed for their EHR.

A few commenters suggested that CMS provide public acknowledgement of organizations who develop or participate in innovative uses of health IT, similar to The Joint Commission's Pioneers in Quality Award or Healthcare Information and Management Systems Society (HIMSS) Davies Award.

A number of commenters suggested that CMS allow providers to receive credit for meeting the eCQM reporting requirement in the Promoting Interoperability Programs, work with hospitals to identify areas of innovative use of health IT that align with the Meaningful Measures framework, and collaborate with federal partners to encourage health IT vendors to support hospitals in their efforts to use eCQMs and health IT to address the highest priority areas for quality measurement and improvement.

One commenter recommended that CMS reward providers and developers working on population health initiatives and require data integration with hospitals with access to adequate data, such as claims data at the patient level. Another commenter recommended that CMS reward the internal quality improvement programs and processes using health IT that already exist and are utilized by hospitals.

A few commenters suggested allowing hospitals to submit and develop quality measures that are meaningful to their patient populations, local needs, and interests, instead of focusing on measures addressing national healthcare quality priorities.

Question 9. A number of commenters responded to CMS' request for feedback on question (9)—What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs? A number of commenters provided suggestions specific to QualityNet, including: (1) Decreasing wait times for reaching the QualityNet helpdesk; (2) updating QualityNet to improve user-experience; (3) increasing QualityNet's capability to receive submissions and send reports; (4) providing more immediate and detailed error messages; and (5) allowing providers to upload encrypted QRDA I files to QualityNet.

One commenter suggested that CMS grant funding to encourage measure development. Some commenters suggested that CMS could increase efficiency of measure testing by: (1) Improving available testing resources; (2) developing a shared infrastructure to test eCQMs or providing a universal testing tool kit for health IT vendors; (3) providing reports that specifically identify how a hospital ''failed'' reporting on a measure; (4) providing immediate and detailed feedback on all errors; (5) encouraging participation in HL7 FHIR® Development Days and HL7 Connect-a-thons for testing capabilities of vendors; and (6) publicly releasing the criteria used to evaluate success or failure in reporting of eCQMs, along with releasing actual results for new measure development and testing.

Commenters' suggestions for improved guidance included: (1) Providing clearer documentation; (2) offering a single source of information and resource to ask questions related to eCQM reporting; (3) clarifying abstraction questions via QualityNet; (4) providing more avenues of communication with CMS; (5) identifying which tools stakeholders should use for which purposes; (6) providing resources geared toward quality improvement to staff and clinicians; (7) providing novice-level guidance on measure development and additional opportunities for engagement with experts; (8) creating a resource to allow stakeholders to share information such as best practices and codes used; (9) adding guidance related to the use of CQL and other newer standards; (10) creating an eCQM measure specification manual similar to the manual for chart-abstracted measures; (11) providing comparisons of how eCQM specifications change between years; and (12) identifying errors in past iterations when new eCQM measure specifications are released.

Some commenters' suggestions focused on improvements that could be made to measure development and measure specifications, including: (1) Simplifying the measure development tools and measure logic; (2) using a standard approach to capturing data elements; (3) exploring natural language processing to capture discrete data elements; (4) developing a standard for EHRs to help implement eCQM reporting; (5) including thresholds and goals for all measures; (6) defining data fields using the Core Measures Data Dictionary; (7) standardizing references to measure timeframes by referencing the reporting period as well as the

payment determination period when referring to measures; and (8) increasing the transparency of the eCQM calculation process by using open source evaluation codes.

Other commenters focused on how CMS could improve the submissions process, including: (1) Providing workflow documents and technical release notes earlier; (2) opening the portal for eCQM data submissions earlier; and (3) implementing a system through which CMS could pull documents from hospitals using a secure direct file transfer or application.

Some commenters suggested refining the reporting requirements for eCQMs, including: (1) Aligning the regulatory and reporting requirements of CMS quality programs; (2) offering flexibility to allow providers to select measures to submit from a pool of available measures in multiple forms; and (3) allowing more time to implement new and updated eCQMs.

Response: We thank all of the commenters for their feedback and suggestions. We will take them into account and consider commenters' views as we develop future policies regarding the potential future development and adoption of eCQMs generally and for future years of the Hospital IQR Program. We note that our solicitation of public comments is part of a larger effort to collect feedback on areas for improvement in the implementation of eCQMs under a variety of CMS programs. We also have been holding listening sessions with hospitals and health IT vendors about EHR and eCQM issues. We will share all these comments with the Office of the National Coordinator for Health Information Technology (ONC) and other partners.

10. Accounting for Social Risk Factors in the Hospital IQR Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38324 through 38326), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[339] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.[340] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress, which was required by the IMPACT Act of 2014, found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act of 2014, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38324), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[341] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[342] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS: To explore other factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged CMS to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

Specifically, in the FY 2018 IPPS/LTCH PPS proposed and final rules for the Hospital Inpatient Quality Reporting (IQR) Program, we invited and received public comment on: (1) Which social risk factors provide the most valuable information to stakeholders; (2) providing hospitals with confidential feedback reports containing stratified results for certain Hospital IQR Program measures, specifically the Pneumonia Readmission measure (NQF #0506) and the Pneumonia Mortality measure (NQF #0468); (3) a potential methodology for illuminating differences in outcomes rates among patient groups within a hospital that would also allow for a comparison of those differences, or

[339] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[340] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[341] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[342] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

disparities, across hospitals; (4) an alternative methodology that compares performance for patient subgroups across hospitals but does not provide information on within hospital disparities and any additional suggested methodologies for calculating stratified results by patient dual eligibility status; and (5) future public reporting of these same measures stratified by patient dual eligibility status on the *Hospital Compare* website (82 FR 38407). For the Hospital IQR Program in general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care (82 FR 38404). Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment (82 FR 38404).

As a next step, we are considering options to reduce health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We are considering implementing the two above-mentioned methods to promote health equity and improve healthcare quality for patients with social risk factors. The first method (the hospital-specific disparity method) would promote quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method would also allow for a comparison of those differences, or disparities, across hospitals, so hospitals could assess how well they are closing disparities gaps compared to other hospitals. The second methodological approach is complementary and would assess hospitals' outcome rates for subgroups of patients, such as dual eligible patients, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors.

We acknowledge the complexity of interpreting stratified outcome measures. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404 through 38409), due to this complexity, and prior to any future public reporting of stratified measure data, we plan to stratify the Pneumonia Readmission measure (NQF #0506) data by highlighting both hospital-specific disparities and readmission rates specific for dual-eligible beneficiaries across hospitals for dual-eligible patients in hospitals' confidential feedback reports beginning fall 2018. In FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38409), we explained that we believe the Pneumonia Readmission measure and the Pneumonia Mortality measure are appropriate first measures to stratify, because we currently publicly report the results of both measures for a large cohort of hospitals. In addition, both measures include a large number of admissions per hospital and therefore have sufficiently large sample sizes for most hospitals to support adequate reliability of stratified calculations. As a first step, in the interest of simplicity and to minimize confusion for hospitals, we are planning to provide confidential feedback reports for the Pneumonia Readmission measure only, using both methodologies.

For the future, we are considering: (1) Expanding our efforts to provide stratified data in hospital confidential feedback reports for other measures; (2) including other social risk factors beyond dual-eligible status in hospital confidential feedback reports; and (3) eventually, making stratified data publicly available on the *Hospital Compare* website, as mentioned in previous rules, to allow consumers and other stakeholders to view critical information about the care and outcomes of subgroups of patients with social risk factors. We believe the stratified results will provide hospitals with information that could illuminate disparities in care or outcome, which could subsequently be targeted through quality improvement efforts. We further believe that public display of this information could drive consumer choice and spark additional improvement efforts. A CMS contractor convened a TEP in the spring of 2018 to solicit feedback from stakeholders on approaches to consider for stratification for the Hospital IQR Program.[343] We anticipate receiving additional input from hospitals when they receive confidential feedback reports of the stratified results and will encourage stakeholders to submit comments during this process. We are also considering how these methodologies may be adapted to apply to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: Many commenters supported CMS' continued evaluation of social risk factors in quality measurement. Some commenters recommended that CMS consider both stratification and risk adjustment methodologies. A number of commenters made recommendations, including suggestions to: (1) Work with measure developers to determine the most accurate way to include and account for social risk factors within each measure; (2) study social risk factors at a program level; (3) stratify social risk factors at the individual measure level because it would provide a more detailed picture of the costs and quality administered among facilities, noting that when data is publicly reported and assigned to an individual clinician, service line, or facility, it is important to be clear about who is responsible for the reported outcomes and/or performance rates through detailed attribution model specifications; and (4) risk-adjust measures for patient SES status when appropriate, but until risk-adjusted measures are available, publicly report stratified measure performance rates on the *Hospital Compare* website.

Response: We thank commenters for their feedback. Risk adjustment and stratification are two distinct ways of accounting for the importance of social risk factors on quality measures and payment programs. The goal of SES risk adjustment is to take into account the increased risk of poor outcomes for patients with social risk factors.

The Assistant Secretary for Planning and Evaluation (ASPE), as required by the IMPACT Act of 2014, studied the impact of social risk factors, including socioeconomic status, on quality and payment measures used in nine Medicare value-based purchasing programs. The report discussed several strategies to account for social risk factors in these programs.[344] It laid out

[343] This TEP, the Hospital Outcome Measurement for Patients with Social Risk Factors, is still ongoing. TEP members will be participating in several teleconference meetings from May through September 2018. For more information on TEPs, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panels.html#0510.*

[344] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

potential merits and limitations of risk adjusting for socioeconomic status in quality measurement. Some drawbacks noted included that adjusting measures for social risks could potentially create a lower standard of care for patients with social risk factors, perpetuate disparities, and disincentivize quality improvement for these vulnerable patients. The report did not specifically express a position in favor of or against risk adjustment for SES at the patient level, but did recommend evaluating measures individually to determine if risk adjustment for socioeconomic status is warranted on a conceptual and empirical basis. Likewise, following the SES two-year trial period, the National Quality Forum (NQF) recommended evaluating the appropriateness of SES risk adjustment on a measure-by-measure basis. We note, however, that, in their final report following the conclusion of the SES two-year trial period, the NQF proposed the presentation of stratified results, as we have described in this final rule, as a potential strategy for consideration.[345] [346]

We will continue to work with measure developers to determine the most accurate way to include and account for social risk factors within each measure, including exploring stratification of social risk factors at the individual measure level. We intend to continue to study social risk factors at a program level and evaluate the effect of social risk factors on outcomes measures and quality programs. As to the commenter's request for detailed technical specifications demonstrating a measure's attribution model, such specifications are available on QualityNet for the readmission measures and include information about the attributed hospital.[347]

With regard to commenters' suggestion that we risk-adjust measures for patient SES status when appropriate, but until risk-adjusted measures are available, publicly report stratified measure performance rates on the *Hospital Compare* website, we note that such adjustment is not appropriate in all cases. Recent reports from ASPE, National Academies of Sciences, Engineering, and Medicine (NAM), and NQF do not specifically make recommendations in favor of or against risk adjustment for SES at the patient level.[348] [349] [350] However, they do propose to report stratified results, as we described in the FY 2019 IPPS/LTCH PPS proposed rule and this final rules as a potential strategy to consider.

We will continue to explore multiple options to account for the effect of social risk factors on quality measures and in quality programs.

Comment: Many commenters supported considering factors beyond dual eligibility when accounting for the impact of social risk factors on quality measurement. Several commenters referred CMS to recent reports by ASPE and the National Academies of Sciences, Engineering, and Medicine (NAM). Commenters identified a number of SES and SDS risk factors for consideration, including: (1) Educational attainment; (2) literacy; (3) health literacy; (4) home language and English language proficiency; (5) availability of primary care and physical therapy; (6) access to medications; (7) marital status and whether one lives alone; employment status; (8) income; (9) race and ethnicity; (10) nativity; (11) payor; (12) insurance product; (13) Medicaid beneficiary status; (14) neighborhood deprivation (including the percent of households under the federal poverty level, crime rates); (15) housing insecurity; (16) distance traveled (derived from zip code); (17) availability of transportation; (18) access to appropriate food; and (19) access to supportive services (including availability of a caretaker).

Response: We appreciate commenters' suggestions for additional social risk factors to consider. Consistent with the findings contained in the ASPE and NAM reports, we will explore opportunities for ways to account for additional social risk factors in the future as we continue to engage with stakeholders and determine the availability and feasibility of accounting for appropriate social risk factors, including the availability of potential data sources, that might influence quality outcomes measures such as readmissions.

Comment: Many commenters supported the use of the first proposed method (hospital-specific disparity method) in stratifying measure results. One commenter asserted the data provided under the hospital-specific disparity method would be valuable in communities that have unique patient populations. Another commenter ''cautiously supported'' the hospital-specific disparity method, but noted it would be critical to first ensure that the methodologies work accurately and reliably, and to establish social risk categorization standards that would be used across all quality reporting programs for hospitals to decrease the reporting burden.

Several commenters supported the use of the second proposed method. One commenter requested that CMS utilize the second proposed method as soon as feasibly possible because they wanted comparison data available to drive improvement. One commenter did not support the second proposed approach because it believed patients would choose to avoid facilities that provide care to large volumes of patients with social risk factors. The commenter noted that considering how the data would be presented on the *Hospital Compare* website would be critical in preventing this kind of bias from being introduced.

Response: We thank the commenters for their support and recommendations with respect to the two disparity measures described in the FY 2019 IPPS/LTCH PPS proposed rule.

We will continue to explore a variety of methodological approaches to ensure we produce accurate and reliable disparity results. In addition, we will work to align approaches to risk stratification across measures to minimize burden on providers. We would like to highlight that the proposed disparity measures would not place any additional burden on hospitals. The two proposed methods focus on dual eligibility as the social risk factor. We use this indicator as a proxy of low income and assets. It has the advantage of being readily available in claims data and therefore does not

[345] National Quality Forum (NQF). ''Evaluation of the NQF Trial Period for Risk Adjustment for Social Risk Factors.'' Available at: *https://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx.*

[346] National Quality Forum (NQF). ''A Roadmap for Promoting Health Equity and Eliminating Disparities: The Four I's for Health Equity.'' Available at: *https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

[347] *2018 Condition-Specific Measures Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Readmission Measures.* Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

[348] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Accounting for Social Risk Factors in Medicare Payment.'' Jan. 2017. Available at: *http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx.*

[349] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[350] National Quality Forum (NQF). ''Evaluation of the NQF Trial Period for Risk Adjustment for Social Risk Factors.'' Available at: *https://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx.*

impose any additional data collection burden.

As to the commenter's concern that the second disparity method might lead patients to avoid hospitals with a large proportion of patients with social risk factors, we note that the goal of the second method (the group-specific outcome rate method) is not to provide patients with information on hospitals' volume of patients with social risk factors, but rather to provide specific outcome rates for patients with social risk factors at the individual hospital level (for example readmission rates for dual eligible patients). Preliminary results have shown that both hospitals caring for a low and a high proportion of patients with social risk factors can perform well or poorly on this measure.

We will also continue to evaluate what may be the best method or methods of publicly displaying stratified outcome measures and disparity information to ensure the public's understanding of the data.

Comment: Many commenters expressly supported CMS' plans to provide stratified Pneumonia Readmissions measure data in confidential, hospital-specific feedback reports because it would allow hospitals adequate time to understand their performance on stratified measures, evaluate the accuracy and impact of the stratification, identify any issues around disparity in the care provided, and inform internal quality improvement efforts. A few commenters requested that CMS allow hospitals sufficient time to review and analyze stratified rates prior to any public reporting, with one commenter requesting receipt of at least two years of confidential feedback reports prior to any public reporting. Commenters also requested that CMS ensure that hospitals have sufficient information to interpret the stratified measures results by providing national and regional benchmarks for the stratifications and detailed specifications of how measures are stratified so that hospitals can replicate this information during their ongoing performance monitoring. A number of commenters suggested that CMS solicit additional feedback from stakeholders before publicly reporting stratified quality data to ensure that data would be reported in a manner that is accurate, reliable, and understandable to patients. A few commenters requested that CMS propose specific measures for stratification through rulemaking.

Response: We thank commenters for their feedback and will take it into consideration. As described in the preamble of this final rule, we are planning to provide confidential reports to hospitals for the Pneumonia Readmission measure (NQF #0506), stratified by patient dual-eligible status. The confidential hospital-specific reports will be provided for hospitals to preview from August 24 through September 24, 2018. During this confidential preview period, we will also provide educational materials to ensure hospitals have sufficient information to understand and interpret their disparity results. Hospital specific reports will include national and regional benchmarks for the two disparity methods. Finally, a technical report will provide detailed specifications on the two disparity methods.

We agree with commenters that the confidential reporting period will allow hospitals to understand the stratified measure data prior to any future public reporting. We acknowledge commenters' concerns about having sufficient time to review and analyze stratified measure data prior to any public reporting on that data. We have not yet determined any future plans with respect to publicly reporting stratified data, and intend to continue to engage with hospitals and relevant stakeholders about their experiences with and recommendations for the stratification of measure data and to ensure the reliability of such data before proposing to publicly display stratified measure data in the future. Any proposal to display stratified quality measure data on the *Hospital Compare* website would be made through future rulemaking.

Comment: A few commenters recommended that CMS consider or incorporate the findings or recommendations from the reports from the APSE, NAM, and a TEP that the NQF convened, per HHS/CMS request. A few commenters suggested that CMS begin incorporating other social risk factors found to be important while also continuing to monitor, study, and refine these efforts over time. Other commenters encouraged the empirical testing and use of neighborhood-level adjustment (that is, integrating patient data with information about contextual factors that influence health outcomes at the community or population level) where the data are available, in order to assess the impact of these adjustments on local provider performance metrics. The commenters noted that based on the results of these tests, CMS and other agencies would be able to prioritize the national collection of data that are most essential for valid risk adjustment methodologies.

A few commenters recommended that CMS work with vendors to collect SES and SDS variables through their EHRs, potentially through the implementation of demonstration projects. The commenters noted that the collected data elements could be used to supplement the claims data already captured by CMS to greatly improve the measure's risk adjustment methodology.

A number of commenters requested that CMS be more transparent during efforts to address social risk factors and to continuously seek stakeholder input, including measure stewards, in order to achieve the goals of attaining health equity for all beneficiaries while also minimizing unintended consequences, as well as to ensure the adjustment approach keeps up with the evolving measurement science around accounting for social risk factors. One commenter requested that CMS provide a work plan and timeline, as well as increase opportunities for collaboration with Medicare Advantage and Medicaid health plans.

Response: We thank commenters for their recommendations. Our work to date on measure stratification and risk-adjustment has been informed by the reports by ASPE, NAM, and the NQF, as recommended by the commenters, as well as feedback directly received from stakeholders such as through the rulemaking public comment process. This includes closely tracking recommendations about social risk factor variables for use and potential methodologies. We are committed to continuing to expand the range of social risk factors incorporated into measure stratification based on the recommendations of the above groups. Consistent with the findings of the ASPE and NAM reports, we will explore accounting for such factors in the future as we continue to engage stakeholders and determine the availability of appropriate community factors that might influence quality outcome measures such as readmission. We will also consider the use of social risk factors obtained through EHRs while balancing concerns about undue data collection and reporting burden on providers.

We also thank commenters for their support on our approach to engaging stakeholders in our stratification methodology development process. As noted, a TEP was convened to receive feedback on the two methods we developed to illuminate disparities. The TEP members came from diverse perspectives and backgrounds, including clinicians, hospitals, purchasers, consumers, and experts in quality improvement and health care disparities. CMS contractors also regularly consulted with an advisory

working group of five patients, family caregivers, and consumer advocates. The working group meetings addressed key issues surrounding the development of the two disparity methods, including the conceptual goal of the methods, their complementarity, and how best to report results for the disparity methods. We also held a webinar to inform hospital and consumer organizations about the two disparity methods and the confidential preview period taking place for the Pneumonia Readmission measure and dual eligibility. We will continue to explore multiple options and will elicit further feedback from stakeholders before determining an approach for public reporting.

Comment: A few commenters did not support the inclusion and modification of risk factors related to socioeconomic status for determining provider reimbursement for Medicare services in all the IPPS programs. One commenter expressed concerns that this approach would not address the underlying disparities that are often associated with poor health outcomes by masking potential disparities or minimizing incentives to improve the outcomes for disadvantaged populations. Specifically, the commenter asserted this approach would create perverse incentives for poor performers to continue with the status quo and for high performers to retreat from their efforts to address disparities in high socioeconomic status populations. Another commenter expressed reservations about adjusting hospitals' performance rates using social factors because it would obscure disparities. Specifically, the commenter disagreed with using the risk-adjustment model because it excludes some important clinical risk factors that cannot be obtained through administrative data, which could have an impact on stratified comparison of disparities if the missing risk factors have different incidence rates across the subgroups. One commenter did not support the use of stratification to account for social risk factors in inpatient quality programs, and recommended the use of risk-adjustment methodology instead, particularly for financial incentive programs.

Response: We thank the commenters for their feedback and appreciate their concerns. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38324 through 38326) and in this final rule, we affirm our commitment to improving beneficiary outcomes, reducing health disparities, and our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care. Our efforts, to date, have been undertaken in response to the feedback we have received from stakeholders and based on the findings contained in reports by ASPE, NAM and NQF. These efforts include closely tracking recommendations about social risk factors variables for use and potential methodologies. We continue to believe that it is important to consider options to address equity and disparity in our quality programs, which is why we will continue working with the public and key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: One commenter, who generally did not support stratification, expressed concern that many hospital quality measures, such as hospital-acquired infection measures, would have limited sample sizes at the individual hospital level, and that this could ultimately limit the statistical reliability of reporting quality measures by race or other sociodemographic characteristics. The commenter also expressed its belief that the quality of race and ethnicity data within the Medicare program is known to be suboptimal for many races outside of white and black, including American Indian/Alaska Native and other races, and recommended that CMS develop a proposal to improve the collection of race and ethnicity data, or propose how to promote public transparency using data that are of mixed quality, before reporting such data publicly.

Response: We thank the commenter for the feedback. We agree with the commenter's concerns about the impact of small samples sizes on the reliability of stratified quality measure results. Furthermore, small sample sizes may be especially challenging for measure stratification because some hospitals may have few patients with social risk factors. Therefore, under the first method (the hospital-specific disparity method), disparities would be reported only for hospitals with at least 25 patients and 10 patients for each sub-group. The second method (the group-specific outcome rate method) would use a cut-off of at least 25 patients for potential public reporting. We note the overall sample size of 25 patients is consistent with the quality outcome measures currently implemented.

We agree with the commenter's concern that race and ethnicity data for Medicare beneficiaries are currently not consistently captured in claims. We believe that examining racial and ethnic disparities in outcomes within hospitals is important since race and ethnicity have been shown to be associated with health care quality, and will continue to examine how best to improve the collection of such data.

We thank the commenters for their views and will take them into consideration as we continue our work on these issues.

11. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the description above. In accordance with the statute, the FY 2019 payment determination will begin the fifth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.org/*. The annual update of electronic clinical quality measure (eCQM) specifications and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*. Hospitals must register and submit quality data through the secure portion of the QualityNet

website. There are safeguards in place in accordance with the HIPAA Security Rule to protect patient information submitted through this website.

b. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20496 through 20497), we did not propose any changes to these procedural requirements.

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20497), we did not propose any changes to the data submission requirements for chart-abstracted measures.

d. Reporting and Submission Requirements for eCQMs

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20497 through 20498), we clarified measure logic used in eCQM development; proposed to extend previously established eCQM reporting and submission requirements for the CY 2019 reporting period/FY 2021 payment determination; and proposed to require hospitals to use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination. These matters are discussed in detail below.

(1) Clarification of the Measure Logic Used in eCQM Development—Transition to Clinical Quality Language (CQL)

Although the measure logic, which represents the lines of logic that comprise a single AND/OR statement composing each population, used in eCQM development is not generally specified through notice and comment rulemaking, in the proposed rule (83 FR 20497), we notified the public that all eCQM specifications published in CY 2018 for the CY 2019 reporting period/FY 2021 payment determination and subsequent years (beginning with the Annual Update that was published in May 2018 and for implementation in CY 2019) will use the Clinical Quality Language (CQL). CQL is a Health Level Seven (HL7) International standard [351] and aims to unify the expression of logic for eCQMs and Clinical Decision Support (CDS).[352] CQL provides the ability to better express logic defining measure populations to improve the accuracy and clarity of eCQMs. In addition, CQL is a high-level authoring language that is intended to be human-readable and allows measure developers to express data criteria and represent it in a manner suitable for language processing.

Prior to CY 2017, eCQM logic was defined by ''Quality Data Model (QDM) Logic,'' an information model that defines relationships between patients and clinical concepts in a standardized format to enable electronic quality performance measurement.[353] We believe that compared to CQL, QDM logic is more complex and difficult to compute. QDM logic limits a measure developer's ability to express the type of comparisons needed to truly evaluate outcomes of care because QDM logic cannot request patient results that indicate outcomes and assess improvement over time; in contrast, CQL's mathematical expression logic allows this type of comparison over time and is independent of the model.[354] Moreover, CQL: (1) Offers improved expressivity; (2) is more precise/unambiguous; (3) can share logic between measures; (4) allows for measure logic to be shared with CDS tools; (5) can be used with multiple information data models (for example, QDM, Fast Healthcare Interoperability Resources (FHIR) [355]); and (6) simplifies calculation engine implementation.[356] CQL replaces the logic expressions defined in the QDM, and QDM (beginning with v5.3 [357]) includes only the conceptual model for defining the data elements.

Measure developers successfully tested CQL for expressing eCQMs from 2016 through 2017.[358] Based on the results, the Measure Authoring Tool (MAT) [359] and the Bonnie [360] tool have been updated to use CQL. We believe replacing the measure logic used in eCQM development from QDM to CQL will enable measure developers to engineer more precise, more interoperable measures that interface with CDS tools, which in turn, will result in availability of better measures of patient outcomes for use in the Hospital IQR Program and other CMS programs. We note that utilization of CQL for the eCQMs currently available for reporting in the Hospital IQR Program measure set would not affect the intent of the measure, the numerator, denominator, or any measure exclusions or exceptions.

For additional information about the CQL transition and its impact on eCQM development, we refer readers to the eCQI Resource Center website at: *https://ecqi.healthit.gov/cql*.

Comment: Several commenters expressed support for the transition to

[351] Additional details about HL7 are available at: *http://www.hl7.org/about/index.cfm?ref=nav*. In addition, readers may learn more under ''Where can I find more information on CQL'' on the eCQI Resource Center website at: *https://ecqi.healthit.gov/cql*.

[352] Additional details about CDS is available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/cds*.

[353] Additional details about QDM Logic are available at: *https://ecqi.healthit.gov/qdm*.

[354] Additional details about How CQL Logic is Different from QDM Logic are available at: *https://ecqi.healthit.gov/qdm/qdm-Qs%26As#QualityDataModelQDMforusewithClinicalQualityLanguageCQL*.

[355] FHIR, developed by Health Level Seven International (HL7), is designed to enable information exchange to support the provision of healthcare in a wide variety of settings. The specification builds on and adapts modern, widely used RESTful practices to enable the provision of integrated healthcare across a wide range of teams and organizations. Additional information available at: *http://hl7.org/fhir/overview-dev.html*.

[356] Additional details on the benefits of Clinical Quality Language (CQL) are available at: *https://ecqi.healthit.gov/system/files/Benefits_of_CQL_May2017-508.pdf*.

[357] Additional details about QDM v5.3 available at: *https://ecqi.healthit.gov/qdm/qdm-news-0/now-available-quality-data-model-qdm-v53*.

[358] Additional details about the Timeline for the Transition to CQL are available at: *https://ecqi.healthit.gov/cql*.

[359] The Measure Authoring Tool (MAT) is a web-based tool that allows measure developers to author electronic Clinical Quality Measures (eCQMs). Using the tool, authors create Clinical Quality Language (CQL) expressions, which have the conceptual portion of the Quality Data Model (QDM) as their foundation (*https://www.emeasuretool.cms.gov/*).

[360] Bonnie is a tool for testing electronic clinical quality measures (eCQMs) designed to support streamlined and efficient pre-testing of eCQMs, particularly those used in the CMS quality programs (*https://bonnie.healthit.gov/*).

CQL measure logic because it will provide improved specificity, precision, clarity, usability, and value to eCQMs to better align with the clinical intent of the measures. One commenter noted that CQL will provide earlier, longer draft periods that could enable hospitals and vendors to perform more testing and provide more feedback. Another commenter specifically suggested use of Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) as part of CQL.

Response: We thank commenters for their support. We will consider use of HL7 FHIR as part of CQL in the future.

Comment: A few commenters recommended monitoring the transition to the CQL measure logic.

Response: We will continue to monitor the experiences of hospitals and vendors as they transition to CQL to proactively address any challenges that might arise.

Comment: A few commenters acknowledged the benefits of CQL but expressed concern that the transition to CQL for the CY 2019 reporting period did not provide enough time to implement the complex changes necessary without increasing burden. One commenter suggested a 24 month delay in requiring implementation.

Response: We agree with the commenter that CQL has many benefits including improved expressivity, precision, and interoperability to facilitate sharing logic between measures and with CDS tools. While we try to be as proactive as possible in providing lead time changes to the Hospital IQR Program, we believe that the CY 2019 reporting period is the appropriate time to transition to CQL because we believe these benefits should be actualized as soon as practicable. We will continue working to provide hospitals with the education, tools, and resources necessary to help seamlessly implement necessary changes while minimizing increase in burden. Further, we will also consider the issues associated with new software, workflow changes, training, et cetera as we continue to improve our education and outreach efforts.

(2) Reporting and Submission Requirements for eCQMs for the CY 2019 Reporting Period/FY 2021 Payment Determination

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38361), we finalized eCQM reporting and submission requirements such that hospitals are required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20498), in alignment with the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), we proposed to extend the same eCQM reporting and submission requirements, such that hospitals would be required to report one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2019 reporting period/FY 2021 payment determination. We believe continuing the same eCQM reporting and submission requirements is appropriate because doing so continues to offer hospitals reporting flexibility and does not increase the information collection burden on data submitters, allowing them to shift resources to support system upgrades, data mapping, and staff training related to eCQM documentation and reporting. We also refer readers to section VIII.D.9. of the preamble of this final rule where similar proposals are discussed for the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs).

Comment: Many commenters supported the proposed eCQM reporting requirements for the CY 2019 reporting period/FY 2021 payment determination, such that hospitals would be required to select and submit one calendar quarter of data for 4 of the available eCQMs. Several comments expressed appreciation for the continued flexibility and consistency CMS has provided for eCQM reporting requirements, acknowledging the operational challenges in implementing eCQM reporting. These commenters noted that maintaining the reporting requirements will make the transition to 2015 Edition CEHRT more seamless, because the upgrade process will make it even more difficult for hospitals to electronically report eCQMs for more than one calendar quarter, especially if they are not able to complete the upgrade to the new CEHRT until the end of the year. One commenter also noted that allowing hospitals to self-select one quarter of data allows for adjustments to assure that the data on which CMS relies for long-term decision-making is accurate.

Response: We thank the commenters for their support.

Comment: Some commenters suggested the proposed eCQM reporting requirements for the CY 2019 reporting period/FY 2021 payment determination should also be finalized for the CY 2020 reporting/FY 2022 payment determination, consistent with the Promoting Interoperability Program proposal.

Response: With respect to extending these reporting requirements for the CY 2020 reporting/FY 2022 payment determination, we will continue to monitor and assess the progress of hospitals implementing eCQM requirements and engage in discussions with hospitals regarding their experiences as we consider policies related to eCQM reporting in future rulemaking. We are committed to staying in alignment with the Promoting Interoperability Program's eCQM-related policies to the greatest extent feasible, and we believe the commenter may have misinterpreted the Promoting Interoperability Program's proposal with regard to eCQM reporting requirements. In alignment with the Hospital IQR Program, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20539), the Promoting Interoperability Program proposed, ''[f]or CY 2019, for eligible hospitals and CAHs that report CQMs electronically, we are proposing the reporting period for the Medicare and Medicaid Promoting Interoperability Programs would be one, self-selected calendar quarter of CY 2019 data.'' Neither the Promoting Interoperability Program, nor the Hospital IQR Program, proposed eCQM reporting requirements for the CY 2020 reporting/FY 2022 payment determination in the FY 2019 IPPS/LTCH PPS proposed rule. We note that the Promoting Interoperability Program had additional proposals related to requirements for attesting to measures and objectives, which may have different requirements and different reporting periods than for reporting CQMs electronically and we refer readers to section VIII.D. of the preamble of this final rule for more information.

Comment: One commenter suggested that eCQMs should be implemented at a faster rate and that the commenter would prefer to report all chart-abstracted measures in an eCQM version because eCQMs are resulting in significant cost-reductions associated with not having to chart-abstract.

Response: We thank the commenter for their suggestion. It is one of our goals to expand EHR-based quality reporting in the Hospital IQR Program using more meaningful measures, which we believe will ultimately reduce burden on hospitals as compared with chart-abstracted data reporting and improve patient outcomes by providing more robust data to support quality improvement efforts. We intend to introduce additional eCQMs into the program as eCQMs that support our program goals become available, but we

want to ensure that we proceed slowly and incrementally to enable hospitals enough time to update systems and workflows in the least burdensome manner possible.

Comment: A few commenters did not support the proposed eCQM reporting requirements for the CY 2019 reporting period/FY 2021 payment determination, such that hospitals would be required to select and submit one calendar quarter of data for 4 of the available eCQMs. Specifically, one commenter recommended that: (1) CMS decrease the number of eCQMs required to be reported to CMS in 2018; and (2) CMS identify one or two specific eCQMs on which it would like all hospitals to report rather than for measures to be removed in subsequent reporting years.

Response: We thank the commenters for their views and suggestions but we believe continuing the same eCQM reporting and submission requirements is appropriate because doing so continues to offer hospitals reporting flexibility and does not increase the information collection burden on data submitters, allowing them to shift resources to support system upgrades, data mapping, and staff training related to eCQM documentation and reporting. Specifically, we do not believe decreasing the number of eCQMs required to be reported is necessary because for the CY 2017 reporting period and the CY 2018 reporting period, over 90 percent of IPPS hospitals successfully reported one quarter of data for 4 eCQMs. As to the suggestion to identify one or two specific eCQMs on which all hospitals would be required to report instead of removing measures for future program years, at this time we believe it is a greater priority to offer flexibility to hospitals in selecting eCQMs that are most relevant to their individual patient populations and quality improvement efforts as they upgrade EHR systems, map data elements, and modify workflows to improve EHR-based quality reporting. We will take this suggestion into consideration and continue to monitor and assess the progress of hospitals implementing eCQM reporting requirements, as well as whether there is a continued need to remove any other eCQMs from the measure set. We will also continue to engage in discussions with hospitals and health IT vendors regarding their experiences as we consider policies related to eCQM reporting in future rulemaking.

Comment: One commenter suggested aligning all Hospital IQR and Promoting Interoperability Program requirements, including requiring one consecutive 90-day reporting period, to eliminate confusion among health care providers.

Response: While we try to align eCQM reporting requirements for the Hospital IQR and Promoting Interoperability Programs to the greatest extent feasible (we refer readers to section VIII.D.9. of the preamble of this final rule where we are finalizing the same eCQM reporting requirements in the Hospital IQR Program as the Promoting Interoperability Programs for the CY 2019 reporting period/FY 2021 payment determination), we are not able to align the Hospital IQR Program with the Promoting Interoperability Program's requirements for attesting to measures and objectives, which allow for one consecutive 90-day reporting period. We note that the Hospital IQR Program can only use quality and cost measures and does not allow for an attestation option.

Comment: One commenter expressed concern that the transition to CQL and the proposed removal of the seven eCQMs would result in considerable burden required to map the necessary data elements from the EHR for 4 eCQMs and some vendors are not properly equipped to collect and transmit such data through the CMS QualityNet secure portal.

Response: We appreciate the commenter's concern that the transition to CQL and removal of the seven eCQMs may result in additional burden required to map the necessary data elements from the EHR for 4 eCQMs, however, hospitals have been successfully reporting one calendar quarter of data for 4 eCQMs and we believe that reporting will become progressively easier with every year of experience, and maintaining these requirements provides continuity, minimizing provider confusion about changing requirements.

After consideration of the public comments we received, we are finalizing our proposal to extend the eCQM reporting and submission requirements previously finalized for the CY 2018 reporting period/FY 2020 payment determination, such that hospitals would be required to report one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2019 reporting period/FY 2021 payment determination as proposed. We also refer readers to section VIII.D.9. of the preamble of this final rule where we are finalizing similar policy under the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs).

(3) Changes to the Certification Requirements for eCQM Reporting Beginning With the CY 2019 Reporting Period/FY 2021 Payment Determination

In the FY 2018 IPPS/LTCH PPS final rule, we finalized a policy to allow flexibility for hospitals to use the 2014 Edition certification criteria, the 2015 Edition certification criteria, or a combination of both for the CY 2018 reporting period/FY 2020 payment determination only (82 FR 38388). This was a change to the policy previously finalized in the FY 2017 IPPS/LTCH PPS final rule that required hospitals to use the 2015 Edition certification criteria for CEHRT for the CY 2018 reporting period/FY 2020 payment determination and subsequent years (81 FR 57171).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20498), to align with the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), for the Hospital IQR Program we proposed to require hospitals to use only the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination. We refer readers to section VIII.D.3. of the preamble of this final rule in which the Medicare and Medicaid Promoting Interoperability Programs discuss more broadly the reasons for and benefits of requiring hospitals to use the 2015 Edition certification criteria for CEHRT, beginning with the CY 2019 reporting period/FY 2021 payment determination. There are certain functionalities in the 2015 Edition of certified electronic health record technology that were not available in the 2014 Edition that we believe will increase interoperability and the flow of information between providers and patients.

In addition, as we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38387 through 38388), specifically as to eCQM reporting, the 2015 Edition includes updates to standards for structured data capture as well as data elements in the common clinical data set which can be captured in a structured format. We continue to believe the use of relevant, up-to-date, standards-based structured data capture with an EHR certified to the 2015 Edition supports electronic clinical quality measurement.

The 2015 Edition certification criteria (that make up CEHRT) within the certification testing process includes features that are designed to improve the functionality and quality of eCQM

data.[361] Specifically, systems must demonstrate they can import and allow a user to export one or more QRDA files. This allows systems to share files and extract data for reporting into another system or send to another system. In addition, testing coverage is much more robust; all measures have >80 percent of test pathways tested in the test bundle with most >95 percent. In addition, the 2015 Edition includes a revised requirement that products must be able to export data from one patient, a set of patients, or a subset of patients, which is responsive to health care provider feedback that their data is unable to carry over from a previous EHR. The 2014 Edition did not include a requirement that the vendor allow the provider to export the data themselves. In the 2015 Edition, the provider has the autonomy to export data themselves without intervention by their vendor, resulting in increased interoperability and data exchange between the two Editions. This includes a new function that supports increased patient access to their health information through email transmission. The increased interoperability in this requirement provides patients more control of their health data to inform the decisions that they make regarding their health.

The 2015 Edition certification criteria for CEHRT also includes optional certification criteria and program specific testing which can also support electronic clinical quality reporting. The filter criteria ensure a product can filter an electronic file based on demographics like sex or race, based on provider or site characteristics like TIN/NPI, and based on a diagnosis or problem. The testing for this function checks that patients are appropriately aggregated and calculated for this new function which supports flexibility, specificity, and more robust analysis of eCQM data. Finally, the 2015 Edition provides optional testing to CMS requirements for reporting, such as form and manner specifications and implementation guides. For these reasons, in the proposed rule, we proposed to require hospitals to use the 2015 Edition certification criteria for CEHRT when reporting eCQMs beginning with the CY 2019 reporting period/FY 2021 payment determination.

We note that the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized the requirement that hospitals use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination (80 FR 62873 through 62875), such that hospitals participating in both the Hospital IQR Program and the Medicare and Medicaid Promoting Interoperability Programs already would be required to use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination.

Comment: Many commenters supported the required use of 2015 Edition of CEHRT because it use enhances interoperability, increases implementation efficiency, shortens product development time, eases provider system integration, addresses health disparities by providing more robust demographic data collection on social determinants of health, includes application programming interfaces (APIs) for consumer access, and promotes a new streamlined approach to privacy and security. For these reasons, commenters believed the benefits outweigh any upgrade costs. Commenters noted that requiring the 2015 Edition CEHRT will help to simplify the Promoting Interoperability Program and eliminate confusion around different objective and measure sets available for reporting. In addition, commenters asserted the 2015 Edition CEHRT will provide patients more control of their health data to inform the decisions that they make regarding their health, helping patients participate as full partners in their care.

Several commenters also believed that a majority of health IT vendors have successfully completed, or are in the process of completing, their certification(s) under the 2015 Edition CEHRT Criteria, and it would significantly and unfairly penalize the diligence of these parties by any delay in order to accommodate those companies who have not complied with the 2015 Edition CEHRT criteria by now.

Response: We thank commenters for their support.

Comment: One commenter urged that, as soon as possible, CMS and ONC ensure that the U.S. Core Data for Interoperability (USCDI) captures more of the patient's full health care record at any given facility, which can then be linked to application programming interfaces (APIs) such as FHIR, enabling even greater functionality of EHRs.

Response: We thank the commenter for the suggestion, and we will consult with ONC regarding interoperability and linking EHRs to APIs, or operating system tools used by developers of software applications. As discussed in section VIII.A.11.d.(1) above, FHIR, or Fast Healthcare Interoperability Resources, is a standards framework developed by Health Level Seven International (HL7) and is designed to enable information exchange to support the provision of healthcare in a wide variety of settings.[362] We will continue to explore this and other opportunities to improve functionality for future years of the Hospital IQR Program.

Comment: A few commenters supported the required use of the 2015 Edition of CEHRT, but recommended CMS delay the requirement until the CY 2020 reporting period/FY 2022 payment determination or allow flexibility for 6 months to a year for implementation. Although most commenters did not anticipate significant labor would be required from providers to implement the new functionalities required, some commenters recommended that CMS grant Extraordinary Circumstances Exceptions (ECEs) to hospitals that are unable to migrate to the 2015 Edition due to vendor backlogs in updating their technology.

Response: We note that, as described above, in both the Hospital IQR and Promoting Interoperability Programs, we have previously delayed requiring the use of the 2015 Edition CEHRT, and do not believe that transition to the 2015 Edition certification criteria for CEHRT for the CY 2019 reporting period will materially impact the percentage of hospitals able to successfully report eCQM data, particularly in light of our change to previously finalized policy to allow flexibility for hospitals to use the 2014 Edition, 2015 Edition, or a combination of both for the CY 2018 reporting period/FY 2020 payment determination. Consistent with the observations of several commenters, we believe a majority of health IT vendors have successfully completed, or are in the process of completing, their certification(s) under the 2015 Criteria, and that the CY 2019 reporting period/FY 2021 payment determination is the appropriate time to require the transition to the 2015 Edition.

With regard to commenters' suggestion that hospitals unable to migrate to the 2015 Edition due to health IT vendor backlogs in updating

[361] For CEHRT definition, we refer readers to 42 CFR 495.4. For additional details about the updates to the 2015 Edition, we refer readers to ONC's Common Clinical Data Set resource, available at: *https://www.healthit.gov/sites/default/files/commonclinicaldataset_ml_11-4-15.pdf.*

[362] FHIR, developed by Health Level Seven International (HL7), is designed to enable information exchange to support the provision of healthcare in a wide variety of settings. The specification builds on and adapts modern, widely used RESTful practices to enable the provision of integrated healthcare across a wide range of teams and organizations. Additional information available at: *http://hl7.org/fhir/overview-dev.html.*

their technology be granted an Extraordinary Circumstances Exception (ECE), we note that if a hospital finds it is unable to meet the eCQM submission deadline or other submission requirements, the hospital should review our criteria for an eCQM-related ECE (81 FR 57182) and consider submitting an ECE request by the ECE request deadline. Our current policy allows hospitals to utilize the existing ECE form to request an exception from the Hospital IQR Program's eCQM reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting (81 FR 57182). Such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification) (80 FR 49695 and 49713). ECE requests for the Hospital IQR Program are considered on a case-by-case basis (81 FR 57182). We will assess the hospital's request on a case-by-case basis to determine if an exception is merited. Therefore, our decision whether or not to grant an ECE will be based on the specific circumstances of the hospital. For additional information about eCQM-related ECE requests, we refer readers to the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775554109*.

Comment: Although commenters acknowledged the 2015 Edition of CEHRT includes important updates to facilitate the exchange of data, many commenters did not support the required use of 2015 Edition of CEHRT because of the costs to hospitals and encouraged CMS to continue to allow hospitals to use the 2014 Edition of CEHRT. In particular, several commenters expressed concern about the ability of rural and solo/small group providers to upgrade EHR systems because they struggle to ensure products are triaged, fully tested, and implemented, with staff trained and workflow adjustments validated to ensure safe, effective, and efficient implementation and use. Some commenters suggested flexible approaches that allow clinicians to incorporate technology into their unique clinical workflows, to mitigate data access and functionality issues that might be unique to their practice, and to use EHRs in a manner that more directly responds to their patients' needs and aligns with their clinical workflow. One commenter noted a recent search of the Certified Health IT Product List shows that there are 338 products currently certified to the 2015 Edition. Of these, most are limited modules for providers and specialties or are limited to specific functionalities, such as a patient portal. The commenter noted, in comparison, there are more than 2,400 EHR products still certified to the 2014 Edition.

Response: Although we acknowledge that facilitating quality improvement for rural and small hospitals present unique challenges and is a high priority under the Meaningful Measures Initiative, we believe the increased interoperability and the flow of information between providers and patients resulting from use of the 2015 Edition justifies the costs of implementation. As stated above, there are certain functionalities in the 2015 Edition that were not available in the 2014 Edition, including features that are designed to improve the functionality and quality of eCQM data. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38387 through 38388), specifically as to eCQM reporting, the 2015 Edition includes updates to standards for structured data capture as well as data elements in the common clinical data set which can be captured in a structured format. We continue to believe the use of relevant, up-to-date, standards-based structured data capture with an EHR certified to the 2015 Edition supports electronic clinical quality measurement.

With respect to the commenter's observation that the number of products currently certified to the 2015 Edition are limited as compared to the number of products available certified to the 2014 Edition, we expect that as more hospitals begin to use the 2015 Edition, the number of products included in the Certified Health IT Product List [363] will quickly multiply. We believe our policy to require use of the 2015 Edition for the CY 2019 reporting period/FY 2021 payment determination is likely to expedite the development of these products.

Comment: One commenter requested CMS update a hyperlink in the proposed rule at 83 FR 20498, footnote 330.

Response: We have updated the hyperlink in the footnote above. We also corrected several other hyperlinks in the proposed rule in a correction notice published in the **Federal Register** (83 FR 28603 through 28604).

Comment: Several commenters requested clarification about whether hospitals are required to use 2015 Edition CEHRT for the full calendar year, or for a 90-day reporting period. A few commenters suggested CMS make the reporting period for all programs that require the use of 2015 Edition CEHRT be 90 days for the CY 2019 reporting period, noting that some CMS programs still require the use of 2015 Edition CEHRT for an entire year. One commenter asked CMS to clarify the date on which this must be certified and recommended that date correspond with the beginning of the chosen reporting period.

Response: Hospitals are not required to have their EHRs certified to the 2015 Edition CEHRT standards for the full calendar year; certification should be obtained prior to the end of the eCQM reporting period to meet program requirements (for example, before December 31, 2019 for the CY 2019 reporting period).

With regard to commenters' suggestion that CMS make the reporting period for all programs that require the use of 2015 Edition CEHRT be 90 days for the CY 2019 reporting period, we are committed to the Hospital IQR and Promoting Interoperability Programs' eCQM-related policies staying in alignment to the greatest extent feasible. We refer readers to sections VIII.A.11.d.(2) and VIII.D.9. of the preamble of this final rule where we are finalizing eCQM reporting requirements in both the Hospital IQR Program and the Promoting Interoperability Programs, which will bring them into greater alignment for the CY 2019 reporting period/FY 2021 payment determination, including with regard to the number of eCQMs (4 measures), the number of calendar quarters of data (one calendar quarter of data), and which Edition of CEHRT to use (2015 Edition) for eCQM reporting. However, we are not able to align the Hospital IQR Program with the Promoting Interoperability Program's requirements for attesting to measures and objectives, which allow for one consecutive 90-day reporting period. We refer readers to section VIII.D.4. of the preamble of this final rule for more information on those requirements. We note that the Hospital IQR Program is limited to measures appropriate for the measurement of quality of care and does not allow for an attestation option.

Comment: One commenter sought guidance on whether new measures will be made a part of the certification pathway, and, if so, whether there is

[363] The Certified Health IT Product List is a listing of health IT products, tested and reviewed by the Office of the National Coordinator for Health IT. We refer readers to: *https://chpl.healthit.gov/*.

sufficient time to fold those new requirements into an update to the 2015 Edition.

Response: With respect to the commenter's request for clarification about the certification pathway, we note that CMS does not establish certification processes; we adopt reporting requirements based on standards set by ONC. We will share with ONC the commenter's recommendation to incorporate new measure requirements into an update to the 2015 Edition certification criteria.

Comment: A few commenters recommended that CMS monitor the transition to the 2015 Edition of CEHRT.

Response: We will continue to monitor the experiences of hospitals and health IT vendors as they transition to the 2015 Edition of CEHRT. We will continue to assess the progress of hospitals implementing certification requirements and engage in discussions with hospitals and health IT vendors regarding their experiences as we consider certification policies related to eCQM reporting in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to require hospitals to use the 2015 Edition certification criteria for CEHRT when reporting eCQMs beginning with the CY 2019 reporting period/FY 2021 payment determination as proposed.

e. Electronic Submission Deadlines

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR Program and the Medicare Promoting Interoperability Program (previously known as the Medicare EHR Incentive Program). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we established eCQM submission deadlines for the Hospital IQR Program. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20498 through 20499), we did not propose any changes to the eCQM submission deadlines.

f. Sampling and Case Thresholds

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20499), we did not propose any changes to our sampling and case threshold policies.

g. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at: *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), we finalized refinements to the three questions of the Pain Management measure in the HCAHPS Survey (now referred to as the Communication About Pain measure). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20499), we did not propose any changes to the HCAHPS Survey administration and submission requirements. However, we refer readers to the CY 2019 OPPS/ASC proposed rule (available at: *https://www.regulations.gov/document?D=CMS-2018-0078-0001*), where we have proposed to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. We note that we did not propose any changes to the HCAHPS Survey administration and submission requirements.

h. Data Submission Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20499), we did not propose any changes to those requirements; however, we refer readers to sections VIII.A.5.a. and VIII.A.5.b.(1) of the preamble of this final rule, in which we discuss finalizing our proposal to remove the Hospital Survey on Patient Safety Culture and Safe Surgery Checklist Use measures as proposed. As a result, no structural measures will remain in the Hospital IQR Program and hospitals will not be required to submit any data for structural measures for the CY 2019 reporting period/FY 2021 payment determination or subsequent years.

i. Data Submission and Reporting Requirements for HAI Measures Reported via NHSN

For details on the data submission and reporting requirements for HAI measures reported via the CDC's NHSN website, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.org/*.

While we did not propose any changes to these requirements in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20499), we refer readers to section VIII.A.5.b.(2)(b) of the preamble of this final rule, in which we discuss finalizing our proposal to remove these measures from the Hospital IQR Program with modification to delay removal for one year. As a result, hospitals will not be required to submit any data for HAI measures via NHSN for the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination or subsequent years. We note that the five HAI measures will remain in the HAC Reduction and Hospital VBP Programs and will continue to be reported via NHSN. We further note that the HCP measure remains in the Hospital IQR Program and will continue to be reported via NHSN. We refer readers to section IV.J. of the preamble of this final rule for more information about how the NHSN HAI measures will be collected and validated under the HAC Reduction Program. We also refer readers to section IV.I.2.c.(2) of the preamble of this final rule where we discuss retaining the NHSN HAI measures in the Hospital VBP Program.

12. Validation of Hospital IQR Program Data

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years. The FY 2013 IPPS/LTCH PPS final rule also contains a comprehensive summary of all procedures finalized in previous years

that are still in effect. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712) for detailed information on the modifications to these processes finalized for the FY 2016, FY 2017, and FY 2018 payment determinations and subsequent years. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20499), we did not propose any changes to the existing processes for validation of either eCQM or chart-abstracted measure data.

b. Existing Processes for Validation of Hospital IQR Program eCQM Data

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), we finalized updates to the validation procedures in order to incorporate a process for validating eCQM data for the FY 2020 payment determination and subsequent years (starting with the validation of CY 2017 eCQM data that would impact FY 2020 payment determinations). We also refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), in which we finalized several proposals regarding processes and procedures for validation of CY 2017 eCQM data for the FY 2020 payment determination, validation of CY 2018 eCQM data for the FY 2021 payment determination, and eCQM data validation for subsequent years. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20499), we did not propose any changes to the existing processes for validation of Hospital IQR Program eCQM data.

c. Existing Process for Chart-Abstracted Measures Validation

In the FY 2015 IPPS/LTCH PPS final rule, we stated that we rely on hospitals to request an educational review or appeal cases to identify any potential CDAC or CMS errors (79 FR 50260). We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38403) for more details on the formalized Educational Review Process for Chart-Abstracted Measures Validation. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20499 through 20500), we did not propose any changes to the validation of chart-abstracted measures, including the educational review process.

While we did not propose any changes to our previously established validation procedures in the proposed rule (83 FR 20499 through 20500), we refer readers to: (1) Section VIII.A.5.b.(8) of the preamble of this final rule, in which we discuss finalizing our proposal to remove three clinical process of care measures (IMM–2, ED–1, and VTE–6) beginning with the CY 2019 reporting period/FY 2021 payment determination, and one clinical process of care measure (ED–2) beginning with the CY 2020 reporting period/FY 2022 payment determination; and (2) section VIII.A.5.b.(2)(b) of the preamble of this final rule, in which we discuss finalizing our proposals to remove five Hospital-Acquired Infection (HAI) chart-abstracted measures from the Hospital IQR Program with modification, such that removal would be delayed by one year beginning with the CY 2020 reporting period/FY 2022 payment determination. As a result: Two chart-abstracted clinical process of care measures (ED–2 and Sepsis measures) and five HAI chart-abstracted measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI measures) will remain in the Hospital IQR Program that will require validation for the FY 2021 and 2022 payment determinations; and only one chart-abstracted clinical process of care measure (Sepsis measure) will remain in the program that would require validation for the FY 2023 payment determination and subsequent years. As our validation processes remain unchanged, we will continue to sample up to 8 cases for each selected chart-abstracted clinical process of care measure. We plan to evaluate our existing validation scoring methodology to ensure that there will be no significant impact to the estimated reliability (ER) of Hospital IQR Program chart-abstracted data validation activities despite any measure removals.

In addition, the CY 2020 reporting period/FY 2022 payment determination will be the last year for which validation will occur under the Hospital IQR Program with respect to the CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI measures because, as discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we are finalizing our proposal to remove these measures with modification to delay removal for one year. Beyond the FY 2022 payment determination, validation of those measures will occur under the HAC Reduction Program, as further discussed in section IV.J.4.e. of the preamble of this final rule.

13. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20500), we did not propose any changes to the DACA requirements.

14. Public Display Requirements

We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* website at: *http://www.medicare.gov/hospitalcompare*, but on occasion are reported on other CMS websites such as: *https://data.medicare.gov*.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20500), we did not propose any changes to the public display requirements. However, we note that in section VIII.A.10. of the preamble of this final rule, we discuss our efforts to provide stratified data by patient dual eligibility status in hospital confidential feedback reports and considerations to make stratified data publicly available on the *Hospital Compare* website in the future.

15. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20500), we did not propose any changes to the reconsideration and appeals procedures.

16. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE

policy. We also refer readers to the QualityNet website at: *http://www.QualityNet.org/* for our current requirements for submission of a request for an exception. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20500), we did not propose any changes to the ECE policy.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

Section 1866(k) of the Act establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program strives to put patients first by ensuring they, along with their clinicians, are empowered to make decisions about their own health care using data-driven insights that are increasingly aligned with meaningful quality measures. To this end, we support technology that reduces burden and allows clinicians to focus on providing high quality health care to their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when participating in CMS programs. In combination with other efforts across the Department of Health and Human Services (HSS), we believe the PCHQR Program incentivizes PCHs to improve their health care quality and value, while giving patients the tools and information needed to make the best decisions.

For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20500 through 20510), we proposed a number of new policies for the PCHQR Program. We developed these proposals after conducting an overall review of the program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of the preambles of the proposed rule and this final rule. The proposals reflect our efforts to ensure that the PCHQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing the following: (1) The reporting burden associated with submitting/reporting quality measures; (2) the burden associated with complying with other programmatic requirements; and/or (3) the burden associated with compliance with other Federal and/or State regulations (if applicable). In addition, we aim to minimize beneficiary confusion by reducing duplicative reporting and streamlining the process of analyzing publicly reported quality measures data. The proposals also reflect our efforts to improve the usefulness of the data that we publicly report in the PCHQR Program, which are guided by the following two goals: (1) To improve the usefulness of CMS quality program data by providing providers with adequate measure information from one program; and (2) to improve consumer understanding of the data publicly reported on *Hospital Compare* or another website by eliminating the reporting of duplicative measure data in more than one program that applies to the same provider setting.

2. Factors for Removal and Retention of PCHQR Program Measures

a. Background and Current Measure Removal Factors

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), we adopted policies for measure retention and removal. We generally retain measures from the previous year's PCHQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. We adopted the following measure removal factors [364] for the PCHQR Program, which are based on factors adopted for the Hospital IQR Program (80 FR 49641 through 49642):

- Factor 1. Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (that is, ''topped-out'' measures): Statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤ 0.10;
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- Factor 7. It is not feasible to implement the measure specifications.

For the purposes of considering measures for removal from the program, we consider a measure to be ''topped-out'' if there is statistically indistinguishable performance at the 75th and 90th percentiles and the truncated coefficient of variation is less than or equal to 0.10.

b. Measure Retention Factors

We have also recognized that there are times when measures may meet some of the outlined criteria for removal from the program, but continue to bring value to the program. Therefore, we adopted the following factors for consideration in determining whether to retain a measure in the PCHQR Program, which also are based on factors established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure aligns with other CMS and HHS policy goals;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move PCHs towards reporting electronic measures.

c. New Measure Removal Factor

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20501 through 20502), we proposed to adopt an additional factor to consider when evaluating potential measures for

[364] We note that we previously referred to these factors as ''criteria'' (for example, 81 FR 57182 through 57183); we now use the term ''factors'' in order to align the PCHQR Program terminology with the terminology we use in other CMS quality reporting and pay for performance value-based purchasing programs.

removal from the PCHQR measure set: Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program.

As we discussed in section I.A.2. of the preambles of the proposed rule and this final rule, with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the PCHQR measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the cost to CMS associated with the program oversight of the measure including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other Federal and/or State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools we need to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the PCHQR Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the PCHQR Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the PCHQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We invited public comment on our proposal to adopt an additional measure removal factor, ''the costs associated with a measure outweigh the benefit of its continued use in the program,'' beginning with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

Comment: One commenter supported the newly proposed measure removal criteria, noting that the broad application of this criterion helps to streamline CMS' quality programs. The commenter encouraged CMS to not remove measures simply because a previously finalized measure was too difficult to implement, thereby creating a gap in the measure set, but rather attempt to identify ways to gather the appropriate data by different means.

Response: We thank the commenter for its support. We note that it is never our intent to remove measures solely based on ease of implementation. Further, implementation concerns are something we take into account when proposing to adopt a measure. As discussed in section VIII.B.2.b of the preamble of this final rule, the removal of measures under the newly proposed Factor 8 will serve to balance the costs of ongoing maintenance, reporting/collection, and public reporting with the benefit associated with the reporting of that data. We intend to be transparent in our assessment of measures under this measure removal factor. As described above, there are various considerations of costs and benefits, direct and indirect, financial and otherwise, that we will evaluate in applying removal Factor 8, and we will take into consideration the perspectives of multiple stakeholders. We believe costs include costs to stakeholders such as patients, caregivers, providers, CMS, and other entities. Additionally, we note that the benefits we will consider center around benefits to patients and consumers as the primary beneficiaries of our quality reporting and value-based payment programs.

Comment: One commenter requested clarification regarding whose benefit is being considered when evaluating whether ''the costs associated with the measure outweigh the benefit of its continued use in the program.'' The commenter noted that there is considerable focus on the cost of the measure, but a transparent process must be put in place to weigh the patient benefit against the cost of the measure. The commenter appreciated that CMS will propose removing measures based on Factor 8 on a case-by-case basis and strongly encouraged CMS to survey patients to understand if they feel the measures are beneficial.

Response: We understand the importance of transparency in our processes, and we reaffirm that we prioritize the impact on patients when assessing the adoption and/or retention of quality metrics in our quality reporting programs. We reiterate that we intend to evaluate each measure on a case-by-case basis, and to balance the costs with the benefits to a variety of stakeholders. These stakeholders include, but are not limited to, patients and their families or caregivers, providers, the healthcare research community, healthcare payers, and patient and family advocates. Because for each measure the relative benefit to each stakeholder may vary, we believe that the benefits to be evaluated for each measure are specific to the measure and the original rationale for including the measure in the program.

Comment: One commenter did not support the proposed adoption and use of Factor 8 in any of CMS' programs, due to lack of transparency around assessment criteria. The commenter noted that the assessment of value must be as transparent as possible with a clear prioritization of the needs of patients/consumers. The commenter urged CMS to develop a standardized evaluation and scoring system with significant multi-stakeholder input, to ensure that Factor 8 appropriately balances the needs of all health care stakeholders.

Response: We thank the commenter for its feedback. We intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient

and family advocates, providers, provider associations, healthcare researchers, data vendors, and other stakeholders with insight into the benefits and costs (financial and otherwise), and will continue to do so in the future when proposing measures for adoption or retention in the PCHQR Program. Further, preliminary stakeholder input on data collection and reporting burden was instrumental in the derivation of the newly proposed removal factor. As discussed in section VIII.B.2.b. of the preamble of this final rule, above, the removal of measures under Factor 8 will function as a balancing test between the cost of ongoing maintenance, reporting/collection, and public reporting against the benefit associated with reporting that data. We note that we intend to assess the costs and benefits to all program stakeholders.

After consideration of the public comments we received, we are finalizing our proposal to adopt the new measure removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program,'' beginning with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

3. Retention and Removal of Previously Finalized Quality Measures for PCHs Beginning With the FY 2021 Program Year

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we finalized five quality measures for the FY 2014 program year and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50847), we finalized one new quality measure for the FY 2015 program year and subsequent years and 12 new quality measures for the FY 2016 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280), we finalized one new quality measure for the FY 2017 program year and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49719), we finalized three new Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) measures for the FY 2018 program year and subsequent years, and finalized the removal of six previously finalized measures for fourth quarter (Q4) 2015 discharges and subsequent years. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57183 through 57184), for the FY 2019 program year and subsequent years, we finalized one additional quality measure and updated the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure. In the FY 2018 IPPS/LTCH PPS final rule, we finalized four new quality measures (82 FR 38414 through 38420) for the FY 2020 program year and subsequent years, and finalized the removal of three previously finalized measures (82 FR 38412 through 38414).

b. Removal of Measures From the PCHQR Program Beginning With the FY 2021 Program Year

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20502 through 20503), we proposed to remove four web-based, structural measures from the PCHQR Program beginning with the FY 2021 program year because they are topped-out:

- Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382);
- Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384);
- Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389).

We also proposed (83 FR 20503) to apply the newly proposed measure removal factor to two National Healthcare Safety Network (NHSN) chart-abstracted measures and, if that factor is finalized, to remove both measures from the PCHQR Program beginning with the FY 2021 program year because we have concluded that the costs associated with these measures outweigh the benefit of their continued use in the program. The measures we proposed to remove on this basis are as follows:

- NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138); and
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139).

(1) Removal of Web-Based Structural Measures

We proposed to remove the following web-based, structural measures beginning with the FY 2021 program year because they are topped-out: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389). We first adopted these measures for the FY 2016 program year in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50841 through 50844). We refer readers to that final rule for a detailed discussion of the measures.

Based on an analysis of data from January 1, 2015 through December 31, 2016, we have determined that these three measures meet our topped-out criteria. This analysis evaluated data sets and calculated the 5th, 10th, 25th, 50th, 75th, 90th, and 95th percentiles of national facility performance for each measure. For measures where higher values indicate better performance, the percent relative difference (PRD) between the 75th and 90th percentiles were obtained by taking their absolute difference divided by the average of their values and multiplying the result by 100. To calculate the truncated coefficient of variation (TCV), the lowest 5 percent and the highest 5 percent of hospital rates were discarded before calculating the mean and standard deviation for each measure.

The following criteria were applied to the results:

- For measures ranging from 0–100 percent, with 100 percent being best, national measure data for the 75th and 90th percentiles have a relative difference of <=5 percent, or for measures ranging from 0–100 percent, with 100 percent being the best, performance achieved by the median hospital is >=95 percent, and national measure data have a truncated coefficient of variation <=0.10.
- For measures ranging from 0–100 percent, with 0 percent being best, national measure data for the complement of the 10th and 25th percentiles have a relative difference of <=5 percent, or for measures ranging from 0–100 percent, with 0 percent being best, national measure data for the median hospital is <=5 percent, or for other measures with a low number indicating good performance, national measure data for the 10th and 25th percentiles have a relative difference of <=5 percent, and national measure data have a truncated coefficient of variation <=0.10.

The results for 2015 and 2016 are set out in the tables below.

TOPPED-OUT ANALYSIS RESULTS FOR PCHQR MEASURES (2015)

Measure	Mean	Median	75th percentile	90th percentile	Relative difference (%)	Topped-out
PCH–14	98.4	99.6	100	100	0	Yes.
PCH–16	92.5	92.3	93.1	94.3	1.2	Yes.
PCH–17	99.7	100	100	100	0	Yes.
PCH–18	98.9	99.4	100	100	0	Yes.

TOPPED-OUT ANALYSIS RESULTS FOR PCHQR MEASURES (2016)

Measure	Mean	Median	75th percentile	90th percentile	Relative difference (%)	Topped-out
PCH–14	99.8	100	100	100	0	Yes.
PCH–16	96.8	96.8	97.3	97.4	0.1	Yes.
PCH–17	99.4	99.6	100	100	0	Yes.
PCH–18	99.0	100	100	100	0	Yes.

Based on this analysis, we have concluded that these four measures are topped-out and, as discussed below, we believe that collecting PCH data on these measures does not further program goals.

We also believe that continuing to collect PCH data on these measures does not further program goals of improving quality, given that performance on the measures is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. We believe that these measures also do not meet the criteria for retention of an otherwise topped-out measure, as they: Do not align with the HHS and CMS policy goal to focus our measure set on outcome measures; do not align with measures used in other CMS programs; and do not support our efforts to develop electronic clinical quality measure reporting for PCHs. If we determine at a subsequent point in the future that PCH adherence to the aforementioned HHS and CMS policy goals, the aforementioned program efforts, and the standard of care established by the measure has unacceptably declined, we may propose to readopt these measures in future rulemaking.

We invited public comment on our proposal to remove these four measures from the PCHQR Program beginning with the FY 2021 program year.

Comment: A few commenters supported the proposed removal of the four web-based, structural measures. The commenters noted that topped-out measures provide little in the way of useful quality differentiation and cannot, by definition, incentivize meaningful quality improvement. Moreover, the removal of these measures will help to reduce the administrative burden of the PCHQR Program.

Response: We thank the commenters for their support.

Comment: One commenter did not support the proposed removal of the Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18) measure from the PCHQR Program. The commenter indicated that this measure is currently included in the CQMC Oncology measure set. As part of a joint effort to implement meaningful measures that will promote accountability and drive improvement across stakeholders, the commenter recommended retaining the measure in the program until the CQMC is able to jointly re-evaluate the measure's inclusion in the Oncology measure set.

Response: We appreciate the commenter's input. However, as demonstrated by the data provided in the tables displaying the 2015 and 2016 results for this measure above, this measure is statistically topped-out. Consequently, continued reporting of the measure provides limited opportunity for continuing quality improvement, while continuing to incur reporting burden to care providers. We believe that the removal of this measure from the PCHQR Program aligns with one of the governing tenets of the Core Quality Measure Collaborative (CQMC): *Promotion of measurement that is evidence-based and generates valuable information for quality improvement.*[365] We note that topped out status is an example of a situation where Factor 1 could be used for measure removal, but is not a prerequisite to its use. Further, the PCHQR Program is not bound to removing measures solely because they are topped out, however, in this scenario, the data for this measure demonstrate that meaningful distinctions and improvements in performance can no longer be made.

Comment: One commenter indicated that the removal of Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384) is unique from the other web-based, structural measures proposed for removal, in that it was validated and endorsed by its measure developer and NQF as a paired measure with the Oncology: Plan of Care for Pain—Medical and Radiation Oncology (NQF #0383). Given that the collection of data for NQF #0384 will continue to be necessary in order to obtain the eligible patient population for NQF #0383, the commenter recommends that these measures either be included or excluded from the PCHQR Program as a pair.

Response: We thank the commenter for its recommendation. While we recognize the pairing of these two measures in the PCHQR Program, the Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384) measure remains statistically topped out, while its companion measure, Oncology: Plan of Care for Pain (NQF #0383) is not. We further note that the Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384) measure is duplicative as a plan of care for pain measure. We therefore believe that the Oncology: Plan of Care for Pain—Medical and Radiation Oncology (NQF #0383) measure suffices to assess cancer patient pain treatment. Further, we believe the Oncology: Plan of Care for Pain measure will continue to

[365] Centers for Medicare and Medicaid Services: ''*Core Measures.*'' Accessed on: June 26, 2018. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.*

incentivize continued quality improvement through public reporting in the PCHQR Program. As the commenter noted, the submission of data does not change, which will allow CMS to monitor for unintended consequences related to the removal of the measure.

After consideration of the public comments we received, we are finalizing the removal of the following web-based, structural measures beginning with the FY 2021 program year: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389).

(2) Removal of National Healthcare Safety Network (NHSN) Chart-Abstracted Measures

We proposed to remove two measures from the PCHQR Program beginning with the FY 2021 program year if the measure removal factor ''the costs associated with the measure outweigh the benefit of its continued use in the program,'' proposed for adoption in section VIII.B.2.c. of the preamble of the proposed rule, is finalized because we have concluded that the costs associated with these measures outweigh the benefit of their continued use in the PCHQR Program. These measures are: (1) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138); and (2) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139). We first adopted the CAUTI and CLABSI measures for the FY 2014 program year in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53557 through 53559); we refer readers to this final rule for a detailed discussion of the measures.

As discussed in section I.A.2. of the preambles of the proposed rule and this final rule, above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We continue to believe the CAUTI and CLABSI measures provide important data for patients and hospitals in making decisions about care and informing quality improvement efforts. However, we believe that removing these measures in the PCHQR Program will reduce program costs and complexities associated with the use of these data by patients in decision-making. We believe the costs, coupled with the high technical and administrative burden on PCHs, associated with collecting and reporting this measure data outweigh the benefits to continued use in the program. Further, we note that it has become difficult to publicly report these measures due to the low volume of data produced and reported by the small number of facilities participating in the PCHQR Program and the corresponding lack of an appropriate methodology to publicly report this data. Consequently, we have been unable to offer beneficiaries the benefit of pertinent information on how these measures assess hospital-acquired infections and impact patient safety.

As we state in section I.A.2. of the preambles of the proposed rule and this final rule, we strive to ensure that patients are empowered to make decisions about their health care by using information from data-driven insights. We continue to believe that these measures evaluate important aspects of patient safety. However, as discussed earlier, we believe the high costs, reporting burden, and difficulties associated with publicly reporting this data for use by patients in making decisions about their care outweigh the benefit associated with the measures' continued use in the PCHQR Program. Therefore, in the proposed rule we stated that if our proposal to adopt the new measure removal factor described in section VIII.B.2.c. of the preambles of the proposed rule and this final rule is finalized as proposed, we proposed that under that factor, we would remove the CAUTI and CLABSI measures from the PCHQR Program beginning with the FY 2021 program year.

We invited public comment on our proposal to remove these two measures from the PCHQR Program beginning with the FY 2021 program year. We are conducting additional data analyses to assess measure performance based on new information provided by the CDC. In acknowledgement of the importance of these measures in assessing patient safety in the PCH setting, we want to be cautious to not prematurely remove measures from the PCHQR Program. As such, we wish to evaluate these data for trends that link positive improvements (*i.e.,* a decrease in the reporting burden and/or cost, and/or demonstrated feasibility for public reporting) to these measures. We note that the data recently submitted by the CDC were not available at the time we proposed the removal of these measures from the PCHQR Program. Moreover, we will reconcile the comments received on the proposed removal of the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) measures in a future 2018 final rule, most likely in the CY 2019 OPPS/ASC final rule targeted for release no later than November 2018. We also note that the deferral to the CY 2019 OPPS/ASC final rule will not affect PCH data submission because we proposed to end data collection beginning in CY 2019.

4. New Quality Measures Beginning With the FY 2021 Program Year

a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278), we indicated that we take many principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In section I.A.2. of the preambles of the proposed rule and this final rule, we also discuss our Meaningful Measures Initiative, and its relation to how we will assess and select quality measures for the PCHQR Program.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Section 1866(k)(3)(B) of the Act provides an exception under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

Using these principles for measure selection in the PCHQR Program, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503 through 20506), we proposed one new measure, described below.

b. New Quality Measure Beginning With the FY 2021 Program Year: 30-Day Unplanned Readmissions for Cancer Patients (NQF #3188)

In an effort to expand the PCHQR Program measure set to include

measures that are less burdensome to report to CMS, but provide valuable information for beneficiaries, we proposed to adopt the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) for the FY 2021 program year and subsequent years. This measure meets the requirement under section 1866(k)(3)(A) of the Act that measures specified for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act (currently the NQF). This measure aligns with recent initiatives to incorporate more outcome measures in quality reporting programs. This measure also aligns with the Promote Effective Communication and Coordination of Care domain of our Meaningful Measures Initiative,[366] and would fill an existing gap area of risk-adjusted readmission measures in the PCHQR Program.

In compliance with section 1890A(a)(2) of the Act, the proposed measure was included on a publicly available document entitled ''2017 Measures under Consideration Spreadsheet,'' [367] a list of quality and efficiency measures under consideration for use in various Medicare programs, and was reviewed by the Measures Application Partnership (MAP) Hospital Workgroup.

(1) Background

Cancer is the second leading cause of death in the United States, with nearly 600,000 cancer-related deaths expected this year. It is estimated roughly 1.7 million Americans will be diagnosed with cancer in 2016, and the number of Americans living with a cancer diagnosis reached nearly 14.5 million in 2014.[368] Cancer disproportionately affects older Americans, with 86 percent of all cancers diagnosed in people 50 years of age and older.[369] It is now the leading cause of death among adults age 40 to 79 years nationwide, and the leading cause of death among all adults in 21 States.[370] Oncology care contributes greatly to Medicare spending, and accounted for an estimated $125 billion in health care spending in 2010.[371] This figure is projected to rise to between $173 billion and $207 billion by 2020.[372] A 2012 audit from the U.S. Government Accountability Office (GAO) revealed that the estimated differences in Medicare payment between PCHs and local PPS teaching hospitals varied greatly across the PCHs; with the largest payment difference at 90.9 percent and the smallest payment difference at 6.7 percent. Overall, the difference between the amount Medicare paid PCHs and the estimated amount Medicare would have paid PPS hospitals for treating comparable cancer patients suggests that Medicare would have saved approximately $166 million in 2012.[373] Further, GAO calculated that, if PCHs were paid for outpatient services in the same way as PPS teaching hospitals, Medicare would have saved approximately $303 million in 2012.[374]

Given the current and projected increases in cancer prevalence and costs of care, it is essential that health care providers look for opportunities to lower the costs of cancer care. Reducing readmissions after hospital discharge has been proposed as an effective means of lowering health care costs and improving the outcomes of care.[375] Research suggests that between 9 percent and 48 percent of all hospital readmissions are preventable, owing to inadequate treatment during the patient's original admission or after discharge.[376] It is estimated that all-cause, unplanned readmissions cost the Medicare program $17.4 billion in 2004.[377] Unnecessary hospital readmissions also negatively impact cancer patients by compromising their quality of life, placing them at risk for health-acquired infections, and increasing the costs of their care.[378] Furthermore, unplanned readmissions during treatment can delay treatment completion and, potentially, worsen patient prognosis.[379]

Preventing these readmissions improves the quality of care for cancer patients. Existing studies in cancer patients have largely focused on postoperative readmissions, reporting readmission rates of between 6.5 percent and 25 percent.[380] One study noted that surgical cancer patients were most often readmitted for surgical complications, while nonsurgical patients were typically readmitted for the same condition treated during the index admission.[381] Together, these studies suggest that certain readmissions in cancer patients are preventable and should be routinely measured for purposes of quality improvement and accountability.

(2) Overview of Measure

Readmission rates have been developed for pneumonia, acute myocardial infarction, and heart failure. However, the development of validated readmission rates for cancer patients has lagged. In 2012, the Comprehensive Cancer Center Consortium for Quality Improvement, or C4QI (a group of 18 academic medical centers that collaborate to measure and improve the quality of cancer care in their centers), began development of a cancer-specific unplanned readmissions measure: 30-Day Unplanned Readmissions for Cancer Patients. This measure incorporates the unique clinical characteristics of oncology patients and results in readmission rates that more accurately reflect the quality of cancer care delivery, when compared with broader readmissions measures. Likewise, this measure addresses gaps in existing readmissions measures (such as the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) stewarded by CMS) related to the evaluation of hospital readmissions associated cancer patients. The 30-Day Unplanned Readmissions for Cancer Patients measure can be used by PCHs to inform their quality improvement efforts. Through adoption in the PCHQR Program, it can increase transparency around the quality of care delivered to patients with cancer.

The 30-Day Unplanned Readmissions for Cancer Patients measure is NQF-

[366] Overview of the CMS Meaningful Measures Initiative available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html.*

[367] 2017 Spreadsheet of Measures Under Consideration. Available at: *http://www.qualityforum.org/Show_Content.aspx?id=30279.*

[368] NIH's National Cancer Institute Statistics. Available at: *https://www.cancer.gov/about-cancer/understanding/statistics.*

[369] American Cancer Society. Cancer facts and figures 2016. 2016. Available at: *http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf.*

[370] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2016. *CA Cancer J Clin.* 2016;66(1):7–30.

[371] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010–2020. *J Natl Cancer Inst.* 2011;103(2):117–128.

[372] Ibid.

[373] U.S. Government Accountability Office. ''Medicare Payments to Certain Cancer Hospitals.'' Accessed on March 9, 2018. Available at: *https://www.gao.gov/modules/ereport/handler.php?1=1&path=/ereport/GAO-15-404SP/data_center_savings/Health/19._Medicare_Payments_to_Certain_Cancer_Hospitals.*

[374] Ibid.

[375] Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. *Arch Intern Med.* 2000;160(8):1074–108.

[376] Ibid.

[377] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med.* 2009;360(14):1418–1428.

[378] Ibid.

[379] Ibid.

[380] Rochefort MM, Tomlinson JS. Unexpected readmissions after major cancer surgery: an evaluation of readmissions as a quality-of-care indicator. *Surg Oncol Clin N Am.* 2012;21(3):397–405, viii.

[381] Ji H, Abushomar H, Chen XK, Qian C, Gerson D. All-cause readmission to acute care for cancer patients. *Healthc Q.* 2012;15(3):14–16.

endorsed (NQF #3188). The MAP Hospital Workgroup reviewed this measure on December 14, 2017 and supported the inclusion of this measure in the PCHQR Program. The MAP acknowledged that this measure is fully developed and tested and further noted this measure fills a current gap in the PCHQR Program by addressing unplanned readmissions of cancer patients.[382] [383]

The proposed readmission measure fits within the Promote Effective Communication and Coordination of Care measurement domain (categorical area), and specifically applies to the associated clinical topic of ''Admissions and Readmissions to Hospitals'' of our Meaningful Measures Initiative. This measure is intended to assess the rate of unplanned readmissions among cancer patients treated at PCHs and to support improved care delivery and quality of life for this patient population. By providing an accurate and comprehensive assessment of unplanned readmissions within 30 days of discharge, PCHs can better identify and address preventable readmissions. Through routine monitoring of these performance data by PCHs, this measure can be used to improve patient outcomes and quality of care.

(3) Data Sources

The proposed 30-Day Unplanned Readmissions for Cancer Patients measure is claims-based. Therefore, PCHs would not be required to submit any new data for purposes of reporting this measure. We proposed that we would calculate this measure on a yearly basis using Medicare administrative claims data. Specifically, we proposed that the data collection period for each program year would span from July 1 of the year, three years prior to the program year to June 30 of the year, two years prior to the program year. Therefore, for the FY 2021 program year, we would calculate measure rates using PCH claims data from October 1, 2018 through September 30, 2019.

We assessed the measure's reliability, and set a minimum case count of 50 index admissions (25 per subset) per PCH. There were 3,502 facilities [384] included in the 100 split-half simulations for CY 2013 through CY 2015. In our reliability assessment, we examined the reliability of the measure by testing the hypothesis that the mean S–B statistic from each year was greater than 0.5. The S–B statistic allows us to project what the reliability would be if the entire sample were used instead of the split sample.

Overall, the consistent calculations between the two data randomly-split subsets for each period provided evidence that performance variations between PCHs were attributable to hospital-level factors, rather than patient-level factors. Regarding the validity of this measure, global sensitivity and specificity scores of 0.879 and 0.896, respectively, confirmed the validity of the Type of Admission/Visit reported via the UB–04 Uniform Bill Locator 14 (Claim Inpatient Admission Type Code [385] in the Medicare SAF) to accurately identify planned and unplanned readmissions, as validated by chart review. Together, these statistics indicate that there are opportunities to utilize this measure to reduced unplanned readmissions in cancer patients, making it useful for performance improvement and public reporting. Additional details on the testing results for this measure are provided in the testing attachment, which is available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=86089*.

(4) Measure Calculation

This outcome measure utilizes claims data to demonstrate the rate at which adult cancer patients have unplanned readmissions within 30 days of discharge from an eligible index admission. The numerator includes all eligible unplanned readmissions to the PCH within 30 days of the discharge date from an index admission to the PCH that is included in the measure denominator. The denominator includes inpatient admissions for all adult Medicare fee-for-service (FFS) beneficiaries where the patient is discharged from a short-term acute care hospital (PCH, short-term acute care PPS hospital, or CAH) with a principal or secondary diagnosis (that is, not admitting diagnosis) of malignant cancer within the defined measurement period. The measure excludes readmissions for patients readmitted for chemotherapy or radiation therapy treatment or with disease progression. The measure will be calculated as the numerator divided by the denominator. Measure specifications for the proposed measure can be accessed on the NQF's website at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=86089*.

(5) Cohort

This measure includes inpatient admissions for all adult Medicare FFS beneficiaries where the patient is discharged from a short-term acute care hospital (PCH, short-term acute care PPS hospital, or CAH) with a principal or secondary diagnosis (that is, not admitting diagnosis) of malignant cancer within the defined measurement period. Additional methodology and measure development details are available on the NQF's website at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=86089*.

(6) Risk Adjustment

This measure is risk-adjusted based on a comparison of observed versus expected readmission rates. Logistic regression analysis is used to estimate the probability of an unplanned readmission, based on the measure specifications and risk factors described herein. The probability of unplanned readmission is then summed over the index admissions for each hospital to calculate the *expected* unplanned readmission rate. Subsequently, the actual or *observed* unplanned readmissions for each hospital are summed and used to calculate the ratio of *observed* unplanned readmissions to *expected* unplanned readmissions for each hospital. Each hospital's ratio was then multiplied by the national or standard unplanned readmissions rate to generate the risk-adjusted *30-Day Unplanned Readmissions for Cancer Patients* rate (as specified in the following formula):

$$Risk-Adjusted\ Rate = \frac{observed\ rate}{expected\ rate} \times national\ or\ standard\ rate$$

[382] 2018 Considerations for Implementing Measures Draft Report-Hospitals. Available at: *http://www.qualityforum.org/Show_Content.aspx?id=30279*.

[383] 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[384] We note that hospital testing occurred prior to our proposal for PCHQR Program inclusion. As such, the sample size is far greater than the number of applicable PCHs for which implementation this measure is being proposed for use to ensure data reliability.

[385] Claim Inpatient Admission Type Code available at: *https://www.resdac.org/cms-data/variables/Claim-Inpatient-Admission-Type-Code*.

We invited public comment on our proposal to adopt the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) for the FY 2021 program year and subsequent years.

Comment: Several commenters supported the proposed adoption of the 30-Day Unplanned Readmissions for Cancer Patients measure. The commenters noted that this measure is fully developed, tested, and NQF-endorsed. Further, the commenters noted that: The MAP supported this measure as filling an unmet measure gap for unplanned readmissions that are cancer-specific in the PCHQR Program; this measure incorporates the unique clinical characteristics of oncology patients and will provide specific readmissions data that more accurately reflects the quality of cancer care delivery that will be hugely beneficial information for patients; this measure includes both surgical and non-surgical cancer patients who are admitted urgently or emergently to cancer hospitals or other hospitals within 30 days of an index admission, while, at the same time, it excludes readmissions for chemotherapy or radiation therapy, as well as patients seeking treatment for disease progression. Moreover, the commenters noted that these features allow hospitals to better identify and address preventable readmissions for cancer patients than current readmissions measures. The commenters stated that ultimately, the inclusion of this measure in the PCHQR Program will promote higher-value care for cancer patients and improve patient outcomes in the domain of hospital readmissions.

Response: We thank the commenters for their support.

Comment: One commenter did not support the proposed adoption of the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188). The commenter expressed concerns that assigning accountability will be particularly challenging for this measure. Specifically, the commenter indicated that due to the severity of illness that many patients experience related to their cancer diagnosis, it would be misguided to assign responsibility and penalize other caregivers for readmissions associated with cancer patients. The commenter also requested clarification regarding the proposed data collection period for the measure because the proposed rule stated that the collection for this measure for the FY 2021 program year would begin July 1, 2018 and go through June 30, 2019 while also identifying the first data collection period for the FY 2021 program year as running from October 1, 2018 through September 30, 2019.

Response: We thank the commenter for its views, however, we disagree that assessing accountability would be difficult with this measure. We are finalizing that the data collection period for the FY 2021 program year and subsequent years for this measure will be October 1 through September 30 of the following calendar year, for each respective program year. Specifically, as indicated in section VIII.B.9.b. of the preamble of this final rule, for the FY 2021 program year, this corresponds to a data collection period of October 1, 2018–September 30, 2019. We note that the date range of July 1, 2018–June 30, 2019, provided in section VIII.B.4.b.(3) of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20505) was an error, and we have corrected it in the corresponding section of the preamble in this final rule. Moreover, this one-year timeframe narrows the examination period for the assessment of caregivers, thereby making it less difficult to evaluate where in the process a readmission could have been preempted, and easier to evaluate provider attribution.

With regards to patient illness severity, we understand that there are confounding healthcare factors that contribute to the severity of illness that many patients experience related to their cancer diagnosis; however, we believe that assessing patient readmissions is a proactive method that PCHs can use to hone in on which (if any) of these factors could be remedied and/or prevented with improved quality care. We believe that it is most beneficial to patients to be able to understand causes and/or, where possible, observe trends in cancer patient readmissions, in an effort to establish practices that eliminate readmissions. We reiterate that we are only assessing the care provided within a one-year timeframe. We also reiterate that the measure excludes readmissions for patients readmitted for chemotherapy or radiation therapy treatment or with disease progression.

After consideration of the public comments we received, we are finalizing the adoption of the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) for the FY 2021 program year and subsequent years. We are also finalizing that the data collection period for the FY 2021 program year and subsequent years for this measure will be October 1 through September 30 of the following calendar year, for each respective program year.

c. Summary of Finalized PCHQR Program Measures for the FY 2021 Program Year and Subsequent Years

The table below summarizes the PCHQR Program measure set for the FY 2021 program year:

FY 2021 PCHQR PROGRAM MEASURE SET

Short name	NQF No.	Measure name
Safety and Healthcare-Associated Infection (HAI)*		
CAUTI*	0138	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.
CLABSI*	0139	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.
Colon and Abdominal Hysterectomy SSI.	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery].
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure.
HCP	0431	National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel.

FY 2021 PCHQR PROGRAM MEASURE SET—Continued

Short name	NQF No.	Measure name
Clinical Process/Oncology Care Measures		
N/A	0383	Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology.
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life.
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice.
Intermediate Clinical Outcome Measures		
EOL–ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life.
EOL–3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days.
Patient Engagement/Experience of Care		
HCAHPS	0166	HCAHPS.
Clinical Effectiveness Measure		
EBRT	1822	External Beam Radiotherapy for Bone Metastases.
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.
N/A**	3188	30-Day Unplanned Readmissions for Cancer Patients.

*As discussed in section VIII.B.3.b.(2) of this final rule, we are deferring finalization of our policies regarding future use of the CLABSI and CAUTI measures in the PCHQR Program until the CY 2019 OPPS/ASC final rule.
**Measure finalized for adoption for the FY 2021 program year and subsequent years.

5. Accounting for Social Risk Factors in the PCHQR Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[386] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[387] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[388] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[389] allowing further examination of social risk factors in outcome measures.

In the FY 2018/CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful

[386] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[387] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[388] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[389] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. Regarding value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: A few commenters supported CMS' continued efforts to account for social risk factors in its quality reporting programs. The commenters noted that stratifying public reporting of program quality measures would help hospitals to balance the task of identifying some of the differences in the way that patients are receiving and responding to care, with adequately evaluating risk adjusting for the disparities in care. The commenters suggested that CMS explore additional social risk factors beyond dual eligibility, such as employment status, homelessness/type of residence, availability of a caretaker, food insecurity, transportation, crime rates, and other social risk factors as appropriate. Due to the complex and detailed nature of the research being undertaken by ASPE, as well as by measure stewards through the quality measure development process, the commenters encouraged CMS to provide more transparency on its efforts to address this issue. The commenters also strongly encouraged CMS to continue working closely with the measure stewards, and other quality organization stakeholders in developing any permanent risk-adjusted reporting changes as determined appropriate. Lastly, commenters encouraged CMS to include representatives on the Technical Expert Panel from across the wide spectrum of stakeholders that comprise the health care continuum.

Response: We thank the commenters for their support, opinions, and recommendations, and will take them into consideration as we continue our work on these issues.

6. Possible New Quality Measure Topics for Future Years

a. Background

As discussed in sections section I.A.2. of the preambles of the proposed rule and this final rule, we have begun analyzing our programs' measures using the framework we developed for the Meaningful Measures Initiative. We have also discussed future quality measure topics and quality measure domain areas in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280), the FY 2016 IPPS/LTCH PPS final rule (80 FR4979), the FY 2017 IPPS/LTCH PPS final rule (81 FR 25211), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38421 through 38423). Specifically, we discussed public comment and suggestions for measure topics addressing: (1) Making care affordable; (2) communication and care coordination; and (3) working with communities to promote best practices of healthy living. In addition, in the FY 2018 IPPS/LTCH PPS final rule, we welcomed public comment and specific suggestions for measure topics that we should consider for future rulemaking, including considerations related to risk adjustment and the inclusion of social risk factors in risk adjustment for any individual performance measures.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20507 through 20508), we again sought public comment on the types of measure topics we should consider for future rulemaking. We also sought public comment on two measures for potential future inclusion in the PCHQR Program:

- Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790); and
- Shared Decision Making Process (NQF #2962).

We discuss these measures and measurement topic areas in more detail below.

b. Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790)

The Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790) measure is an outcome measure. It assesses postoperative complications and operative mortality, which are important negative outcomes associated with lung cancer resection surgery. Specifically, the measure assesses the number of patients 18 years of age or older undergoing elective lung resection (Open or video-assisted thoracoscopic surgery (VATS) wedge resection, segmentectomy, lobectomy, bilobectomy, sleeve lobectomy, pneumonectomy) for lung cancer who developed one of the listed postoperative complications described in the measure's specifications.[390] The lung cancer resection risk model utilized in this measure identifies predictors of these outcomes, including patient age, smoking status, comorbid medical conditions, and other patient characteristics, as well as operative approach and the extent of pulmonary resection. Knowledge of these predictors informs clinical decision-making by enabling physicians and patients to understand the associations between individual patient characteristics and outcomes. Further, with continuous feedback of performance data over time, knowledge of these predictors and their relationship with patient outcomes also will foster quality improvement.

This measure aligns with recent initiatives to incorporate more outcome measures in quality reporting programs. This measure also aligns with the Promote Effective Prevention and Treatment of Chronic Disease domain of our Meaningful Measures Initiative,[391] and would fill an existing gap area of risk-adjusted mortality measures in the PCHQR Program. This measure has not

[390] Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790) Measure Specifications. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.*

[391] Overview of CMS ''Meaningful Measures'' Initiative available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html.*

yet been reviewed by the MAP. Additional information on this measure is available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*, under the ''Candidate Consensus Standards Review: Phase-1'' section.

We requested public comment on the possible inclusion of this measure in future years of the program.

Comment: A few commenters supported the possible inclusion of the Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer measure in future years of the PCHQR Program, but expressed concern regarding certain aspects of the measure. The commenters noted that not all cancer hospitals perform inpatient thoracic surgeries and, of those that do, not all participate in the Society of Thoracic Surgeons (STS) General Thoracic Surgery program. Further, participation in the STS program incurs cost and considerable burden given that the measure is registry-based and requires manual abstraction of cases. The commenters urged CMS to consider whether this measure can be collected in a less burdensome manner before incorporating it into the PCHQR Program. In addition, the commenters requested that CMS work to clarify the data collection and submission process, measure calculation process, and any appropriate risk adjustment. Commenters also expressed concern about the omission of small volume centers in the model that STS used to validate the risk adjusted morbidity and mortality for lung cancer resection metric as able to sort out high performing vs. acceptable vs. low performing centers. Lastly, the commenters noted that the data used for developing the models are older and may not fit as well with current figures.

Response: We thank the commenters for their support. We will collaborate with the measure steward (where appropriate) to ensure that the measure calculation and risk adjustment methodologies are thoroughly outlined, should we decide to move forward with a proposal to adopt this measure in future years of the PCHQR Program. We will also share the concerns related to data sampling continuity, the inclusion of small volume centers, and the impact of the cost and burden of participation in the STS General Thoracic Surgery Program on data extrapolation with the measure's steward.

Comment: One commenter expressed concern over the possible future inclusion of the Risk-Adjusted Morbidity and Mortality for Lung Resection measure. Specifically, the commenter noted that the measure may have negative implications for lung cancer care. In the absence of a lung cancer risk-adjusted model, the commenter expressed concern that this measure may penalize centers that choose to serve more complex, high-risk patients.

Response: We acknowledge the commenter's concern, and note that this measure does incorporate a lung cancer risk-adjusted model. Specifically, the lung cancer resection risk model utilized in this measure accounts for patient age, smoking status, comorbid medical conditions, and other patient characteristics, as well as operative approach and the extent of pulmonary resection. Additional information on the specifications is available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

We thank the commenters and we will consider their views as we develop future policy regarding the potential inclusion of the Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790) measure in the PCHQR Program.

c. Shared Decision Making Process (NQF #2962)

The Shared Decision Making Process (NQF #2962) measure is a patient-reported outcome measure. This measure asks patients who have had any of seven preference-sensitive surgical interventions to report on the interactions they had with their providers when the decision was made to have the surgery. Specifically, this measure assesses patient answers to four questions about whether three essential elements of shared decision-making: (1) Laying out options; (2) discussing the reasons to have the intervention and not to have the intervention; and (3) asking for patient input—were part of the patient's interactions with providers when the decision was made to have the procedure. When faced with a medical problem for which there is more than one reasonable approach to treatment or management, shared decision-making means providers should outline for patients that there is a choice to be made, discuss the pros and cons of the available options, and make sure that patients have input into the final decision. The result will be decisions that align better with patient goals, concerns, and preferences.

This measure aligns with recent initiatives to include patient-reported outcomes and experience of care into quality reporting programs, as well as to incorporate more outcome measures generally. This measure also aligns with the Strengthen Person and Family Engagement as Partners in Their Care domain of our Meaningful Measures Initiative,[392] and would fill an existing gap area of care aligned with the person's goals in the PCHQR Program. This measure has not yet been reviewed by the MAP. Additional information on this measure is available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=80842*.

We requested public comment on the possible inclusion of this measure in future years of the program.

Comment: A few commenters supported the future inclusion of the Shared Decision Making Process measure. The commenters indicated that this measure is essential for cancer patients, as it allows for the opinion of the patient to be a determinant of their care. The commenters were also appreciative of the fact that this measure places strong emphasis on the quality of dialogue between physicians and patients. Moreover, the commenters expressed that adoption of this measure would positively impact physician-patient communication, and thereby improve patient care. Lastly, the commenters suggested that CMS consider the need for expanded psychometric testing of the patient-reported outcome (PRO) survey and further specification and validation of the patient-reported outcome performance measure [393] (PRO–PM) for breast and prostate cancer.

Response: We thank the commenters for their support, and will take these comments into consideration should we propose to adopt this measure in the future.

Comment: Some commenters expressed concerns about the Shared Decision Making Process measure. The commenters indicated that the measure may pose significant tracking, reporting, and validation challenges because data collection for this measure would require significant changes to how Electronic Health Records are currently structured. The commenters also expressed concern that, in the absence of tools to validate the fulfillment of this measure, implementing the measure may not result in the practice change it is intended to achieve. The commenters indicated that most of shared decision-making processes associated with lung cancer resection occurs in an outpatient setting, in a clinic, or in a private office, and may not be easily or even accurately attributed to a particular hospital. This

[392] Ibid.

[393] National Quality Forum. ''Patient-Reported Outcomes Tools & Performance Measures.'' Accessed on: June 25, 2018.

has the potential to require redundant record keeping in order to demonstrate auditable compliance with the metric. The commenters also indicated that the description of the Shared Decision Making Process measure antedates lung cancer screening, which was not included in the data to develop the measure. Lung cancer screening requires a shared decision-making discussion with a health care professional before implementation, which should be considered as this measure is rolled out.

Response: We acknowledge the commenters' concerns. We note that this measure (as currently specified) is not an electronic clinical quality measure (eCQM). Should we propose to include this measure in future years as an eCQM, we will ensure that it is amenable to the existing infrastructure for data capture of eCQMs to avoid any structural or functional challenges. We also recognize the importance of the validity in quality metrics, and will ensure that adequate reliability and validity testing has been conducted, should we move forward with implementing this measure in future program years. Regarding the attribution issue, we note that this measure has been tested on nearly 3,000 patients, across 6 different clinical sites; [394] with most of the usable data coming from the Dartmouth Medical Center,[395] which is comprised of inpatient hospitals as well as outpatient clinical sites. Regarding the consideration of lung cancer screening, we agree that shared decision-making is pertinent in the screening process for this clinical condition. However, we do not believe that the omission of this particular procedure invalidates the measure or undermines its suitability for the PCHQR Program. To be responsive to commenters' concerns, we will communicate with the measure steward about the possible addition of lung cancer screening to the list of procedures as a future refinement of the measure.

Comment: A few commenters expressed concern about the essential elements defined within the Shared Decision Making Process measure. Specifically, the commenters indicated that the measure's essential elements (that is, laying out options, discussing the reasons to have the intervention and not to have the intervention, and asking for patient input) are transactional and lack the specificity required to prevent ''check-the-box'' activity. Further, these essential elements do not go far enough in assessing whether a patient's preferences, goals, and values were integrated into the care decision. Lastly, these essential elements do not address the cost component of the value equation. The commenters expressed concern that the essential elements, as currently specified, are limiting, and as a result, providers will not discuss other options. For example, a cancer patient may want information on prognosis if he or she chooses to not have surgery or whether radiation therapy is an option. The commenters suggested the integration of components that identify whether a patient's preferences, values, and goals were elicited and used to drive the healthcare decision. The commenters also suggested that this measure should require condition- or procedure-specific questions.

Response: We believe that the measure's essential elements are satisfactory as specified. The results for this measure demonstrate that compared to the baseline data, the participating clinical sites showed significant improvement (higher than the current national average [396]), which supports the argument that outcome measures based on patient reports are linked to the way that clinical practices are trying to interact with patients. Further, these results convey that the current questions suffice to capture a patient's preferences, values, and goals when deriving a healthcare decision. Specifically, for the overall scores, the correlations were .50 (p.<.001) and .38 (p=.004) for adjuvant therapy and surgery decisions respectively, and with minimum sample sizes of 25, there was an overall average reliability of .61.[397]

We thank the commenters and we will consider their views related to the inclusion of a question that gauges patients' assessment of cost, and the inclusion of procedure-specific questions as we develop future policy regarding the potential inclusion of the Shared Decision Making Process (NQF #2962) measure in the PCHQR Program.

Comment: A few commenters provided suggested revisions to some of the questions currently utilized in the Shared Decision Making Process measure. The commenters expressed concern with the first two questions. Specifically, the questions include the wording ''how much'', then offer ''a lot'' and ''some'' as response options. The commenters stated that sometimes a treatment plan is very clear and it would not be reasonable to do ''a lot'' of discussion about why not to do a clearly medically indicated, curative-intent procedure outside the normal discussion of possible adverse outcomes. The commenters requested that the two questions be rewritten as such: ''*Were the advantages and disadvantages of the planned procedure and alternative procedures discussed to your satisfaction?*'', with a yes/no response option. The commenters also expressed concern with the third and fourth questions. The commenters noted that these two questions only establish whether the patient understood that he or she had the option to accept or decline the procedure. To better evaluate whether patients engaged in a discussion that would improve the likelihood that care would align with their goals for treatment, the commenters suggested that the survey might instead ask: ''*Did the doctors ask for your input into the decision about whether or not to perform [the intervention]?*'' or, ''*Did the doctors ask you whether [the intervention] was consistent with your values and goals?*''

Response: We acknowledge the commenters' concerns and we thank them for the suggested wording revisions for the specified questions. We will share these suggestions with the measure steward for consideration during the next endorsement maintenance review of this measure with NQF.

Comment: One commenter stated that patients should have the opportunity to engage in a shared-decision making process with their provider, other health care professionals, and loved ones. Because treatment decisions are highly personalized, the commenter asked that CMS include a measure that assesses whether or not providers encourage patients to use shared decision-making tools to develop a set of personalized questions based on what each individual patient values most.

Response: We thank the commenter for its recommendation and will consider the impact of using additional decision-making tools (that is, training modules or toolkits for specialty or primary care) in tandem with the Shared Decision Making Process measure as we develop future policy regarding the potential inclusion of the measure in the PCHQR Program.

We thank the commenters and we will consider their views as we develop future policy regarding the potential inclusion of the Shared Decision Making Process (NQF #2962) measure in the PCHQR Program.

[394] ''Shared Decision Making Process Measure Testing Attachment.'' Accessed on: June 26, 2018. Available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=80842.*

[395] Ibid.

[396] Ibid.

[397] Ibid.

d. Future Measurement Topic Areas

As discussed in section I.A.2. of the preambles of the proposed rule and this final rule, we intend to review and assess the quality measures that we collect and score in our quality programs. As a part of the review process, we are continually evaluating the existing PCHQR measures portfolio and identifying gap areas for future measure adoption and/or development. In tandem with this portfolio evaluation, we have conducted a measure environmental scan. We believe that staying abreast of the cancer measurement environment and staying in communication with the cancer measure development community are vital to the ensure that the PCHQR Program measure portfolio remains aligned with current CMS and HHS goals. As a part of our efforts to include a comprehensive set of cancer measures in the PCHQR Program, we are currently assessing whether we should redefine the scope of new quality metrics we implement in the PCHQR Program in future years. Specifically, we are trying to determine whether the PCHQR Program would most benefit from the inclusion of more quality measures that examine general cancer care (that is, outcome measures that assess cancer care) or more measures that examine cancer-specific clinical conditions (such as prostate cancer, esophageal cancer, colon cancer, or uterine cancer).

We welcomed public comment and specific suggestions on the inclusion of quality measures that examine general cancer care versus the inclusion of quality measures that examine cancer-specific clinical conditions in future rulemaking.

Comment: A few commenters expressed support for the development of a balanced scorecard that includes both general cancer care measures and measures that focus on cancer-specific clinical conditions. The commenters encouraged CMS to continue to advance a portfolio of measures for the PCHQR Program that assess both general cancer care and cancer-specific clinical conditions, such as breast, colon, prostate, lung, and other types of cancer. The commenters also suggested that CMS prioritize the inclusion of new measures based on the importance and utility of the information assessed, which will naturally result in a balanced portfolio of both general and specific measures.

Response: We thank the commenters for their support and suggestions.

Comment: One commenter expressed support for the PCHQR Program moving towards general cancer care measures based on its belief that as cancer care is increasingly built around a multi-disciplinary team, a move toward more general measures is appropriate so that more providers can report them. The commenter also stated that implementing specific cancer measures can be challenging due to the need for PCHs to meet the case minimum necessary for meaningful analysis. In addition, the commenter stated that general cancer measures are a better use of the extensive time and effort needed to develop measures because they are more applicable to a larger number of patients, providers and practices, and can be utilized in multiple quality programs.

Response: We thank the commenter for its insight, and will consider the implications associated with measure implementation feasibility as we examine measures for future inclusion into the PCHQR Program measure set.

Comment: One commenter urged CMS to promote the development and adoption of claims-based metrics of survival for major cancer types, with careful attention to attribution and risk-adjustment, in future rulemaking. The development of a reliable, adequately risk-adjusted metric of survival rates by major cancer type would vastly improve the PCHQR Program's ability to provide meaningful, easily understood information to patients seeking high-quality, high-value care.

Response: We thank the commenter for its feedback, and will consider performance measures that assess cancer patient survival rates as we move forward with expanding the PCHQR Program measure set.

Comment: One commenter noted that there remains a gap in measures that are evaluating the patient experience. The commenter encouraged CMS to adopt measures that document whether providers have assessed patients for distress or other measures that comprehensively evaluate the patient experience.

Response: We thank the commenter for its feedback, and will consider performance measures that assess patient experience and engagement as we move forward with expanding the PCHQR Program measure set.

Comment: One commenter encouraged CMS to develop more measures around end-of-life conversations. The commenter noted that because cancer patients who are hospitalized tend to have advanced disease, complications, or a very aggressive cancer, it is incredibly important that cancer patients are provided with the tools and resources to engage in shared decision-making around end-of-life decisions. The commenter further noted that to ensure that patients receive high-quality, appropriate care throughout the trajectory of their cancer journey, it is essential that they have conversations with their care team and loved ones about what type of care they would like to receive, what they value, and when they would like to transition into hospice or only receive supportive care rather than curative therapy.

Response: We thank the commenter for its feedback. We note that as indicated in section VIII.B.4.c. of the preamble of this final rule, there are currently four measures in the PCHQR measure set that assess end-of-life care. However, we recognize the importance of this type of treatment for cancer patient and will continue to consider the feasibility of implementing additional end-of-life measures as we move forward with expanding the PCHQR Program measure set.

We thank the commenters and we will consider their views as we develop future policy regarding the inclusion of quality measures that examine general cancer care versus the inclusion of quality measures that examine cancer-specific clinical conditions.

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet website at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863*.

We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program.

8. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS website.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we finalized that although we would continue to use rulemaking to establish what year we would first publicly report data on each measure, we would publish the data as soon as feasible during that year. We also stated that our intent is to make the data available on at least a yearly basis, and that the time period for PCHs to review their data before the data are made public would be approximately 30 days in length. We announce the exact data review and public reporting timeframes on a CMS website and/or on our applicable Listservs.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38422 through 38424), we listed our finalized public display requirements for the FY 2020 program year.

PREVIOUSLY FINALIZED PUBLIC DISPLAY REQUIREMENTS FOR THE FY 2020 PROGRAM YEAR

Summary of previously finalized public display requirements	
Measures	Public reporting
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)*	2016 and subsequent years.
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384).*	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).*	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).*	
• HCAHPS (NQF #0166).	
• CLABSI (NQF #0139)**	Deferred.
• CAUTI (NQF #0138).**	
• External Beam Radiotherapy for Bone Metastases (NQF #1822)	Beginning when feasible in 2017 and for subsequent years.

* Measure finalized for removal beginning with the FY 2021 program year.

** As discussed in section VIII.B.3.b.(2) of this final rule, we are deferring finalization of our policies regarding future use of the CLABSI and CAUTI measures in the PCHQR Program until the CY 2019 OPPS/ASC final rule. Public reporting of these measures was deferred in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192).

We recognize the importance of being transparent with stakeholders and keeping them abreast of any changes that arise with the PCHQR Program measure set. As such, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20508 through 20509), we provided a discussion of some recent changes affecting the timetable for the public display of data for specific PCHQR Program measures in the section below.

b. Deferment of Public Display of Four Measures

We adopted the Colon and Abdominal Hysterectomy SSI (NQF #0753) measure in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50839 through 50840) and the MRSA measure (NQF #1716), the CDI measure (NQF #1717) and the HCP measure (NQF #0431) in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49715 through 49718).

At present, all PCHs are reporting Colon and Abdominal Hysterectomy SSI, MRSA, CDI, and HCP data to the NHSN under the PCHQR Program. However, performance data for these measures are new, and do not span a long enough measurement period to draw conclusions about their statistical significance at this point. Specifically, in 2016, the Centers for Disease Control and Prevention (CDC) announced that HAI data reported to NHSN for 2015 will be used as the new baseline, serving as a new ''reference point'' for comparing progress.[398] These current rebaselining efforts make year-to-year data comparisons inappropriate at this time. However, in FY 2019, we will have 2 years of comparable data to properly assess trends.[399] Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20509), we proposed to delay the public reporting of data for the SSI, MRSA, CDI, and HCP measures until CY 2019.

We invited public comment on our proposal to delay public reporting of these four measures until CY 2019.

Comment: One commenter supported the proposal to defer the public reporting of the SSI, MRSA, CDI, and HCP measures until statistical significance and reliability can be determined.

Response: We thank the commenter for its support.

Comment: One commenter did not support the proposal to delay the public reporting of the Influenza Vaccination Coverage Among Healthcare Personnel measure. The commenter noted that vaccinating healthcare personnel against influenza has been shown to improve patient safety and reduce disease transmission, which is essential for immunocompromised patients in the cancer hospital setting. Empowering patients and caregivers with the ability to assess cancer hospitals based on this measure could ultimately result in improved outcomes for patients through lower complications.

Response: We thank the commenter for its feedback. We agree that empowering patients and caregivers with the ability to assess cancer hospitals could ultimately result in improved outcomes for patients, however, we want to ensure that the information provided to consumers is adequate and accurate. We reiterate that performance data for these measures are new, and do not span a long enough measurement period to draw conclusions about their statistical significance at this point, however, we will modify our proposal, such that we will provide stakeholders with performance data as soon as practicable.

After consideration of the public comments we received, we are finalizing a modification to our proposal to delay public reporting of data for the SSI, MRSA, CDI, and HCP measures until CY 2019. Instead, we are finalizing that we will provide stakeholders with performance data as soon as practicable (that is, if useable data is available sooner than CY 2019, we will publicly report it on Hospital Compare via the next available Hospital Compare release. We will continue to monitor the progress of the current rebaselining efforts being made by CDC.

[398] Centers for Disease Control and Prevention. ''Paving Path Forward: 2015 Rebase line.'' Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html.*

[399] Rebase line Timeline FAQ Document. Available at: *https://www.cdc.gov/nhsn/pdfs/rebaseline/faq-timeline-rebaseline.pdf.*

c. Clarification of Public Display of External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822) Measure

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282 through 50283), we finalized that PCHs would begin reporting the External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822) measure beginning with January 1, 2015 discharges and for subsequent years. We finalized that PCHs would report this measure to us via a CMS web-based tool on an annual basis (July 1 through August 15 of each respective year). Lastly, we finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192) that we would begin to display the measure data during CY 2017, and that we would use a CMS website and/or our applicable Listservs to announce the exact timeframe.

We publicly reported data on this measure in December of 2017, and that data can be accessed on *Hospital Compare* at: *https://www.medicare.gov/hospitalcompare/cancer-measures.html*. We note that this measure is updated on an annual basis, and that new *Hospital Compare* data is published four times each year: April, July, October, and December. As such, given the time necessary to assess the data provided for this measure's annual update, we anticipate an update of EBRT measure data to be available in December of 2018.

d. Summary of Public Display Requirements for the FY 2021 Program Year

Our public display requirements for the FY 2021 program year are shown in the following table:

PUBLIC DISPLAY REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR

Summary of newly finalized public display requirements	
Measures	Public reporting
• HCAHPS (NQF #0166)	2016 and subsequent years.
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753)*.	* Deferred.
• National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716).*	
• National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).*	
• National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).*	
• CLABSI (NQF #0139).**	
• CAUTI (NQF #0138).**	
• External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822)	2017 and subsequent years.

* Newly finalized in this FY 2019 IPPS/LTCH PPS final rule.

** As discussed in section VIII.B.3.b.(2) of this final rule, we are deferring finalization of our policies regarding future use of the CLABSI and CAUTI measures in the PCHQR Program until the CY 2019 OPPS/ASC final rule. Public reporting of these measures was deferred in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192).

9. Form, Manner, and Timing of Data Submission

a. Background

Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228*.

b. Reporting Requirements for the Newly Finalized 30-Day Unplanned Readmissions for Cancer Patients Measure

As further described in section VIII.B.4.b. of the preamble of this final rule, we are finalizing the adoption of a new measure beginning with the FY 2021 program year, the 30-Day Unplanned Readmissions for Cancer Patients measure. This is a claims-based measure, therefore, there will be no separate data submission requirements for PCHs related to this measure as CMS will calculate measure rates using PCH claims data. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20510), we proposed that the data collection period would be from July 1 of the year, three years prior to the program year to June 30 of the year, two years prior to the program year. Therefore, for the FY 2021 program year, we would collect data from October 1, 2018 through September 30, 2019.

We invited public comment on this proposal.

Comment: One commenter supported the proposed timeframe for the reporting of the 30-Day Unplanned Readmissions for Cancer Patients measure.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing the proposal to collect data on this measure from October 1, 2018 through September 30, 2019, for the FY 2021 program year.

10. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

In our experience with other quality reporting and performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to increase their burden unduly during these times. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848), we finalized our policy that, for the FY 2014 program year and subsequent years, PCHs may request and we may grant exceptions (formerly referred to as waivers) [400] with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. The PCH may request a reporting extension or a complete exception from the requirement to submit quality data for one or more quarters. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38424 through 38425), we finalized modifications to the extraordinary circumstances exceptions (ECE) policy

[400] ECEs were originally referred to as ''waivers.'' This term was changed to ''exceptions'' in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286).

to extend the deadline for a PCH to submit a request for an extension or exception from 30 days following the date that the extraordinary circumstance occurred to 90 days following the date that the extraordinary circumstance occurred and to allow CMS to grant an exception or extension due to CMS data system issues which affect data submission. In addition, to ensure transparency and understanding of our process, we have clarified that we will strive to provide our response to an ECE request within 90 days of receipt.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background

The LTCH QRP is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Under the LTCH QRP, the Secretary reduces by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more detailed information on the requirements we have adopted for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426).

Although we have historically used the preamble to the IPPS/LTCH PPS proposed and final rules each year to remind stakeholders of all previously finalized program requirements, we have concluded that repeating the same discussion each year is not necessary for every requirement, especially if we have codified it in our regulations. Accordingly, the following discussion is limited as much as possible to a discussion of our proposals, responses to comments submitted on those proposals, and policies we are finalizing for future years of the LTCH QRP, and represents the approach we intend to use in our rulemakings for this program going forward.

Comment: Several commenters supported streamlining the LTCH QRP, specifically CMS' effort to align areas of best practices with other quality reporting programs. Another commenter supported the proposed changes to the LTCH QRP, recognizing that these changes are part of a multi-year process to reform patient assessment and quality reporting across multiple levels of care.

Response: We appreciate the commenters' support.

2. General Considerations Used for the Selection of Measures for the LTCH QRP

a. Background

For a detailed discussion of the considerations we historically used for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

We received comments related to the IMPACT Act and the availability of data for LTCHs, both of which are summarized and discussed below.

Comment: A few commenters supported the goals and objectives of the IMPACT Act, noting the interdependence of the four post-acute care settings and their respective payment systems and the critical need for sound analysis of data from all levels of care. One commenter supported the delay of the implementation of the IMPACT Act requirements to ensure that measures are valid and valuable.

Commenters also supported the development of standardized patient assessment data elements. One commenter recommended that, as part of the standardized patient assessment data elements that could be incorporated into the post-acute care assessment instruments, CMS streamline adult immunization quality measures across health care settings. One commenter expressed that CMS communicate and collaborate more with LTCHs and other post-acute care providers on IMPACT Act implementation, encouraging CMS to include LTCHs in the development of standardized patient assessment data elements and all other CMS initiatives related to the implementation of the IMPACT Act. The commenter also noted that CMS should develop and refine measures that are either required by the IMPACT Act or will otherwise facilitate cross-setting measurement and eliminate measures that are not required under the IMPACT Act.

Response: While we did not propose changes to the LTCH QRP's policies on standardized patient assessment data elements, quality measures, or public engagement pertaining to the implementation of the IMPACT Act, we will take these comments into account as we engage in future development of these policies. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49728) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38426 through 38433) for additional information on the IMPACT Act and its applicability to LTCHs.

Comment: Some commenters requested that CMS provide opportunity for stakeholders of all post-acute care settings to access aggregate patient assessment data, including LTCH CARE Data Set data, to allow providers to analyze data and to provide meaningful input to CMS, noting that this data is available for SNFs, IRFs, and HHAs, but not, however, for LTCHs.

Response: We acknowledge the commenters' requests to make the LTCH CARE Data Set data publicly available for research purposes. We intend to make the data available as soon as feasible.

b. Accounting for Social Risk Factors in the LTCH QRP

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[401] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.[402] As we noted in the FY

[401] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[402] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress, which was required by the IMPACT Act, found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[403] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[404] allowing further examination of social risk factors in outcome measures.

In the FY 2018/CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS: to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, we are considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: Many commenters supported the continued evaluation of social risk factors for the LTCH QRP measures, specifically for displaying stratification by social risk factors, expressed willingness to support efforts with CMS or NQF on this issue, and requested that attribution be addressed in technical specifications.

Response: We thank the commenters for their comments and will take these comments into account as we further consider how to appropriately account for social risk factors in the LTCH QRP. We also refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), where we discussed displaying stratification by social risk factors and other related issues.

3. New Measure Removal Factor for Previously Adopted LTCH QRP Measures

As a part of our Meaningful Measures Initiative, discussed in section I.A.2. of the preambles of the proposed rule and this final rule, we strive to put patients first, ensuring that they, along with their clinicians, are empowered to make decisions about their own healthcare using data-driven information that is increasingly aligned with a parsimonious set of meaningful quality measures. We began reviewing the LTCH QRP's measures in accordance with the Meaningful Measures Initiative, and we are working to identify how to move the LTCH QRP forward in the least burdensome manner possible, while continuing to incentivize improvement in the quality of care provided to patients.

Specifically, we believe the goals of the LTCH QRP and the measures used in the program cover most of the Meaningful Measures Initiative priorities, including making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable.

We also evaluated the appropriateness and completeness of the LTCH QRP's current measure removal factors. We have previously finalized that we would use notice and comment rulemaking to remove measures from the LTCH QRP based on the following factors:[405]

- Factor 1. Measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.
- Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.
- Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.
- Factor 7. Collection or public reporting of a measure leads to negative

[403] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[404] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

[405] We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615) for more information on the factors we consider for removing measures.

unintended consequences other than patient harm.

We continue to believe that these measure removal factors are appropriate for use in the LTCH QRP. However, even if one or more of the measure removal factors applies, we may nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could, in turn, result in poor quality, or in the event that a given measure is statutorily required. We note further that, consistent with other quality reporting programs, we apply these factors on a case-by-case basis.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20511 through 20512), we proposed to adopt an additional factor to consider when evaluating potential measures for removal from the LTCH QRP measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As we discussed in section I.A.2. of the preambles of the proposed rule and this final rule, with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the LTCH QRP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) The provider and clinician information collection burden and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the cost to CMS associated with the program oversight of the measure including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable).

For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools we need to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the LTCH QRP, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the LTCH QRP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the LTCH QRP may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

Comment: Many commenters supported the proposal to add measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, in the LTCH QRP. Commenters appreciated the consideration of costs beyond those associated with data collection and submission. One commenter agreed that the burden associated with data collection should be balanced with the value these measures have to providers, patients, and others. Another commenter suggested that CMS also consider the costs associated with tracking performance and resources invested for quality improvement. A few commenters encouraged CMS to continue to apply the measure removal factors to other measures in the LTCH QRP, including those more recently adopted in the program, to reduce regulatory burden on providers so that they may focus instead on improving patient outcomes.

Response: We appreciate the support and suggestions regarding the addition of this measure removal factor to the LTCH QRP. With respect to considering the costs associated with tracking performance and resources invested for quality improvement, we believe that investing resources in quality improvement is an inherent part of delivering high-quality, patient-centered care and, therefore, is generally not considered a part of the quality reporting program requirements.

Comment: A few commenters noted the existing seven removal factors are sufficient for appropriate measure evaluation.

Response: While we acknowledge that there are seven factors currently adopted that may be used for considering measure removal from the LTCH QRP, we believe the proposed new measure removal factor adds a new criterion that is not captured in the other seven factors. The proposed new measure removal factor will help advance the goals of the Meaningful Measures Initiative, which aims to improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers.

Comment: One commenter questioned the process involved with Factor 1, or ''topped-out'' measures, and requested clarity on the process and timeline for determining whether a measure is ''topped out.''

Response: While we did not use Factor 1 as justification for removing any LTCH QRP measures in the proposed rule, we acknowledge the commenter's request for clarification about the process and timeline for this measure removal factor. In our evaluation of LTCH QRP measures, we look at measure performance using methodology and a timeline that are appropriate, based on each measure's specifications. If we determine that measure performance is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made, we will detail our process in the proposed rule and solicit public comment after making such a determination.

Comment: Some commenters expressed concern related to proposed Factor 8. A few commenters stated that the measure removal factor only

accounts for the cost of reporting without considering the cost to patients, their families, and the Medicare program. The commenters requested more measures and financial incentives to spur higher quality care and hold providers accountable if they fail to prevent errors and infections.

One commenter cautioned that measure removal should not be solely based on associated cost and recommended that CMS implement measures even at a high cost if it benefits patients. Another commenter requested clarification about the methods or criteria used to assess when the measure cost or burden outweighs the benefits of retaining it.

Lastly, one commenter expressed concern that Factor 8 compares the costs with the ''use in the program,'' indicating that the usefulness of the measures should be self-evident and directly relate to the purpose of the program. The commenter believed that the removal of a measure would decrease the ability of that measure to improve patient care and reduce Medicare costs and, as a result, would reduce the effectiveness of the quality reporting program. The commenter also noted that Factor 8 does not describe a specific method to be used to evaluate the usefulness of a measure or describe how the number of measures kept within the program shall be determined.

Response: We intend to apply measure removal Factor 8 on a case-by-case basis because the costs and benefits associated with each measure are unique to that measure. However, we believe these costs include costs to all stakeholders, including but not limited to, patients, caregivers, providers, CMS, and other entities. We agree with the commenter's observation that for measures that serve beneficiaries, the costs may be outweighed by the benefits, and intend to evaluate measures on a case-by-case basis to achieve this balance.

With regard to the request for clarification about criteria used to assess costs and burden, we provided examples of five different costs that could be considered in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20512). We note that we intend to assess the costs and benefits to all program stakeholders, including but not limited to, those listed above. We intend to be transparent in our assessment of costs and burden for each measure. As described above, there are various considerations of costs and benefits, direct and indirect, financial and otherwise, that we will evaluate when evaluating a measure under removal Factor 8, and we will take into consideration the perspectives of multiple stakeholders. However, because we intend to evaluate each measure on a case-by-case basis, and because each measure has been adopted to fill different needs in the LTCH QRP, we do not believe it would be meaningful to identify a specific set of assessment criteria to apply to all measures.

Lastly, in response to the comment that the removal of measures would reduce the effectiveness of the LTCH QRP, we do not believe that more measures equate to better care. Retaining a strong measure set that addresses critical issues is one benefit that we would consider in analyzing measures for potential removal from the LTCH QRP measure set. We will continue to monitor and evaluate our programs to identify their benefit with respect to quality of care and patient safety as well as their costs.

After consideration of the public comments we received, we are finalizing our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, in the LTCH QRP.

We also proposed to codify both the removal factors we previously finalized for the LTCH QRP, as well as the new the measure removal Factor 8 that we are finalizing in this final rule, at § 412.560(b)(3) of our regulations.

Comment: A few commenters supported the proposal to codify all eight measure removal factors, including the proposed Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to codify both the removal factors we previously finalized for the LTCH QRP, as well as the new the measure removal factor that we are finalizing in this final rule, at § 412.560(b)(3) of our regulations. We are also making minor grammatical edits to the LTCH QRP measure removal factor language to align with the language of other programs.

4. Quality Measures Currently Adopted for the FY 2020 LTCH QRP

The LTCH QRP currently has 19 measures for the FY 2020 program year, which are outlined in the following table:

QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2020 LTCH QRP

Short name	Measure name and data source
LTCH CARE Data Set	
Pressure Ulcer	Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).*
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Patient Influenza Vaccine	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay.
Ventilator Liberation	Ventilator Liberation Rate.

QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2020 LTCH QRP—Continued

Short name	Measure name and data source
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).
MRSA	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).
VAE	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)-Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
DTC	Discharge to Community-Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).

* The measure was replaced with the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, effective July 1, 2018.

Comment: One commenter suggested that CMS consider adding Kennedy terminal ulcers as an item in the LTCH CARE Data Set in order to differentiate a Kennedy ulcer from a facility-acquired pressure ulcer/injury.

Response: While we did not solicit comments on the items on the LTCH CARE Data Set, we appreciate the commenter's suggestion for additional pressure ulcer/injury items and will take this into consideration as we continue our evaluation and refinement of pressure ulcer/injury items used to calculate skin integrity quality measures for PAC settings. Kennedy terminal ulcers, which are unavoidable skin breakdown that occur as part of the dying process, are not considered to be pressure ulcers/injuries and are therefore not currently coded on the LTCH CARE Data Set and not included in the calculation of the skin integrity measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), or the replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We will continue to provide training and clarification regarding coding of pressure ulcer/injury items through training events, FAQs, and help desk.

Comment: One commenter requested a more precise definition of the phrase ''potential clinically significant medication issues'' under the Drug Regimen Review Conducted with Follow-Up for Identified Issues measure. This commenter was concerned that policies in other CMS programs would hinder appropriate prescribing of antipsychotic medications.

Response: While we did not propose any changes to the previously finalized measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP, we responded to comments regarding the definition of a clinically significant medication issue in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57219 through 57223), and we refer readers to that detailed discussion. We also refer readers to the LTCH QRP Manual Version 4.0 for more information about coding the drug regimen review data elements, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual.html*.

Comment: A few commenters supported maintaining the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) quality measure in the LTCH QRP. A commenter also supported the public reporting of the quality measure.

Response: We appreciate the commenters' support.

Comment: A few commenters expressed views on measures for future consideration for the LTCH QRP. One commenter suggested a measure that addresses mental health. Another commenter encouraged CMS to move forward with the development and adoption of a standardized patient experience survey given CMS' focus on strengthening person and family engagement as part of the Meaningful Measures framework.

Response: While we did not solicit public comment about future measures, we appreciate the input and will take it into consideration in future LTCH QRP measure development.

5. Removal of Three LTCH QRP Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20513 through 20515), we proposed to remove three measures from the LTCH QRP measure set. Beginning with the FY 2020 LTCH QRP, we proposed to remove two measures: (1) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); and (2) National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure. We proposed to remove one measure beginning with the FY 2021 LTCH QRP: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680). We discuss these proposals below.

a. Removal of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)

We proposed to remove the measure, National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF

#1716), from the LTCH QRP beginning with the FY 2020 LTCH QRP.

As discussed in section VIII.C.3. of the preambles of the proposed rule and this final rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures available to track patient outcomes and impact. We currently collect data on two measures of healthcare-associated bacteremia infections in the LTCH QRP: (1) NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139); and (2) NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).

In our review of these measures used in the LTCH QRP, we believe that it is appropriate to remove the NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) based on: (1) Factor 6, a measure that is more strongly associated with desired patient outcomes for the particular topic is available; and (2) Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We believe that the NHSN CLABSI Outcome Measure (NQF #0139) is more strongly associated with the desired patient outcome for bloodstream infections than the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716). Bloodstream infections are serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality. The NHSN CLABSI Outcome Measure (NQF #0139) assesses the results of the quality of care provided to patients, and it is risk-adjusted to compare the infection rate for a particular location or locations in a hospital with an expected infection rate for those locations (which is calculated using national NHSN data for those locations in a predictive model). The NHSN CLABSI Outcome Measure (NQF #0139) is more strongly associated with the desired patient outcome of better results in the quality of care provided to patients because it covers a wide range of blood-stream infections, while the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) only covers MRSA observed hospital-onset unique blood source MRSA laboratory-identified events. The NHSN CLABSI Outcome Measure (NQF #0139) also captures the MRSA blood-stream events, creating potential duplicative collection and reporting.

We also believe that the costs associated with the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) outweigh the benefit of its continued use in the LTCH QRP. The NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) was adopted to assess MRSA infections caused by a strain of MRSA bacteremia that has become resistant to antibiotics commonly used to treat MRSA infections. The NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) and NHSN CLABSI Outcome Measure (NQF #0139) capture the same type of MRSA infection. This overlap results in the data submission on two measures that cover the same quality issue. We believe that this results in redundant efforts on the part of LTCHs that are costly and burdensome. In addition, the maintenance of these two measures in the LTCH QRP is costly for CMS. Lastly, we believe that the removal of the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) would benefit the public by eliminating the potential confusion of seeing two different measure rates on LTCH Compare that capture MRSA bacteremia.

We stated in the proposed rule that if our proposal is finalized, LTCHs would continue to report MRSA bacteremia events associated with central line use as part of the NHSN CLABSI Outcome Measure (NQF #0139), and LTCHs would also report as part of that measure other acquired central line-associated bloodstream infections. As a result, duplication of data submission of the same MRSA bacteremia event for these two measures would be eliminated and only a single bacteremia outcome measure would be publicly reported on *LTCH Compare.*

For these reasons, we proposed to remove the NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) from the LTCH QRP beginning with the FY 2020 LTCH QRP under: (1) Factor 6, a measure that is more strongly associated with desired patient outcomes for the particular topic is available; and (2) Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We stated in the proposed rule that if our proposal is finalized as proposed, LTCHs would no longer be required to submit data on this measure for the purposes of the LTCH QRP beginning with October 1, 2018 admissions and discharges.

Comment: Several commenters, including MedPAC, supported the proposed removal of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) from the LTCH QRP. Commenters noted that this removal aligns with CMS' focus on the Meaningful Measures Initiative and expressed that the removal of this measure would decrease costs and administrative burden for LTCHs, allowing them more time to focus on patient care.

In addition, several commenters agreed that the NHSN CLABSI Outcome Measure (NQF #0139) is more strongly associated with the desired patient outcome for bloodstream infections than the NHSN MRSA Bacteremia Outcome Measure (NQF #1716) and that maintaining both measures in the LTCH QRP would represent duplicative data collection and reporting. Another commenter qualified its support with a recommendation that CMS study the overlap between MRSA and CLABSI since MRSA bacteremias are often, but not always, CLABSIs.

Response: We appreciate the support from MedPAC and other commenters for the proposed removal of the NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) from the LTCH QRP. We are aligned with the Centers for Disease Control and Prevention's (CDC's) interest in examining the CDC NHSN measures, and the CDC is considering further study on the overlap of bacteremias within the MRSA and CLABSI measures.

Comment: Some commenters expressed concern with the proposed removal of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) from the LTCH QRP.

Some commenters expressed concern that removing this measure would decrease the ability of providers to continually monitor and address critical patient safety issues and the ability of patients and families, employers, and payers to make informed decisions about their health care. These commenters stated that the public reporting of patient safety measures helps focus and strengthen efforts to improve healthcare quality and safety.

Commenters also stated that patient safety should continue to be assessed in

a manner which provides minimal interruption to data collection and burden on LTCHs. In addition, several commenters noted that, with such a small measure set, CMS should strive to maintain key outcome measures.

Other commenters believed that the NHSN CLABSI Outcome Measure (NQF #0139), alone, was not sufficient to capture the desired outcome of bloodstream infections, and stated that the two measures on this topic address different issues which are dependent upon different processes for prevention.

Response: We would like to clarify that providers have the ability to continually monitor and address patient safety issues with the continued public reporting of the NHSN CLABSI Outcome Measure (NQF #0139), which captures MRSA bloodstream events, on *LTCH Compare,* even with the removal of the NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).

We agree with the commenters that patient safety should continue to be assessed in a manner that provides minimal interruption to data collection and burden on LTCHs. Through the Meaningful Measures Initiative, it is our goal to maximize patient safety with minimal burden on providers. We continue to monitor hospital acquired infections in the LTCH setting through the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138), the NHSN Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139), and the NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717). In addition, we agree with several commenters that CMS should strive to maintain key outcome measures, and we will continually review, evaluate, and amend, if necessary, these measures within our quality programs.

Lastly, we disagree with the commenter who stated that the CLABSI and MRSA measures address different issues which are dependent upon different processes for prevention. We are clarifying that MRSA bacteremia LabID event reporting is only based on the proxy measure of a positive laboratory finding with no clinical consideration. MRSA bacteremia LabID event reporting is different from CLABSI reporting, which is based on specific infection criteria. Since CLABSI reporting is based on standardized case definitions, there is confidence in the data that can be used to impact prevention efforts as well as increased comparability between clinical settings.

For example, an increased CLABSI standardized infection ratio (SIR) would be viewed as an opportunity for improvement in overall standard of care practices. In addition, the monitoring conducted under CLABSI reporting is not limited to MRSA bloodstream infections and includes all organisms identified in blood culture collection, pathogens and common commensal organisms. Thus, the CLABSI measure data can inform broader preventive programs than the NHSN Facility-wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).

After consideration of the public comments we received, we are finalizing our proposal to remove the NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) from the LTCH QRP beginning with the FY 2020 LTCH QRP. LTCHs will no longer be required to submit data on this measure for the purposes of the LTCH QRP beginning with October 1, 2018 admissions and discharges.

b. Removal of the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure

We proposed to remove the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP beginning with the FY 2020 LTCH QRP based on Factor 6, a measure that is more strongly associated with desired patient outcomes for the particular topic is available.

We finalized the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305) to assess whether LTCHs monitor ventilator use and identify improvements in preventing complications associated with mechanical ventilation. We have also adopted for the LTCH QRP three other assessment-based quality measures on the topic of ventilator support: (1) Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) (79 FR 50298 through 50301); (2) Compliance with Spontaneous Breathing Trials (SBT) by Day 2 of the LTCH Stay (82 FR 38439 through 38443); and (3) Ventilator Liberation Rate (82 FR 38443 through 38446).

We believe that these three other assessment-based quality measures are more strongly associated with desired patient outcomes than the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure that we proposed to remove. The three assessment-based measures assess activities that reduce the potential for serious complications and other adverse events as a result of mechanical ventilation. Specifically, the Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) focuses on improvement in functional mobility for patients requiring mechanical ventilation. The Compliance with SBT by Day 2 of the LTCH Stay measure focuses on successfully liberating patients from mechanical ventilation as soon as possible, which reduces the risk associated with events as a result of prolonged ventilator support. The Ventilator Liberation Rate measure assesses whether the patient was fully liberated from mechanical ventilation at discharge. Together, these three ventilator-related assessment-based quality measures assess positive outcomes and track patient goals of avoiding adverse outcomes associated with mechanical ventilation and successful ventilator weaning.

The inclusion in the LTCH QRP measure set of these three ventilator-related assessment-based measures, which focus on quality of care through promotion of positive outcomes, have reduced poor outcomes associated with the complications of ventilator care, which is the same focus of the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure (for example, worsening oxygenation, infection or inflammation, ventilator-associated pneumonia, or even death). As a result, we do not believe that it is necessary to retain all four of these measures in the LTCH QRP. By retaining the three ventilator-related assessment-based measures but removing the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure, we believe that we can focus on the topic of mechanical ventilation measures that promote positive outcomes while indirectly promoting a reduction in ventilator support complications.

For these reasons, we proposed to remove the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP beginning with the FY 2020 LTCH QRP under Factor 6, the measure that is more strongly associated with

desired patient outcomes for the particular topic is available.

We stated in the proposed rule that if our proposal is finalized as proposed, LTCHs would no longer be required to submit data on this measure for the purposes of the LTCH QRP beginning with October 1, 2018 admissions and discharges.

Comment: Several commenters, including MedPAC, supported the proposed removal of the NHSN VAE Outcome Measure from the LTCH QRP. Commenters agreed that this removal aligns with CMS' Meaningful Measures Initiative and the removal of this measure would decrease costs and administrative burden for LTCHs, allowing them more time to focus on patient care. Several commenters agreed that the measure is duplicative of the three ventilator-related assessment-based quality measures and that the NHSN VAE Outcome Measure might not be as strongly associated with the desired patient outcomes as these three measures.

Response: We appreciate the support and suggestions from MedPAC and other commenters for the proposed removal of the NHSN VAE Outcome Measure from the LTCH QRP.

Comment: A few commenters were appreciative of the removal of the NHSN VAE Outcome Measure and agreed that it overlaps unnecessarily with the other ventilator-related measures in the LTCH QRP, but recommended that CMS instead remove the process measure, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay, from the LTCH QRP.

Response: We appreciate the commenters' feedback; however, we disagree with the recommendation to remove the Compliance with SBT by Day 2 of the LTCH Stay measure instead of the NHSN VAE Outcome Measure that we proposed to remove. The Compliance with SBT by Day 2 of the LTCH Stay measure, when taken together with the two other ventilator-related assessment-based quality measures Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) and Ventilator Liberation Rate, assesses positive outcomes and track patient goals of avoiding adverse outcomes associated with mechanical ventilation and successful liberation off the ventilator.

As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38439 through 38440), the Compliance with SBT by Day 2 of the LTCH Stay measure is important for encouraging implementation of evidence-based weaning protocols that reduces the risk of negative ventilator-associated outcomes such as ventilator-associated pneumonia.

Comment: Several commenters expressed concern with the proposed removal of the NHSN VAE Outcome Measure from the LTCH QRP. Some commenters were concerned that removing this measure would decrease the ability of providers to continually monitor and address critical patient safety issues, patients and families to make informed decisions about their health care, and employers and purchasers to obtain better value for their contracts and purchasing programs. The commenters stated that public reporting of patient safety measures helps focus and strengthen efforts to improve healthcare quality and safety.

Several commenters stated that patient safety should continue to be assessed in a manner that provides minimal interruption to data collection and burden on LTCHs. In addition, several commenters noted that, with such a small measure set, CMS should strive to maintain key outcome measures. Several commenters also emphasized the importance of the NHSN VAE Outcome Measure for epidemiological tracking, with a few commenters adding that this measure has only been required since January 2016 and that only a baseline has been established. Another commenter advised CMS to monitor rates of worsening oxygenation, infection, inflammation, and ventilator-associated pneumonia to ensure that the measure's removal does not unintentionally lead to a rising trend in these events. A few commenters stated that preventing VAEs requires different processes than preventing central line infections and thus, should continue to be monitored in addition to the three current ventilator assessment-based quality measures currently in the LTCH QRP.

Response: We acknowledge the concerns raised by the commenters. As we note above, the other three ventilator assessment-based quality measures currently in the LTCH QRP measure set (Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632); Compliance with Spontaneous Breathing Trials (SBT) by Day 2 of the LTCH Stay; and Ventilator Liberation Rate) assess activities that reduce the potential for serious complications and other adverse events to occur as a result of mechanical ventilation. We believe that encouraging implementation of evidence-based weaning protocols, improving mobility, and liberating patients off mechanical ventilation addresses critical patient safety issues, allows patients and families to make informed decisions based on positive outcomes, and strengthens the value of healthcare.

We agree with the commenters that patient safety should continue to be assessed in a manner which provides minimal interruption to data collection and burden on LTCHs. Through the Meaningful Measures Initiative, one of our goals is to ensure that our measures are strongly associated with the desired patient outcomes. We are continuing to monitor hospital acquired infections in the LTCH setting with the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138), the NHSN Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) and the NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717). In addition, we agree with several commenters that CMS should strive to maintain key outcome measures, and we will continually review, evaluate, and amend, if necessary, these measures within our quality programs.

We also agree that epidemiological tracking of VAE is important and that providers should be able to continue monitoring events such as worsening oxygenation, infection, inflammation, and ventilator-associated pneumonia to ensure these events will not rise. LTCHs can continue to report VAE data to NHSN on a voluntary basis, as well as use NHSN for their own internal tracking of local VAE incidence.

Data on LTCH QRP measures that are also collected by the CDC for other purposes are reported by LTCHs to the CDC through the NHSN, and the CDC then transmits the relevant data to CMS. Even with the removal of the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP, the CDC will continue to use VAE data in the production of national and State-level SIRs as a way to track progress towards prevention goals. We recognize that preventing VAEs requires different processes than preventing central line infections. However, as noted above, we believe that the other LTCH QRP VAE-related measures assess positive outcomes and track patient goals of avoiding adverse outcomes associated with mechanical ventilation and successful liberation off the ventilator.

After consideration of the public comments we received, we are finalizing our proposal to remove the National Healthcare Safety Network

(NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP beginning with the FY 2020 LTCH QRP. LTCHs will no longer be required to submit data on this measure for the purposes of the LTCH QRP beginning with October 1, 2018 admissions and discharges.

c. Removal of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) Measure

We proposed to remove the process measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2021 LTCH QRP under measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

This process measure reports the percentage of stays in which a patient was assessed and appropriately given the influenza vaccine for the most recent influenza vaccination season and was adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627) to assess vaccination rates among older adults with the goal of reducing the incidence of influenza in this population. Specifically, adoption of the measure in the LTCH QRP was intended to act as a safeguard for patients who did not receive vaccinations prior to admission to an LTCH, since many patients receiving care in the LTCH setting are older adults (those 65 years and older) and are considered to be the target population for the influenza vaccination.

In our evaluation of the LTCH QRP measure set, our analysis of this particular measure revealed that for the 2016–2017 influenza season, nearly every patient was assessed by the LTCH upon admission and that less than 0.04 percent of patients were not assessed for the vaccination. Of those assessed, the data show that most patients who could receive the vaccine had already received the vaccine outside of the LTCH facility, prior to admission.

In addition, we have heard from stakeholders that the data collection associated with this measure is administratively costly and burdensome for LTCHs, and that the process of assessing whether vaccination is needed is often a duplicative process for patients who were already screened during their proximal stay at an acute care facility. We believe that removing this measure would reduce provider costs and burden by eliminating duplicative patient assessments across healthcare settings, minimizing data collection and reporting, and avoiding potentially confusing public reporting of other influenza-related quality measures, such as the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure.

We recognize that influenza is a major public health issue. However, based on our analysis of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure, including data showing that most LTCH patients are vaccinated before they are admitted to the LTCH, we believe that LTCH patients will continue to be assessed and immunized when appropriate in the absence of this measure. As a result, removal of this measure would alleviate the operational costs and burden that LTCHs currently incur with respect to collecting the data necessary to report this measure.

Therefore, we proposed to remove this measure from the LTCH QRP beginning with the FY 2021 LTCH QRP under measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We stated in the proposed rule that if our proposal is finalized as proposed, LTCHs would no longer be required to report the data elements necessary to calculate this measure beginning with October 1, 2018 [406] admissions and discharges. We stated in the proposed rule that we plan to remove the data elements from the LTCH CARE Data Set as soon as feasible. We also proposed that beginning with October 1, 2018 admissions and discharges, LTCHs should enter a dash (–) for O0250A, O0250B, and O0250C until the next LTCH CARE Data Set is released.

Comment: Several commenters, including MedPAC, supported the proposal to remove the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure from the LTCH QRP. The commenters emphasized that collecting data on this measure is costly, burdensome, and duplicative since many patients admitted to LTCHs are transferred from the acute care setting where influenza vaccinations are already being tracked. Other commenters stated that if providers are successfully meeting the established standards set by CMS, then data collection is an unnecessary process. In addition, the commenters stated that removing the measure will result in less administrative burden without compromising the quality of care and will allow providers to focus on more meaningful measures to promote better health outcomes for patients and to align with the Meaningful Measures Initiative.

Response: We appreciate the support from MedPAC and other commenters for the proposed removal of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure from the LTCH QRP.

Comment: Several commenters did not support the removal of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure from the LTCH QRP. Commenters were concerned with consequences related to patient care, suggesting that the benefits of the measure far outweigh the costs of retaining the measure. One commenter stated that the high performance of the measure is a clear indicator of the success of the measure and continuing to track immunizations should be a priority because patients in LTCHs are susceptible to the acquisition and spread of infectious diseases. Another commenter suggested that an outbreak is more likely to occur and would be costlier than the burden of reporting the measure. Another commenter noted that confusion between the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure and the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure is unlikely and should not be used as a rationale to remove the measure.

Response: We recognize that assessing and appropriately vaccinating patients is an important component of the care process, and the vaccination of the majority of patients before admission to LTCHs protects against the spread of infectious disease. Our analysis has shown that most patients admitted to LTCHs are admitted from an acute-care setting where influenza vaccinations are

[406] The target period for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure is the influenza season, which begins July 1 and ends June 30 of the following year. The influenza vaccination season falls within the influenza season of a given year and starts October 1 and ends March 31 of the following year. This measure includes all patients who were in an LTCH at least one day during the influenza vaccination season. The October 1, 2018 date is proposed as the date in which LTCHs would no longer be required to report the data elements necessary to calculate this measure because October 1, 2018 marks the start of the influenza vaccination season for the 2018–2019 influenza season.

being tracked, which is why we believe that collecting and reporting data on this measure would be duplicative. Further, high performance of the measure across LTCHs is positive, which makes assessing variations in provider performance difficult.

We strive to align with the Meaningful Measures Initiative by prioritizing measures most vital to improving patient outcomes and focusing on issues that are most meaningful to patients and their families. We considered feedback from subject matter experts who have noted the potential for confusion between the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) and the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measures. Removal of measures will ultimately ease provider burden and allow LTCHs to devote more time to provide efficient and effective care to improve patient outcomes.

After consideration of the public comments we received, we are finalizing our proposal to remove the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure from the LTCH QRP, beginning with the FY 2021 LTCH QRP. LTCHs will no longer be required to report the data elements necessary to calculate this measure beginning with October 1, 2018 admissions and discharges.

6. IMPACT Act Implementation Update

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38449), we stated that we intended to specify two measures that would satisfy the domain of accurately communicating the existence and provision of the transfer of health information and care preferences under section 1899B(c)(1)(E) of the Act no later than October 1, 2018, and intended to propose to adopt them for the FY 2021 LTCH QRP with data collection beginning on or about April 1, 2019.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20515), we stated that as a result of the input provided during a public comment period between November 10, 2016 and December 11, 2016, input provided by a technical expert panel (TEP), and pilot measure testing conducted in 2017, we are engaging in continued development work on these two measures, including supplementary measure testing and providing the public with an opportunity for comment in 2018. We stated that we would reconvene a TEP for these measures in mid-2018 which occurred in April 2018. We stated that we now intend to specify the measures under section 1899B(c)(1)(E) of the Act no later than October 1, 2019 and intend to propose to adopt the measures for the FY 2022 LTCH QRP, with data collection beginning with April 1, 2020 admissions and discharges. For more information on the pilot testing, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

We did not receive any public comments regarding this IMPACT Act implementation update.

7. Form, Manner, and Timing of Data Submission Under the LTCH QRP

Under our current policy, LTCHs report data on LTCH QRP assessment-based measures and standardized patient assessment data by reporting the designated data elements for each applicable patient on the LTCH CARE Data Set patient assessment instrument and then submitting the completed instruments to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system. Data on LTCH QRP measures that are also collected by the CDC for other purposes are reported by LTCHs to the CDC through the NHSN, and the CDC then transmits the relevant data to CMS. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38454 through 38456) for the data collection and submission timeframes that we finalized for the LTCH QRP.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20515), we sought input on whether we should move the implementation date of any new version of the LTCH CARE Data Set from the usual release date of April to October in the future.

Comment: Some commenters supported moving the implementation date of the LTCH CARE Data Set from April to October. One commenter supported the proposal as long as significant changes are noted in proposed rulemaking and CMS provides additional time to prepare and comply with new reporting requirements. Another commenter had no position in support of or against the concept of moving the implementation date of a new LTCH CARE Data Set from April to October. Another commenter encouraged CMS to keep the LTCH CARE Data Set update in April as it would allow for changes or comments to be included in the proposed rule.

Response: We appreciate the commenters' input as we determine whether to propose moving the implementation date of the LTCH CARE Data Set from April to October. We would like to clarify that in proposing any updates to the LTCH CARE Data Set, the implementation date of the new version of the LTCH CARE Data Set would not occur until the following year at the earliest. For example, if we propose this change in April 2019, then the implementation of the new version of the LTCH CARE Data Set would not occur until October 1, 2020 at the earliest, as opposed to April 1, 2020. This would give LTCHs an additional 6 months (April-October) to update their systems so that they can comply with new reporting requirements.

8. Changes to the LTCH QRP Reconsideration Requirements

Section 412.560(d)(1) of our regulations states that CMS will send an LTCH written notification of a decision of noncompliance with the measures data and standardized patient assessment data reporting requirements for a particular fiscal year. It also states that CMS will use the QIES ASAP system to provide notification of noncompliance to the LTCH.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20515), we proposed to revise § 412.560(d)(1) to expand the methods by which we would notify an LTCH of noncompliance with the LTCH QRP requirements for a program year. Revised § 412.560(d)(1) would state that we would notify LTCHs of noncompliance with the LTCH QRP requirements via a letter sent through at least one of the following notification methods: the QIES ASAP system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). We believe this change will address feedback from providers who requested additional methods for notification.

We also proposed to revise § 412.560(d)(3) to clarify that we will notify LTCHs, in writing, of our final decision regarding any reconsideration request using the same notification process.

Comment: Many commenters supported the efforts by CMS to provide more methods of communication for notifying LTCHs of LTCH QRP noncompliance and reconsideration decisions. The commenters requested additional details about the timelines and logistics of these methods of notification, such as how providers should specify the recipients of notifications from the MAC. Another

commenter recommended that CMS work with providers to develop a formal notification protocol and, at a minimum, clarify how the proposal will affect current notification procedures before finalizing the proposal.

In addition, some commenters expressed concerns that multiple notification methods and lack of specificity would cause confusion, add uncertainty, and cause delays in the notification process. One commenter suggested that CMS revise the process so that: (1) LTCHs can designate one person at the hospital or within the hospital organization to receive these notices, and (2) LTCHs can choose one method of notification from CMS out of the three options.

Response: We thank commenters for their support. We will use at least one method of notification, and providers will be notified regarding the specific method of communication that we will use via the LTCH QRP Reconsideration and Exception & Extension website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html* and announcements via the PAC listserv. The announcements will be posted annually following the May 15th data submission deadline prior to the distribution of the initial notices of noncompliance determination in late spring/early summer. Messaging will include the method of communication for the notices of noncompliance, instructions for sending a reconsideration request, and the final deadline for submitting the request. This policy would be effective October 1, 2018.

In response to the concerns regarding the multiple notification methods, it is our intent that the announcements posted on our website and sent via the PAC listserv will alleviate any confusion regarding noncompliance decisions and the reconsideration process. With regard to the comment about specifying the recipients of notifications for a specific facility, our notifications are sent to the point of contact on file in the QIES database. This information is populated via the Automated Survey Processing Environment (ASPEN) system. It is the responsibility of the facility to ensure that this information is up-to-date. For information regarding how to update provider information in QIES, we refer providers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/How-to-Update-LTCH-Demographic-Data-1-4-18-Final.pdf*.

After consideration of the public comments we received, we are finalizing our proposal to revise § 412.560(d)(1) of our regulations to state that we will notify LTCHs of noncompliance with the LTCH QRP via a notification sent through at least one of the following methods: the QIES ASAP system, the United States Postal Service, or via an email from the MAC. We are also finalizing our proposal to revise § 412.560(d)(3) of our regulations to clarify that we will notify LTCHs, in writing, of our final decision regarding any reconsideration request using the same notification process.

D. Changes to the Medicare and Medicaid EHR Incentive Programs (Now Referred to as the Medicare and Medicaid Promoting Interoperability Programs)

1. Background and Summaries of Final Policies Included in This Final Rule

a. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare are available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs or eCQMs) using CEHRT. Incentive payments are available to Medicare Advantage (MA) organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that meaningfully use CEHRT.

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated reporting periods. Section 1853(m)(4) of the Act establishes a negative payment adjustment to the monthly prospective payments of a qualifying MA organization if its affiliated eligible hospitals are not meaningful users of CEHRT, beginning in 2015. Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and meaningfully use CEHRT.

b. Summaries of Final Policies Included in This Final Rule

In this final rule, we are adopting final policies based on proposals in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20515 through 20544) to continue advancement of CEHRT utilization, focusing on burden reduction, interoperability and patient access to their health information.

For the reasons discussed in section VIII.D.4. of the preamble of this final rule, we are finalizing an EHR reporting period of a minimum of any continuous 90-day period in CY 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency.

For the reasons discussed in sections VIII.D.5. and VIII.D.6. of the preamble of this final rule, we are finalizing with modification the proposed performance-based scoring methodology, which consists of a smaller set of objectives including e-Prescribing, Health Information Exchange, Provider to Patient Exchange and Public Health and Clinical Data Exchange. We are finalizing the Query of PDMP measure as proposed.

We are finalizing the Verify Opioid Treatment Agreement measure as optional in CY 2019 and CY 2020, with the ability to earn 5 bonus points per year. In addition, eligible hospitals and CAHs must earn a minimum total score of 50 points in order to satisfy the requirement to report on the objectives and measures of meaningful use, which is one of the requirements for an eligible hospital or CAH to be considered a meaningful EHR user and earn an incentive payment and/or avoid a Medicare payment reduction.

For the reasons discussed in section VIII.D.6. of the preamble of this final rule, we are finalizing the new measures Query of PDMP, Verify Opioid Treatment Agreement, and Support Electronic Referral Loops by Receiving and Incorporating Health Information. In addition, we are finalizing the removal of the Coordination of Care Through Patient Engagement objective and its associated measures Secure Messaging, View, Download or Transmit, and Patient Generated Health Data as well as the measures Request/Accept Summary of Care, Clinical Information Reconciliation and Patient-Specific Education. Finally, we are renaming measures within the Health Information Exchange objective. These changes include changing the name from Send a Summary of Care to Support Electronic Referral Loops by Sending Health Information and

renaming the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange objective with the requirement to report on any two measures of the eligible hospital or CAH's choice. In addition, we are renaming the Patient Electronic Access to Health Information objective to Provider to Patient Exchange objective, and renaming the remaining measure, Provide Patient Access to Provide Patients Electronic Access to Their Health Information. We are also finalizing the removal of the exclusion criteria from all of the Stage 3 measures retained except for the measures associated with the Electronic Prescribing objective, Public Health and Clinical Data Exchange objective and the new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information.

For reasons discussed in section VIII.D.9. of the preamble of this final rule, we are finalizing the removal of certain CQMs beginning with the reporting period in CY 2020 as well as the CY 2019 reporting requirements as proposed to align the CQM reporting requirements for the Promoting Interoperability Programs with the Hospital IQR Program.

For reasons discussed in sections VIII.D.10. and VIII.D.11. of the preamble of this final rule, we are finalizing the proposed codification of policies for subsection (d) Puerto Rico hospitals and amending our regulations under Parts 412 and 495 such that the provisions that apply to eligible hospitals would include subsection (d) Puerto Rico hospitals unless otherwise indicated.

For reasons discussed in section VIII.D.12. of the preamble of this final rule, we are finalizing the $500,000 prior approval threshold for contracts and RFPs by amending §§ 495.324(b)(2) and (3) and 495.324(d). We are also finalizing the deadlines for enhanced FFP under the Medicaid Promoting Interoperability Programs,

We also note that we received many comments that were unrelated to the Promoting Interoperability Programs or otherwise outside the scope of the proposed rule, and we have not responded to these comments in this final rule. These comments included requirements specific to the Merit-based Incentive Payment System (MIPS), regulation pertaining to vendors, information blocking clarification, functionality requirements for application programming interfaces (APIs), the 2015 Edition of CEHRT and issuance of Medicaid incentive payments in CY 2021. We thank all the commenters for their suggestions and feedback on the Promoting Interoperability Programs.

2. Renaming the EHR Incentive Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20516), we proposed scoring and measurement policies to move beyond the three stages of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. To better reflect this focus, we have changed the name of the Medicare and Medicaid EHR Incentive Programs to the Promoting Interoperability (PI) Programs, and the new name applies for Medicare fee-for-service, Medicare Advantage, and Medicaid. We believe this change will help highlight the enhanced goals of the program and better contextualize the program changes discussed in the following sections. We also noted that the former name, Medicare and Medicaid EHR Incentive Programs, does not adequately reflect the current status of the programs, as the incentive payments under Medicare generally have ended (with the exception of subsection (d) Puerto Rico hospitals as discussed in section VIII.D.10. of the preambles of the proposed rule and this final rule) and will end under Medicaid in 2021.

3. Certification Requirements Beginning in 2019

Beginning with the EHR reporting period in CY 2019, participants in the Promoting Interoperability Programs are required to use the 2015 Edition of CEHRT pursuant to the definition of CEHRT under § 495.4. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20516 through 20517), we did not propose to change this policy, and we continue to believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. In reviewing the state of health information technology, it is clear the 2014 Edition certification criteria are out of date and insufficient for provider needs in the evolving health IT industry. In addition, we indicated it would be beneficial to health IT developers and health care providers to move to more up-to-date standards and functions that better support interoperable exchange of health information and improve clinical workflows.

Eligible hospitals and CAHs will see a reduction in burden through relief from being required to certify to a legacy system, and can use the 2015 Edition to better streamline workflows and utilize more comprehensive functions to meet patient safety goals and improve care coordination across the continuum. Maintaining only one edition of certification requirements would also reduce the burden for health IT developers as well as ONC-authorized testing laboratories and certification bodies because they would no longer have to support two, increasingly distant sets of requirements.

One of the major improvements in the 2015 Edition is the API functionality. API functionality supports health care providers and patient electronic access to health information, contributes to quality improvement, and offers greater interoperability between systems.

The 2015 Edition also includes certification criterion specifying a core set of data that health care providers have noted are critical to interoperable exchange and can be exchanged across a wide variety of other settings and use cases, known as the Common Clinical Data Set (C–CDS) (80 FR 62603). The US Core Data for Interoperability (USCDI) builds off the Common Clinical Data Set definition adopted for the 2015 Edition of certified health IT and referenced in the EHR Incentive Program, for instance as the data which must be included in a summary care record. The USCDI aims to support the goals set forth in the 21st Century Cures Act by specifying a common set of data classes that are required for interoperable exchange and identifying a predictable, transparent, and collaborative process for achieving those goals. The USCDI is referenced by the Draft Trusted Exchange Framework,[407] which is intended to enable HINs and Qualified HINs to securely exchange electronic health information in support of a range of permitted purposes, including treatment, payment, operations, individual access, public health, and benefits determination.

We also note that the Provide Patients Electronic Access to Their Health Information measure's technical requirements are updated in the 2015 Edition and support health care providers' interest in providing patients with access to their data in a manner that is helpful to the patient and aligns with the API requirement in the Promoting Interoperability Program. This includes a new function that supports patient access to their health information through email transmission to any third party the patient chooses and through a second encrypted method of transmission.

In working with ONC we were able to estimate the percentage of eligible clinicians, eligible hospitals and CAHs that have 2015 Edition CEHRT available

[407] *https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf.*

to them based on vendor readiness and information, and it appears that the transition from the 2014 Edition to the 2015 Edition is on schedule for the EHR reporting period in CY 2019.

We continue to recognize there is a burden associated with development and deployment of new technology, but we believe requiring use of the most recent version of CEHRT is important in ensuring health care providers use technology that has improved interoperability features and up-to-date standards to collect relevant patient health information. The 2015 Edition includes key updates to functions and standards that support improved interoperability and clinical effectiveness through the use of health IT.

We received many comments regarding the requirement to use the 2015 Edition of CEHRT beginning in 2019. As we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20516), we were not proposing to change the requirement. Because the requirement was not a subject of this rulemaking, we are not responding to the comments we received, although we will consider them to inform our future policy making in this subject area.

4. Revisions to the EHR Reporting Period in 2019 and 2020

For the reasons discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20517 through 20518), we proposed that the EHR reporting periods in 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency would be a minimum of any continuous 90-day period within each of the respective calendar years. Eligible professionals (EPs) that attest to a State for the State's Medicaid Promoting Interoperability Program and eligible hospitals and CAHs attesting to CMS or the State's Medicaid Promoting Interoperability Program would attest to meaningful use of CEHRT for an EHR reporting period of a minimum of any continuous 90-day period from January 1, 2019 through December 31, 2019 and from January 1, 2020 through December 31, 2020, respectively.

We proposed corresponding changes to the definition of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4.

Comment: The majority of commenters strongly supported CMS' proposal to use a 90-day EHR reporting period in 2019 and 2020 in order to maximize the time available to implement and roll out system revisions.

Response: We appreciate the commenters' support of a 90-day EHR reporting period in 2019 and 2020 and believe this will reduce the burden on health care providers, EHR developers and vendors by allowing sufficient time for system upgrades, testing and implementation of the 2015 Edition of CEHRT functionalities and adjustment to the new scoring methodology, objectives and measures that we are finalizing in section VIII.D.5 and VIII.D.6.

Comment: Multiple commenters requested clarification on whether the 2015 Edition of CEHRT has to be in place by January 1, 2019 for the 2019 reporting year.

Response: For the Promoting Interoperability Programs, the 2015 Edition of CEHRT must be implemented for an EHR reporting period in CY 2019, which will be a minimum of 90 days as established in this final rule. It does not need to be implemented on January 1, 2019.

Comment: A few commenters requested a 90-day EHR reporting period in 2021 for both the objectives and measures and CQMs.

Response: We believe it is premature to establish policy beyond CY 2020 and decline to extend the 90-day EHR reporting period beyond CY 2020. We are finalizing the EHR reporting period specific to CYs 2019 and 2020 in order to provide the additional flexibility for vendors and health care providers that are in the process of implementing the 2015 Edition of CEHRT for an EHR reporting period beginning in CY 2019, reduce burden and allow eligible hospitals and CAHs to adjust to the new scoring and reporting methodology.

After consideration of the public comments we received, we are finalizing as proposed that the EHR reporting period is a minimum of any continuous 90-day period in CY 2019 and 2020 for new and returning participants in the Promoting Interoperability Programs attesting to CMS or their State Medicaid agency. Eligible professionals, eligible hospitals, and CAHs may select an EHR reporting period of a minimum of any continuous 90-day period in CY 2019 from January 1, 2019 through December 31, 2019 and in CY 2020 from January 1, 2020 through December 31, 2020.

The applicable incentive payment year and payment adjustment years for the EHR reporting period in 2019 and 2020, as well as the deadlines for attestation and other related program requirements, will remain the same as established in prior rulemaking.

We are finalizing as proposed the corresponding changes to the definition of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4.

5. Scoring Methodology for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program

a. Background

As we considered the future direction of EHR reporting for the Promoting Interoperability Program, we considered how to increase the focus of EHR reporting on interoperability and sharing data with patients. We also considered the history of the program stages, as well as the increased flexibility provided by Public Law 115–123, the Bipartisan Budget Act of 2018. We refer readers to section VIII.D.5. of the preamble of the proposed rule for a discussion of the program stages. In light of these considerations, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20518 through 20524), we proposed a new performance-based scoring methodology with fewer measures, which would move away from the threshold-based methodology that we currently use. We stated that we believe this change would provide a more flexible, less burdensome structure, allowing eligible hospitals and CAHs to put their focus back on patients. The introduction of a performance-based scoring methodology would continue to encourage hospitals to push themselves on measures that we continue to hear are most applicable to how they deliver care to patients, instead of increasing thresholds on measures that may not be as applicable to an individual hospital. We stated that our goal is to provide increased flexibility to eligible hospitals and CAHs without compromising the integrity of the Medicare Promoting Interoperability Program and enable them to focus more on patient care and health data exchange through interoperability.

We proposed that the performance-based scoring methodology would apply to eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019. This would include ''Medicare-only'' eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use) as well as ''dual-eligible'' eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the

Medicare payment reduction for failing to demonstrate meaningful use, and are also eligible to earn a Medicaid incentive payment for meaningful use).

We did not propose to apply the performance-based scoring methodology to ''Medicaid-only'' eligible hospitals (those that are only eligible to earn a Medicaid incentive payment for meaningful use of CEHRT, and are not eligible for an incentive payment under Medicare for meaningful use and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use) that submit an attestation to their State Medicaid agency for the Medicaid Promoting Interoperability Program. Instead, as discussed in section VIII.D.7. of the preambles of the proposed rule and this final rule, we proposed to give States the option to adopt the performance-based scoring methodology along with the measure proposals discussed in section VIII.D.6. of the preambles of the proposed rule and this final rule for their Medicaid Promoting Interoperability Programs through their State Medicaid HIT Plans.

To accomplish our goal of a performance-based program that reduces burden while promoting interoperability, and taking into account the feedback from our stakeholders, we outlined a proposal using a performance-based scoring methodology in the proposed rule and the following sections of the preamble of this final rule. We believe the proposal promotes interoperability, helps to maintain a focus on patients, reduces burden and provides greater flexibility. The proposal takes an approach that weighs each measure based on performance, and allows eligible hospitals and CAHs to emphasize measures that are most applicable to their care delivery methods, while putting less emphasis on those measures that may be less applicable.

We stated that if we did not finalize a new scoring methodology, we would maintain the current Stage 3 methodology with the same objectives, measures and requirements, but we would include the two new opioid measures proposed in section VIII.D.6.b. of the preamble of the proposed rule, if finalized. The current structure of the Stage 3 objectives and measures under § 495.24(c) for eligible hospitals and CAHs attesting to CMS requires them to report on six objectives that include 16 measures. This structure requires the eligible hospital or CAH to report on all measures and meet the thresholds for most of the measures or claim an exclusion as part of demonstrating meaningful use to avoid the payment adjustment, or to earn an incentive in the case of subsection (d) Puerto Rico hospitals. A general summary overview of the current objectives, measures, and reporting requirements is included in the table below.

EXISTING STAGE 3 OBJECTIVES, MEASURES AND REPORTING REQUIREMENTS FOR THE MEDICARE EHR INCENTIVE PROGRAM FOR ELIGIBLE HOSPITALS AND CAHS

Objective	Measure (stage 3 threshold)	Reporting requirement
Protect Patient Health Information	Security Risk Analysis (Yes/No)	Report.
Electronic Prescribing	e-Prescribing (>25%)	Report and meet threshold.
Patient Electronic Access to Health Information.	Provide Patient Access (>50%) Patient Specific Education (>10%).	Report and meet thresholds.
Coordination of Care Through Patient Engagement.	View, Download or Transmit (at least one patient) Secure Messaging (>5%). Patient Generated Health Data (>5%).	Report all, but only meet the threshold for two.
Health Information Exchange	Send a Summary of Care (>10%) Request/Accept Summary of Care (>10%). Clinical Information Reconciliation (>50%).	Report all, but only meet the threshold for two.
Public Health and Clinical Data Registry Reporting.	Immunization Registry Reporting Syndromic Surveillance Reporting. Electronic Case Reporting. Public Health Registry Reporting. Clinical Data Registry Reporting. Electronic Reportable Laboratory Result Reporting.	Report Yes/No to Three Registries.

b. Performance-Based Scoring Methodology

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20518 through 20524), we proposed a new scoring methodology to include a combination of new measures, as well as the existing Stage 3 measures of the EHR Incentive Program, broken into a smaller set of four objectives and scored based on performance and participation. We believe this is a significant overhaul of the existing program requirements, which include six objectives, scored on a pass/fail basis. The smaller set of objectives would include e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. We proposed these objectives to promote specific HHS priorities. We included the e-Prescribing and Health Information Exchange objectives in part to capture what we believe are core goals for the 2015 Edition in line with section 1886(n)(3)(A) of the Act. These core goals promote interoperability between health care providers and health IT systems to support safer, more coordinated care. The Provider to Patient Exchange objective promotes patient awareness and involvement in their health care through the use of APIs, and ensures patients have access to their medical data. Finally, the Public Health and Clinical Data Exchange objective supports the ongoing systematic collection, analysis, and interpretation of data that may be used in the prevention and controlling of disease through the estimation of health status and behavior. The integration of health IT systems into the national network of health data tracking and promotion improves the efficiency, timeliness, and effectiveness of public health surveillance.

Under the proposed scoring methodology, eligible hospitals and CAHs would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure would be scored based on the eligible hospital or CAH's performance for that measure, except for the Public Health and Clinical Data Exchange objective, which requires a yes/no attestation. Each

measure would contribute to the eligible hospital or CAH's total Promoting Interoperability score. The scores for each of the individual measures would be added together to calculate the total Promoting Interoperability score of up to 100 possible points for each eligible hospital or CAH. A total score of 50 points or more would satisfy the requirement to report on the objectives and measures of meaningful use under § 495.24, which is one of the requirements for an eligible hospital or CAH to be considered a meaningful EHR user under § 495.4 and thus earn an incentive payment and/or avoid a Medicare payment reduction. Eligible hospitals and CAHs scoring below 50 points would not be considered meaningful EHR users.

While this approach maintains some of the same requirements of the EHR Incentive Program, we note that we proposed to reduce the overall number of required measures from 16 to 6. We also note that the measures we proposed to include contribute to the goal of increased interoperability and patient access, and no longer require the burdensome predefined thresholds of the EHR Incentive Program, and thus allow new flexibility for eligible hospitals and CAHs in how they are scored. We stated that we believe this proposal allows eligible hospitals and CAHs to achieve high performance in one area where they excel, in order to offset performance in an area where they may need additional improvement. In this manner, we stated that we believe eligible hospitals and CAHs could still be considered meaningful EHR users while continuing to monitor their progress on each of the measures. This approach also helps further promote interoperability by requiring all measures and thus all forms of interoperability across the three objectives.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20520), we also considered an alternative approach in which scoring would occur at the objective level, instead of the individual measure level, and eligible hospitals or CAHs would be required to report on only one measure from each objective to earn a score for that objective. Under this scoring methodology, instead of six required measures, the eligible hospital or CAH's total Promoting Interoperability score would be based on only four measures, one measure from each objective. Each objective would be weighted similarly to how the objectives are weighted in our proposed methodology, and bonus points would be awarded for reporting any additional measures beyond the required four. In the proposed rule, we sought public comment on this alternative approach, and whether additional flexibilities should be considered, such as allowing eligible hospitals and CAHs to select which measures to report on within an objective and how those objectives should be weighted, as well as whether additional scoring approaches or methodologies should be considered.

In our proposed scoring methodology, the Electronic Prescribing objective would contain three measures each weighted differently to reflect their potential availability and applicability to the hospital community. In addition to the existing e-Prescribing measure, we proposed to add two new measures to the Electronic Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. For more information about these two proposed measures, we refer readers to section VIII.D.6.b. of the preambles of the proposed rule and this final rule. The e-Prescribing measure would be required for reporting and weighted at 10 points in CY 2019, because we believe it would be applicable to most eligible hospitals and CAHs. In the event that an eligible hospital or CAH meets the criteria and claims the exclusion for the e-Prescribing measure in 2019, the 10 points available for that measure would be redistributed equally among the measures under the Health Information Exchange objective:

- Support Electronic Referral Loops By Sending Health Information Measure (25 points)
- Support Electronic Referral Loops By Receiving and Incorporating Health Information (25 points)

In the proposed rule, we sought public comment on whether this redistribution is appropriate for 2019, or whether the points should be distributed differently.

We stated that the Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement measures would be optional for EHR reporting periods in 2019. These new measures may not be available to all eligible hospitals and CAHs for an EHR reporting period in 2019 as they may not have been fully developed by their health IT vendor, or not fully implemented in time for data capture and reporting. Therefore, we did not propose to require these two new measures in 2019, although eligible hospitals and CAHs may choose to report them and earn up to 5 bonus points for each measure. We proposed to require these measures beginning with the EHR reporting period in 2020, and we sought public comment on this proposal. We note that due to varying State requirements, not all eligible hospitals and CAHs would be able to e-prescribe controlled substances, and thus these measures would not be available to them. For these reasons, we proposed an exclusion for these two measures beginning with the EHR reporting period in 2020. The exclusion would provide that any eligible hospital or CAH that is unable to report the measure in accordance with applicable law would be excluded from reporting the measure, and the 5 points assigned to that measure would be redistributed to the e-Prescribing measure.

As the two new opioid measures become more broadly available in CEHRT, we proposed each of the three measures within the Electronic Prescribing objective would be worth 5 points beginning in 2020. We note that requiring these two measures would add 10 points to the maximum total score as these measures would no longer be eligible for optional bonus points. To maintain a maximum total score of 100 points, beginning with the EHR reporting period in 2020, we proposed to reweight the e-Prescribing measure from 10 points down to 5 points, and reweight the Provide Patients Electronic Access to Their Health Information measure from 40 points down to 35 points as illustrated in the table below. We proposed that if the eligible hospital or CAH qualifies for the e-Prescribing exclusion and is excluded from reporting all three of the measures associated with the Electronic Prescribing objective as described in section VIII.D.6.b. of the preambles of the proposed rule and this final rule, the 15 points for the Electronic Prescribing objective would be redistributed evenly among the two measures associated with the Health Information Exchange objective and the Provide Patients Electronic Access to Their Health Information measure by adding 5 points to each measure.

In the proposed rule, we sought public comment on the proposed distribution of points beginning with the EHR reporting period in 2020, but we did not receive any comments on this proposal.

After consideration of the public comments we received, we are finalizing our proposed scoring for the Electronic Prescribing objective as proposed but with the modifications discussed at the end of this section VIII.D.5. of the preamble of this final rule. The e-Prescribing measure is finalized as proposed, the Query of PDMP measure is finalized as proposed, and the Verify Opioid Treatment Agreement measure is finalized with

modification. We are finalizing the regulation text for the Electronic Prescribing objective scoring at § 495.24(e)(5). In addition, we refer readers to section VIII.D.6.b. of the preamble of this final rule where we discuss our reasons for adopting the Query of PDMP measure as proposed and the Verify Opioid Treatment Agreement measure with modification.

For the Health Information Exchange objective, we proposed to change the name of the existing Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information, and proposed a new measure which combines the functionality of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures into a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. For more information about the proposed measure and measure changes, we refer readers to section VIII.D.6.c. of the preambles of the proposed rule and this final rule. Eligible hospitals and CAHs would be required to report both of these measures, each worth 20 points toward their total Promoting Interoperability score. These measures are weighted heavily to emphasize the importance of sharing health information through interoperable exchange in an effort to promote care coordination and better patient outcomes. Similar to the two new measures in the Electronic Prescribing objective, the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure may not be available to all eligible hospitals and CAHs as it may not have been fully developed by their health IT vendor, or not fully implemented in time for an EHR reporting period in 2019. For these reasons, we proposed an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure; any eligible hospital or CAH that is unable to implement the measure for an EHR reporting period in 2019 would be excluded from having to report this measure.

In the event that an eligible hospital or CAH claims an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information measure, and that measure would then be worth 40 points. In the proposed rule, we sought public comment on whether this redistribution is appropriate, or whether the points should be redistributed to other measures instead.

We did not receive any comments regarding the redistribution of points if an exclusion is claimed for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure.

We are finalizing our proposed scoring of the Health Information Exchange objective as proposed. We are finalizing the regulation text for the Health Information Exchange objective and measure scoring at § 495.24(e)(6). In addition, measure specification details can also be found in section VIII.D.6.c. of the preamble of this final rule.

We proposed to weight the one measure in the Provider to Patient Exchange objective, the Provide Patients Electronic Access to Their Health Information measure, at 40 points toward the total Promoting Interoperability score in 2019 and 35 points beginning in 2020. We proposed that this measure would be weighted at 35 points beginning in 2020 to account for the two new opioid measures, which would be worth 5 points each beginning in 2020 as proposed above. We believe this objective and its associated measure get to the core of improved access and exchange of patient data in promoting interoperability and are the crux of the Medicare Promoting Interoperability Program. This exchange of data between health care provider and patient is imperative in order to continue to improve interoperability, data exchange and improved health outcomes. We believe that it is important for patients to have control over their own health information, and through this highly weighted objective, we are aiming to show our dedication to this effort.

Comment: Many commenters supported CMS' proposed weighting of the Provide Patients Electronic Access to Their Health Information measure.

Response: We appreciate the support regarding the weight of this measure. We agree that it is an essential part of the Promoting Interoperability Program and therefore deserves to be highly weighted.

Comment: One commenter suggested that reporting on the Provide Patients Electronic Access to Their Health Information measure should be similar to the Security Risk Analysis measure in that it would be attested to by eligible hospitals and CAHs, but would not be scored.

Response: We thank the commenter for its recommendation. We decline to follow the approach the commenter recommended for the Provide Patients Electronic Access to Their Health Information measure. As we indicated in the proposed rule (83 FR 20516), we were increasing our focus on interoperability and improving patient access to health information. In addition, in the proposed rule (83 FR 20521) we stated that we believe the measure gets to the core of improved access and exchange of patient data in promoting interoperability and is the crux of the Medicare Promoting Interoperability Program, therefore it was heavily weighted due to its importance and focus. We will consider this recommendation in future policy decisions regarding the Promoting Interoperability Program.

Comment: One commenter requested that CMS score the Provide Patients Electronic Access to Their Health Information measure based on the total percentage of their patient population who have electronic access to their medical records, as opposed to the proposed number/denominator performance-based scoring that includes the entire patient population.

Response: We believe that is important that every patient has access to their health information electronically, we also believe that as we are moving forward to improving interoperability the patient should be the main partner in their health. We are committed to making sure that patients have access to their data electronically and believe this number will increase rapidly over the years. Therefore, we think that it is in the best interest of the Promoting Interoperability Program to include all patients in the denominator in part in order to ensure every patient is provided access and to better understand the amount of patients accessing their data electronically. As a result we will continue with the numerator/denominator performance-based scoring methodology.

After consideration of the comments, we are finalizing with modification the Provider to Patient Exchange objective scoring. The Provide Patients Electronic Access to Their Health Information measure will be worth up to 40 points beginning in CY 2019. We are finalizing the regulation text for this final policy at § 495.24(e)(7). For additional measure information, we refer readers to section VIII.6.d. of the preamble of this final rule.

The measures under the Public Health and Clinical Data Exchange objective are reported using yes/no responses and thus cannot be scored based on performance. We proposed that for this objective, the eligible hospital or CAH would be required to meet this objective in order to receive a score and be considered a meaningful user of EHR. We proposed that the eligible hospital

or CAH will be required to report the Syndromic Surveillance Reporting measure and one additional measure of the eligible hospital or CAH's choosing from the following: Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, Electronic Reportable Laboratory Result Reporting. We proposed an eligible hospital or CAH would receive 10 points for the objective if they attest a ''yes'' response for both the Syndromic Surveillance Reporting measure and one additional measure of their choosing. If the eligible hospital or CAH fails to report either one of the two measures required for this objective, the eligible hospital or CAH would receive a score of zero for the objective, and a total score of zero for the Promoting Interoperability Program. We understand that some hospitals may not be able to report the Syndromic Surveillance Reporting measure, or may not be able to report some of the other measures under this objective. Therefore, we proposed to maintain the current exclusions for these measures that were finalized in previous rulemaking. If an eligible hospital or CAH claims an exclusion for one or both measures required for this objective, we proposed the 10 points for this objective would be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the proposed Provider to Patient Exchange objective, making that measure worth 50 points in 2019 and 45 points beginning in 2020. Reporting more than two measures for this objective would not earn the eligible hospital or CAH any additional points. We refer readers to section VIII.D.6.e. of the preambles of the proposed rule and this final rule in regards to the proposals for the current Public Health and Clinical Data Exchange objective and its associated measures.

Comment: A few commenters expressed concern that the Public Health and Clinical Data Exchange measures would be deemphasized if a minimum score of 50 points is required for reporting on the Promoting Interoperability objectives and measures or if the number of measures that must be reported is reduced from three to two.

Response: We appreciate the commenters' feedback. We value the importance of the Public Health and Clinical Data Exchange objective. As we noted in the proposed rule (83 FR 20535 through 20536), stakeholders have indicated that some of the existing active engagement requirements are complicated and confusing and contribute to unintended burden, and our proposals were intended to address these concerns. We disagree that our proposals would deemphasize the Public Health and Clinical Data Exchange measures because eligible hospitals and CAHs would be required to report on (or claim exclusions for) two of these measures. Failure to do so would result in a score of zero for the Promoting Interoperability Program. Requiring the measures to be reported as part of the program confirms the importance of the Public Health and Clinical Data Exchange objective. While it would not be required, eligible hospitals and CAHs may choose to report on additional Public Health and Clinical Data Exchange measures, as they deem appropriate for their daily workflow, although they would not receive additional points for such reporting.

After consideration of the public comments we received, we are finalizing our proposal for scoring the Public Health and Clinical Data Exchange objective as proposed but with the following modification. Instead of requiring eligible hospitals and CAHs to report the Syndromic Surveillance Reporting measure and one additional measure of their choosing, we will allow them to choose both of the measures that they will report. Eligible hospitals and CAHs must select two of the following measures to report on: Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Electronic Reportable Laboratory Result Reporting. As stated in section VIII.6.e. of the preamble of this final rule, we believe the Syndromic Surveillance Reporting measure should not be required as we understand some hospitals and local jurisdictions are not able to send and receive syndromic surveillance files. In addition, allowing eligible hospitals and CAHs to report on any two measures of their choice promotes flexibility in reporting and allows them to focus on the public health measures that are most relevant to them and their patient populations. For additional measure information, we refer readers to section VIII.6.e. of the preamble of this final rule. We are finalizing the regulation text for this policy at § 495.24(e)(8).

We proposed that the Stage 3 objective, Protect Patient Health Information, and its associated measure, Security Risk Analysis, would remain part of the program, but would no longer be scored as part of the objectives and measures, and would not contribute to the hospital's total score for the objectives and measures. To earn any score in the Promoting Interoperability Program, we proposed eligible hospitals and CAHs would have to attest that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the EHR reporting period occurs. We believe the Security Risk Analysis measure involves critical tasks and note that the Health Insurance Portability and Accountability Act (HIPAA) Security Rule requires covered entities to conduct a risk assessment of their health care organization. This risk assessment will help eligible hospitals and CAHs comply with HIPAA's administrative, physical, and technical safeguards.[408] Therefore, we believe that every eligible hospital and CAH should already be meeting the requirements for this objective and measure as they are required by HIPAA. We still believe this objective and its associated measure is imperative in ensuring the safe delivery of patient health data. As a result, we would maintain the Security Risk Analysis measure as part of the Promoting Interoperability Program, but we would not score the measure. We sought public comment on whether the Security Risk Analysis measure should remain part of the program as an attestation with no associated score, or whether there should be points associated with this measure.

Comment: A few comments suggested that CMS should assign points for completing the actions of the Security Risk Analysis measure.

Response: As we discussed in the proposed rule (83 FR 20521 through 20522), we do not believe that the Security Risk Analysis measure should be scored because it includes actions required under HIPAA and ensures in part that the eligible hospitals and CAHs are in compliance with administrative, physical, and technical safeguards. We believe no additional points should be awarded because eligible hospitals and CAHs should already have been performing these actions.

Comment: The majority of commenters supported CMS' proposal to require eligible hospitals and CAHs to attest to the completion of the actions of the Security Risk Analysis measure with no associated score in order to be eligible to receive an overall score in the Promoting Interoperability Program as they believed this measure is a requirement in order to safely transmit their patient data and successfully participate in the Promoting Interoperability Program.

[408] *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html.*

Response: As discussed in the preceding response, we agree that this measure should not be scored.

After consideration of the public comments we received, we are finalizing our proposal to require, as a condition of earning a score in the Promoting Interoperability Program, eligible hospitals and CAHs to attest that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the EHR reporting period occurs. We are finalizing the regulation text for this policy at § 495.24(e)(4).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20522), we stated that, similar to how eligible hospitals and CAHs currently submit data, the eligible hospital or CAH would submit their numerator and denominator data for each performance measure, and a yes/no response for each of the two reported measures under the proposed Public Health and Clinical Data Exchange objective. To earn a score greater than zero, in addition to completing the activities required by the Security Risk Analysis measure, the hospital would submit their complete numerator and denominator or yes/no data for all required measures. The numerator and denominator for each performance measure would then translate to a performance rate for that measure and would be applied to the total possible points for that measure. For example, the e-Prescribing measure is worth 10 points. A numerator of 200 and denominator of 250 would yield a performance rate of (200/250) = 80 percent. This 80 percent would be applied to the 10 total points available for the e-Prescribing measure to determine the performance score. A performance rate of 80 percent for the e-Prescribing measure would equate to a measure score of 8 points (performance rate * total possible measure points = points awarded toward the total Promoting Interoperability score; 80 percent * 10 = 8 points). These calculations and application to the total Promoting Interoperability score, as well as an example of how they would apply are set out in the tables below.

When calculating the performance rates and measure and objective scores, we stated that we would generally round to the nearest whole number. For example, if an eligible hospital or CAH received a score of 8.53 the nearest whole number would be 9. Similarly, if the eligible hospital or CAH received a score of 8.33 the nearest whole number would be 8. In the event that the eligible hospital or CAH receives a performance rate or measure score of less than 0.5, as long as the eligible hospital or CAH reported on at least one patient for a given measure, a score of 1 would be awarded for that measure. We stated that we believe this is the best method for the issues that might arise with the decimal points and is the easiest for computations.

In order to meet statutory requirements and HHS priorities, we stated that the eligible hospital or CAH would need to report on all of the required measures across all objectives in order to earn any score at all. Failure to report the numerator and denominator of any required measure, or reporting a ''no'' response on a required yes/no response measure, unless an exclusion applies would result in a score of zero.

As stated earlier, an eligible hospital or CAH would need to earn a total Promoting Interoperability score of 50 points or more in order to satisfy the requirement to report on the objectives and measures of meaningful use under § 495.4. Our aim is that every patient has control of and access to their health data, and we believe that the proposed minimum Promoting Interoperability score is consistent with the current goals of the program that focus on interoperability and providing patients access to their health information. Our vision is for every eligible hospital and CAH to perform at 100 percent for all of the objectives and associated measures. However, we understand the constraints that health care providers face in providing care to patients and seek to provide flexibility for hospitals to create their own score using measures that are best suited to their practice. We also believe it is important to be realistic about what can be achieved. This required score may be adjusted over time as eligible hospitals and CAHs adjust to the new focus and scoring methodology of the Medicare Promoting Interoperability Program. We believe that the 50-point minimum Promoting Interoperability score provides the necessary benchmark to encourage progress in interoperability and also allows us to continue to adjust this benchmark as eligible hospitals and CAHs progress in health IT. We believe that this approach allows eligible hospitals and CAHs to achieve high performance in one area to offset performance in an area where a participant may need additional improvement. In the proposed rule, we sought public comment on whether this minimum score is appropriate, or whether a higher or lower minimum score would be better suited for the first year of this new scoring methodology.

Comment: The majority of commenters supported the proposed 50-point minimum Promoting Interoperability score to satisfy the requirement to report on the objectives and measures of meaningful use under § 495.4. A few commenters requested a lower minimum score so that eligible hospitals and CAHs would have an opportunity to adjust to the new measures and scoring methodology.

Response: We appreciate the feedback regarding the proposed minimum 50-point score. We decline to lower the minimum score as we continue to believe that 50 points is a necessary benchmark to encourage progress in interoperability and also allows us to continue to adjust this benchmark as eligible hospitals and CAHs progress in health IT. We believe that this approach allows eligible hospitals and CAHs to achieve high performance in one area to offset performance in an area where a participant may need additional improvement.

After consideration of the public comments we received, we are finalizing that for an eligible hospital or CAH to earn a score greater than zero, in addition to completing the activities required by the Security Risk Analysis measure, the hospital must submit their complete numerator and denominator or yes/no data for all required measures. The numerator and denominator for each performance measure will translate to a performance rate for that measure and will be applied to the total possible points for that measure. In addition, we are finalizing that an eligible hospital or CAH must earn a total Promoting Interoperability score of 50 points or more in order to satisfy the requirement to report on the objectives and measures of meaningful use under § 495.24, which is one of the requirements for an eligible hospital or CAH to be considered a meaningful EHR user under § 495.4. We are finalizing regulatory text at § 495.24(e) to reflect this final policy.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20522), we stated that we believe our proposal increases flexibility and helps to ease the burden on eligible hospitals and CAHs as well as provide additional options for meeting the required objectives. The proposed changes would allow the eligible hospital or CAH to focus on the measures that are more appropriate for the ways in which they deliver care to patients and types of services that they provide and improve on areas in which an eligible hospital or CAH might need some support. We believe that with this new proposed approach we are reducing administrative burden and allowing

health care providers to focus more on their patients. The tables below illustrate our proposal for the new scoring methodology and an example of application of the proposed scoring methodology.

PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN 2019

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	10 points.
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus.
	Bonus: Verify Opioid Treatment Agreement	5 points bonus.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points.
Public Health and Clinical Data Exchange.	Syndromic Surveillance Reporting (Required)	10 points.
	Choose one or more additional:	
	Syndromic Surveillance Reporting.	
	Immunization Registry Reporting.	
	Electronic Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Electronic Reportable Laboratory Result Reporting.	

PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY BEGINNING WITH EHR REPORTING PERIODS IN 2020

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	5 points.
	Query of Prescription Drug Monitoring Program (PDMP)	5 points.
	Verify Opioid Treatment Agreement	5 points.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	35 points.
Public Health and Clinical Data Exchange.	Syndromic Surveillance Reporting (Required)	10 points.
	Choose one or more additional:	
	Immunization Registry Reporting.	
	Electronic Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Electronic Reportable Laboratory Result Reporting.	

In the proposed rule, we sought public comment on whether these measures are weighted appropriately, or whether a different weighting distribution, such as equal distribution across all measures would be better suited to this program and this proposed scoring methodology. We also sought public comment on other scoring methodologies such as the alternative we considered and described earlier in this section.

PROPOSED SCORING METHODOLOGY EXAMPLE

Objective	Measures	Numerator/ denominator	Performance rate	Score
e-Prescribing	e-Prescribing	200/250	80%	8 points.
	Query of Prescription Drug Monitoring Program	150/175	86%	5 bonus points.
	Verify Opioid Treatment Agreement	N/A	N/A	0 points.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information.	135/185	73%	15 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	145/175	83%	17 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information.	350/500	70%	28 points
Public Health and Clinical Data Exchange.	Syndromic Surveillance Reporting (Required)	Yes.		
	Choose one or more additional:			
	Immunization Registry Reporting Electronic Case Reporting. Public Health Registry Reporting. Clinical Data Registry Reporting. Electronic Reportable Laboratory Result Reporting.	Yes	N/A	10 points.
Total Score				83 points.

We also sought public comment on the feasibility of the new scoring methodology in 2019 and whether eligible hospitals and CAHs would be able to implement the new measures and reporting requirements under this performance-based scoring methodology. In addition, we note that in section VIII.D.8. of the preamble of the proposed rule, we sought public comment on how the Promoting Interoperability Program should evolve in future years regarding the future of the new scoring methodology and related aspects of the program.

We proposed to codify the proposed new scoring methodology in a new paragraph (e) under § 495.24. We also proposed to revise the introductory text of § 495.24 and the heading to paragraph (c) of this section to provide that the criteria specified in proposed new paragraph (e) would be applicable for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years. Further, we proposed to revise the introductory text of § 495.24 and the heading to paragraph (d) of this section to provide that the criteria specified in paragraph (d) would be applicable for eligible hospitals and CAHs attesting to a State for the Medicaid Promoting Interoperability Program for 2019 and subsequent years.

Comment: Many commenters supported CMS' proposed scoring methodology in which eligible hospitals and CAHs would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level.

Some commenters supported CMS' alternative approach to scoring in which scoring would occur at the objective level, instead of the individual measure level, and eligible hospitals or CAHs would be required to report on only one measure from each objective to earn a score for that objective.

Response: We appreciate the many commenters who supported the proposed scoring methodology. We decline to finalize the alternative approach to scoring. Many commenters suggested that the Public Health and Clinical Data Exchange objective would be deemphasized by reducing the reporting requirement to only one measure. In addition, the other objectives containing more than one measure are the Electronic Prescribing objective and the Health Information Exchange objective. For the Electronic Prescribing objective, we note that both the Query of PDMP and Verify Opioid Treatment Agreement measures are optional for reporting for CY 2019; therefore we believe this objective could require reporting on only one measure as opposed to multiple measures.

Comment: Many commenters supported CMS' proposal to reduce the number of measures to be reported as part of the Promoting Interoperability Program.

Response: We appreciate commenters support of our proposal to reduce the number of measures required to be reported as part of the Promoting Interoperability Program. We believe the reduction in reporting will relieve provider burden through a more flexible, performance-based approach.

Comment: One commenter asked if CMS was removing the Stage 3 requirements and indicated that the timeframe for implementation of the proposed scoring methodology and measure proposals were not adequate considering the historical timeframes needed for upgrades, workflow changes and training.

Response: We did not propose to remove all the Stage 3 requirements; we proposed to change the Stage 3 methodology by removing, adding, changing or maintaining certain objectives and measures. The Query of PDMP measure will be optional for CY 2019. This will allow additional time to develop, test and refine certification criteria and standards and workflows, while taking an aggressive stance to combat the opioid epidemic. While we appreciate the work that needs to be done to fully operationalize this measure, we believe this measure is a critical step in combatting the opioid crisis. Therefore, we are moving forward with requiring the measure beginning in CY 2020. The Verify Opioid Treatment Agreement measure will be optional for an EHR reporting period in 2019 and 2020 The Support Electronic Referral Loops by Receiving and Incorporating Health Information includes exclusion criteria for health care providers that are unable implement this measure for an EHR reporting period in 2019. In addition, we believe that maintaining the same certification criteria and standards currently required for the Stage 3 measures would reduce the time necessary to implement the new measure requirements.

Comment: One commenter requested clarification on whether the required reporting of at least one patient for each measure refers to one patient in the denominator or the numerator.

One commenter disagreed with the scoring methodology of reporting ''at least one unique patient'' for each proposed measure and recommended that CMS maintain threshold scoring for measures.

Response: As we stated in the proposed rule (83 FR 20522), the eligible hospital or CAH would submit their numerator and denominator data for each performance measure, and a yes/no response for each of the two reported measures under the Public Health and Clinical Data Exchange objective. For measures that include a numerator and denominator, the eligible hospital or CAH must submit a numerator of at least one patient.

We decline to maintain the current threshold based scoring methodology. In changing the scoring methodology to a performance-based, we are allowing hospitals the flexibility to focus on measures that are most applicable to how they delivery care to patients. This flexibility allows eligible hospitals and CAHs the opportunity to push themselves on measures they do well in, while continuing to improve in challenging areas. This provides them the opportunity to reach the minimum total score of 50 points in order to satisfy the requirement to report on the objectives and measures of meaningful use. This is one of the requirements for an eligible hospital or CAH to be considered a meaningful EHR user and earn an incentive payment and/or avoid a Medicare payment reduction.

Comment: One commenter expressed concern about vendors' ability to change the reporting structure to fit the new scoring methodology and costs associated with the changes.

Reponses: The proposed scoring methodology primarily would eliminate or revise existing measures, which should only require consolidation of existing workflows and actions. In addition, the certification criteria and standards remain the same as finalized in the October 16, 2015 final rule titled ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications.''

In addition, we proposed two new opioid measures, which we are finalizing as optional for EHR reporting periods in 2019. We are requiring reporting on the Query of PDMP measure in CY 2020. This will allow additional time for vendors to update EHR systems. The Verify Opioid Treatment Agreement measure will remain as optional in CY 2020. For additional information regarding our rationale we refer readers to section VIII.D.6.b. of the preamble of this final rule. The Support Electronic Referral Loops by Receiving and Incorporating Health information combines the functionality of the existing Request/

Accept Summary of Care and Clinical Information Reconciliation measures into a new measure, which also includes exclusion criteria for 2019 for eligible hospitals and CAHs that cannot implement the measure in 2019. Lastly, we are finalizing an EHR reporting period of a minimum of any continuous 90-day period in 2019 and 2020 to provide flexibility to health care providers as they are becoming familiar with the new scoring methodology and measures finalized in this rule. We believe that this will allow EHR developers and vendors adequate development time to test and incorporate the new scoring system and measures for deployment and implementation.

Comment: A commenter noted that measures without a numerator and denominator are less burdensome for eligible hospitals and CAHs.

Response: We appreciate the comment and will consider this feedback in the future development of policy for the Promoting Interoperability Program.

Comment: A commenter requested clarification on reporting for eligible hospitals and CAHs with multiple CEHRTs, who switch CEHRT mid-reporting, or merge CEHRTs.

Response: As established in this final rule, the EHR reporting period for eligible hospitals and CAHs is a minimum of any continuous 90-day period in CY 2019 and 2020. Therefore, we would expect hospitals to select and plan their EHR reporting period with respect to the switching and/or merging of their CEHRT. For those who have multiple CEHRTs, the measure specifications remain the same.

c. Summary of Final Scoring Methodology

As discussed above, after consideration of the comments we received, we are finalizing our proposed performance-based scoring methodology for eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019, with modifications, as described below.

For additional measure-specific information, we refer readers to section VIII.D.6. of the preamble of this final rule.

Promoting Interoperability Score

We are finalizing that eligible hospitals and CAHs are required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure is scored based on the eligible hospital or CAH's performance for that measure, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require a yes/no attestation. Each measure will contribute to the eligible hospital or CAH's total Promoting Interoperability score. The scores for each of the individual measures are added together to calculate the total Promoting Interoperability score of up to 100 possible points for each eligible hospital or CAH. A total score of 50 points or more will satisfy the requirement to report on the objectives and measures of meaningful use under § 495.24, which is one of the requirements for an eligible hospital or CAH to be considered a meaningful EHR user under § 495.4 and thus earn an incentive payment and/or avoid a Medicare payment reduction. Eligible hospitals and CAHs scoring below 50 points will not be considered meaningful EHR users.

We are finalizing that for an eligible hospital or CAH to earn a score greater than zero, in addition to completing the actions included in the Security Risk Analysis measure, the hospital must submit their complete numerator and denominator or yes/no data for all required measures. The numerator and denominator for each performance measure will translate to a performance rate for that measure and will be applied to the total possible points for that measure. The eligible hospital or CAH must report on all of the required measures across all of the objectives in order to earn any score at all. Failure to report any required measure, or reporting a ''no'' response on a yes/no response measure, unless an exclusion applies will result in a score of zero. We are finalizing the regulation text for this final policy is at § 495.24(e).

Security Risk Analysis Measure

We are finalizing our proposal that eligible hospitals and CAHs must attest to having completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the EHR reporting period occurs. The Security Risk Analysis measure is not scored and does not contribute any points to the hospital's total score for the objectives and measures. We are finalizing the regulation text for this final policy is at § 495.24(e)(4).

Electronic Prescribing Objective Scoring

We are finalizing the Electronic Prescribing objective as proposed with the following modifications. The e-Prescribing measure is worth up to 10 points in CY 2019 and up to 5 points in CY 2020. The Query of Prescription Drug Monitoring Program (PDMP) measure is optional in CY 2019 and worth up to 5 bonus points and is a required measure beginning in CY 2020, worth up to 5 points.

The Verify Opioid Treatment Agreement measure is optional in CY 2019 and 2020, and worth up to five bonus points. We intend to reevaluate the status of the Verify Opioid Treatment Agreement measure for subsequent years in future rulemaking.

An exclusion is available for the e-Prescribing measure as described in section VIII.D.6. of the preamble of this final rule. If an exclusion is claimed for the e-Prescribing measure for CY 2019, the 10 points for the e-Prescribing measure will be redistributed equally among the measures associated with the Health Information Exchange objective. We are finalizing a policy beginning in CY 2020 that an eligible hospital or CAH that qualifies for the e-Prescribing measure exclusion is also excluded from reporting on the Query of PDMP measure.

In addition, separate exclusion criteria are available for the Query of PDMP measure beginning in CY 2020 as described in section VIII.D.6. of the preamble of this final rule. If an exclusion is claimed for the Query of PDMP measure in CY 2020, the points will be equally redistributed among the measures associated with the Health Information Exchange objective. Since the Verify Opioid Treatment Agreement measure is optional and eligible for bonus points, no exclusions are available. We are finalizing our proposal with modification and finalizing § 495.24(e)(5) of the regulation text to reflect this policy.

Health Information Exchange Objective Scoring

We are finalizing the Health Information Exchange objective as proposed. The Support Electronic Referral Loops by Sending Health Information measure is worth up to 20 points. There are no exclusions available for the measure. The new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, is worth up to 20 points. An exclusion is available for this measure in CY 2019, as described in section VIII.D.6. of the preamble of this final rule. If the exclusion is claimed, the 20 points would be redistributed to the other measure within this objective, the Support Electronic Referral Loops by Sending Health Information measure, which would be worth up to 40 points. We are finalizing the regulation text for this final policy is at § 495.24(e)(6).

Provider to Patient Exchange Objective Scoring

We are finalizing the Provider to Patient Exchange objective with modifications. The Provide Patients Electronic Access to Their Health Information measure is worth up to 40 points beginning with the EHR reporting period in CY 2019. No exclusions are available for this measure. We are finalizing the regulation text for this final policy is § 495.24(e)(7).

Public Health and Clinical Data Exchange Objective Scoring

We are finalizing the Public Health and Clinical Data Exchange objective as proposed with the following modifications. Eligible hospitals and CAHs must submit a yes/no response for any two measures associated with the Public Health and Clinical Data Exchange objective to earn 10 points for the objective. Failure to report on two measures or submitting a ''no'' response for a measure will earn a score of zero. Exclusions available for this objective are discussed in section VII.6.e. of the preamble of this final rule. If an exclusion is claimed for one measure, but the eligible hospital or CAH submits a ''yes'' response for another measure, they would earn the 10 points for the Public Health and Clinical Data Exchange objective. If an eligible hospital or CAH claims exclusions for both measures they select to report on, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective. We are finalizing the regulation text for this policy at § 495.24(e)(8).

The tables below reflects the final policy for the objectives, measures, and maximum points available for the EHR reporting periods in CY 2019 and CY 2020. Please note, the maximum points available do not include points that would be redistributed in the event that an exclusion is claimed:

FINAL PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN CY 2019

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	10 points.
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 points *bonus*.
	Bonus: Verify Opioid Treatment Agreement	5 points *bonus*.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points.
Public Health and Clinical Data Exchange.	*Choose any two of the following:*	10 points.
	Syndromic Surveillance Reporting.	
	Immunization Registry Reporting.	
	Electronic Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Electronic Reportable Laboratory Result Reporting.	

Note: Security Risk Analysis is retained, but not included as part of the scoring methodology.

FINAL PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN CY 2020

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	5 points.
	Query of Prescription Drug Monitoring Program (PDMP)	5 points.
	Bonus: Verify Opioid Treatment Agreement	5 points *bonus*.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points.
Public Health and Clinical Data Exchange.	*Choose any two of the following:*	10 points.
	Syndromic Surveillance Reporting.	
	Immunization Registry Reporting.	
	Electronic Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Electronic Reportable Laboratory Result Reporting.	

Note: Security Risk Analysis is retained, but not included as part of the scoring methodology.

We are finalizing the codification of the scoring methodology in new paragraph (e) under § 495.24. We are finalizing the revisions to the introductory text of § 495.24 and the heading to paragraph (c) of this section to provide that the criteria specified in the new paragraph (e) are applicable for eligible hospitals and CAHs attesting to CMS for CY 2019 and subsequent years. Further, we are finalizing the revisions to the introductory text of § 495.24 and the heading to paragraph (d) of this section to provide that the criteria specified in paragraph (d) are applicable for eligible hospitals and CAHs attesting to a State for the Medicaid Promoting Interoperability Program for 2019 and subsequent years.

6. Measures for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program

a. Measure Summary Overview

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20524 through 20537), we proposed a number of changes to the Stage 3 objectives and measures in connection with the proposed scoring methodology for

eligible hospitals and CAHs discussed in the preceding section. Our intent was to ensure the measures better focus on the effective use of health IT, particularly for interoperability, and to address concerns stakeholders have raised through public forums and in public comments related to the perceived burden associated with the current measures in the program.

We proposed three new measures: Query of PDMP; Verify Opioid Treatment Agreement; and Support Electronic Referral Loops by Receiving and Incorporating Health Information.

We proposed to remove the Coordination of Care Through Patient Engagement objective and its three associated measures (Secure Messaging; View, Download or Transmit; and Patient Generated Health Data), as well as the measures Request/Accept Summary of Care, Clinical Information Reconciliation, and Patient-Specific Education.

Finally, we proposed to rename the Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information; rename the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange; rename the Patient Electronic Access to Health Information objective to Provider to Patient Exchange; and rename the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information.

We proposed to remove the exclusion criteria from all of the Stage 3 measures we are retaining, except for the measures associated with the Electronic Prescribing objective, Public Health and Clinical Data Exchange objective, and the new measures (Query of PDMP, Verify Opioid Treatment Agreement, and Support Electronic Referral Loops by Receiving and Incorporating Health Information), which would include exclusion criteria.

We proposed the changes as certain measures have proven burdensome to health care providers in ways that were unintended and detract from health care providers' progress on current program priorities, align with broader HHS priorities and/or focus on program priorities related to increasing interoperability, exchange of health care information, patient access to their health information and advanced functions of CEHRT.

We indicated in the proposed rule that the measures would no longer need to be attested to if we finalize the proposal to remove them, although health care providers may still continue to use the standards and functions of those measures based on their preferences and practice needs.

In addition, we sought public comment on a potential new measure Health Information Exchange Across the Care Continuum under the Health Information Exchange objective in which an eligible hospital or CAH would send an electronic summary of care record, or receive and incorporate an electronic summary of care record, for transitions of care and referrals with a provider of care other than an eligible hospital or CAH including but not limited to long term care facilities, and postacute care providers such as skilled nursing facilities, home health, and behavioral health settings.

We proposed that all of these measure proposals would apply to eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019, including Medicare-only and dual-eligible eligible hospitals and CAHs. We did not propose to apply these measure proposals to Medicaid-only eligible hospitals that submit an attestation to their State Medicaid agency for the Medicaid Promoting Interoperability Program. Instead, as discussed in section VIII.D.7. of the preambles of the proposed rule and this final rule, we proposed to give States the option to adopt these measure proposals along with the proposed performance-based scoring methodology for the Medicaid Promoting Interoperability Program through their State Medicaid HIT Plans.

We proposed that if we did not finalize a new scoring methodology, we would maintain the current Stage 3 methodology with the same objectives, measures and requirements, but we would include the two new opioid measures, if they are finalized. In addition, we proposed if we did not finalize a new scoring methodology, the proposals to remove objectives and measures as well as proposals to change objective and measure names would no longer be applicable.

Comment: The majority of commenters supported the removal of the patient action measures and overall reduction to the number of measures.

Response: We appreciate the support for the proposal to remove the measures including those requiring patient action, such as View, Download or Transmit, Patient Generated Health Data and Secure Messaging. Previous stakeholder feedback through correspondence, public forums, and listening sessions indicated there is ongoing concern with measures, which require health care providers to be accountable for patient actions. We further understand that there are barriers, which could negatively impact an eligible hospital or CAHs ability to successfully meet a measure requiring patient action, such as a patient's location in remote, rural areas and their inability to access technology such as computers, internet and/or email. As the issues described contribute to reporting burden and could negatively impact an eligible hospital or CAH's successful participation in the Promoting Interoperability Programs, we agree that removing the patient action measures reduces reporting burden and allows for focus on program goals which include improving interoperability, prioritizing actions completed electronically, use of advanced CEHRT functionalities and patient access to their health information.

Comment: One commenter requested that removed measure functionalities remain in CEHRT moving forward.

Response: We have stated in previous rulemaking (80 FR 62786) that functions and standards related to measures that are no longer required for the Promoting Interoperability Programs could still hold value for some healthcare providers and may be utilized as best suits their practice and the preferences of their patient population. We did not propose to remove the functionality from CEHRT. Removal of measures that are not aligned with the current emphasis of the Medicare Promoting Interoperability Program, which aim to increase interoperability and leverage the most current health IT functions and standards, is primarily to reduce reporting burden and is not intended to reflect upon the utility of the measure concepts for other purposes, such as providers' internal performance monitoring and improvement activities. Removal of a measure from program requirements does not require providers to remove the measures, associated data, or any functionalities from the health IT that they use.

Comment: A few commenters disagreed with the proposed removal of the exclusion criteria related to broadband availability and the number of transitions or referrals received and patient encounters in which the provider has never previously encountered the patient because they believed it would limit flexibility.

Response: As discussed in the proposed rule (83 FR 20525), we believe that there are valid reasons for the removal of the exclusion criteria. We do not believe the exclusion criteria would impact flexibility as we noted there are currently no counties that have less than 4 Mbps of broadband availability,

therefore, the exclusion could not be claimed. Also as we noted during the review of the 2016 Modified Stage 2 attestation data for eligible hospitals and CAHs, no eligible hospital or CAH claimed an exclusion based on broadband availability. In addition, based on our review of the 2016 Modified Stage 2 attestation data, we noted that we did not believe the exclusion criteria specific to transitions or referrals received and patient encounters in which the provider has never previously encountered the patient would be necessary.

Comment: One commenter stated that CMS should include a new exclusion for eligible hospitals and CAHs who cannot attest to a measure due to actions beyond their control.

Response: We decline to implement a new exclusion based on actions beyond the control of health care providers. We note that under our existing policy, eligible hospitals and CAHs may request a significant hardship exception based on extreme and uncontrollable circumstances.

Comment: One commenter requested that CMS retain the exclusion criteria related to broadband availability because the commenter indicated that tele-health services are dependent on the bandwidth of the internet for many applications, and the commenter believes an exclusion for increased bandwidth may be necessary in the future. The commenter noted that certain tele-health applications can require higher minimal speeds than what is currently part of the exclusion criteria.

Response: We decline to retain the exclusion criteria related to broadband availability. As we stated in the proposed rule (83 FR 20525), the Fixed Broadband Deployment Data from Federal Communications Commission (FCC) form 477 [409] indicate no counties have less than 4 Mbps of broadband availability, and no eligible hospital or CAH claimed an exclusion based on broadband availability according to the 2016 Modified Stage 2 attestation data. In addition, eligible hospitals and CAHs may request a significant hardship exception in cases of insufficient internet connectivity. We will reevaluate in the future the minimum broadband speed required to provide tele-health services and determine whether an exclusion would be warranted, but as stated above, we decline to retain the existing exclusion criteria.

Comment: Many commenters supported the proposed changes to the measures including the removal of certain measures and renaming of certain measures.

Response: We thank the commenters for their support and reiterate the proposed changes were meant to remove measures that were burdensome to health care providers in ways that were unintended and detract from health care providers' progress on current program priorities, align with broader HHS priorities and/or focus on program priorities related to increasing interoperability, exchange of health care information, patient access to their health information and advanced functions of CEHRT. We believe the changes more accurately reflect the goals of the program moving forward.

Comment: One commenter requested that CMS not propose additional changes to the objectives and measures that will apply beginning in CY 2019 for at least two years.

Response: We acknowledge that changes we finalize to objectives and measures require additional time and resources for EHR developers, vendors and health care providers to perform necessary updates to CEHRT and workflows, as well as training of staff. We are committed to reducing burden as well as being responsive to the concerns of stakeholders in the Promoting Interoperability Programs and consider many factors prior to proposing changes to the requirements.

Comment: One commenter requested that CMS provide data to eligible hospitals and CAHs on their performance with respect to current program measures before proposing changes.

Response: We will continue to work to promote data transparency and provide data on health care provider participation and performance and post data files for public use on the data and reports web page of the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html*.

After consideration of the public comments we received, we are finalizing the changes to the objectives, measures, and exclusion criteria as proposed for eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019, including Medicare-only and dual-eligible eligible hospitals and CAHs, with the modifications described in the sections below.

We are finalizing amendments to the regulation text at § 495.24(e) and § 495.24(c) to reflect these final policies.

(2) Summary of Finalized Measures Beginning With the EHR Reporting Period in CY 2019

The table below provides a summary of the measures we are finalizing in this final rule.

SUMMARY OF REMOVED AND FINAL MEASURES BEGINNING WITH THE EHR REPORTING PERIOD IN CY 2019

Measure status	Measure
Measures retained from Stage 3 with no modifications *	e-Prescribing. Immunization Registry Reporting. Syndromic Surveillance Reporting. Electronic Case Reporting. Public Health Registry Reporting. Clinical Data Registry Reporting. Electronic Reportable Laboratory Result Reporting.
Measures retained from Stage 3 with modifications	Supporting Electronic Referral Loops by Sending Health Information (formerly Send a Summary of Care). Provide Patients Electronic Access to Their Health Information (formerly Provide Patient Access).

[409] *https://www.fcc.gov/general/broadband-deployment-data-fcc-form-477*.

SUMMARY OF REMOVED AND FINAL MEASURES BEGINNING WITH THE EHR REPORTING PERIOD IN CY 2019—Continued

Measure status	Measure
Removed measures	Request/Accept Summary of Care. Clinical Information Reconciliation. Patient-Specific Education. Secure Messaging. View, Download or Transmit. Patient Generated Health Data.
New measures	Query of Prescription Drug Monitoring Program (PDMP). Verify Opioid Treatment Agreement. Support Electronic Referral Loops by Receiving and Incorporating Health Information.

* Security Risk Analysis is retained, but not included as part of the scoring methodology.

b. Final Policy for the Electronic Prescribing Objective

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20526 through 20530), we proposed to add two new measures to the Electronic Prescribing objective under § 495.24(e)(5)(iii) that are based on electronic prescribing for controlled substances (EPCS): Query of PDMP, and Verify Opioid Treatment Agreement, which align with the broader HHS efforts to increase the use of PDMPs to reduce inappropriate prescriptions, improve patient outcomes and promote more informed prescribing practices. We refer readers to the proposed rule for a detailed discussion of the rationale for these proposals. These measures build upon the meaningful use of CEHRT as well as the security of electronic prescribing of Schedule II controlled substances while preventing diversion. For both measures, we proposed to define opioids as Schedule II controlled substances under 21 CFR 1308.12, as they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence. We also proposed to apply the same policies for the existing e-Prescribing measure under § 495.24(e)(5)(iii) to both the Query of PDMP and Verify Opioid Treatment Agreement measures, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. Eligible hospitals and CAHs have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law (80 FR 62834; 81 FR 77227). However, we indicated because the intent of these two new measures is to improve prescribing practices for controlled substances, eligible hospitals and CAHs would have to include Schedule II opioid prescriptions in the numerator and denominator of the Query of PDMP and Verify Opioid Treatment Agreement measures or claim the applicable exclusion.

In addition, we stated if we finalized the new scoring methodology proposed in the proposed rule, eligible hospitals and CAHs that claim the broader exclusion under the e-Prescribing measure would automatically receive an exclusion for all three of the measures under the Electronic Prescribing objective; they would not have to also claim exclusions for the other two measures—Query of PDMP and Verify Opioid Treatment Agreement.

However, we stated if we did not finalize the new scoring methodology we proposed in the proposed rule, but we finalized the proposed measures of Query of Prescription Drug Monitoring Program and Verify Opioid Treatment Agreement under the Electronic Prescribing objective, we would continue to apply the Stage 3 requirements finalized in previous rulemaking, and we proposed that eligible hospitals and CAHs would be required to report all three measures under the Electronic Prescribing objective, but would only be required to meet the threshold for the e-Prescribing measure, or claim an exclusion. In addition, if the new scoring methodology we proposed was not finalized, we would retain the existing e-Prescribing measure threshold of 25 percent under § 495.24(c)(2)(ii).

In addition to comments specific to each proposed measure, we received general public comments on both these proposals, which we summarize below.

Comment: Several commenters supported the addition of the Query of PDMP and Verify Opioid Treatment Agreement measures, indicating they are important measures for reducing inappropriate prescriptions and improving patient outcomes.

Response: We thank the commenters for their support and feedback of the proposed new measures under the Electronic Prescribing objective. We believe the measures are important to promoting care coordination between health care providers and reducing inappropriate prescribing practices. We anticipate that integration of PDMPs into certified EHR technology will become more widespread increasing efficiency with health care provider workflows.

Comment: One commenter requested that CMS work with ONC to harmonize consistency in interoperability requirements, as there are differences in e-Prescribing standards for the 2015 Edition (Script 10.6) and Medicare Advantage final rule (Script 2017071).

Response: We intend to continue collaboration with ONC on the certification and standards criteria. Any proposed revisions to the e-prescribing certification criteria and standards would be included in separate rulemaking.

Comment: A commenter requested clarification on the e-Prescribing measure calculation for 2019 and whether or not hospitals can choose to exclude controlled substances.

Response: We did not propose any changes to the e-Prescribing measure specifications. As we stated in the proposed rule (83 FR 20527), eligible hospitals and CAHs have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law (80 FR 62834; 81 FR 77227). Eligible hospitals and CAHs reporting on the Query of PDMP and Verify Opioid Treatment Agreement measures would have to include Schedule II opioid prescriptions in the numerator and denominator.

Comment: Many commenters requested that the Query of PDMP and Verify Opioid Treatment Agreement measures remain as optional in CY 2020 with an associated bonus score as the timeline for implementation is unreasonable especially without certification criteria and standards.

Response: We understand that the Query of PDMP and Verify Opioid Treatment Agreement measures could require eligible hospitals and CAHs to incur additional burden due to workflow changes at the point of care. In addition, we understand eligible hospitals and CAHs that have integrated PDMPs within an EHR may be required to manually calculate the measure, as automated functionality for this measure is not currently supported through certification criteria for Health IT Modules. However, we also stated in the proposed rule that health care providers would have the flexibility to query the PDMP in any manner allowed under their State law (83 FR 20527). This would include using relevant included capabilities of their CEHRT, such as those required by the 2015 Edition electronic prescribing criterion at 45 CFR 170.315(b)(3).

We are finalizing the Query of PDMP measure as proposed. As stated above, we anticipate that integration of PDMPs into certified EHR technology will become more widespread increasing efficiency with health care provider workflows. We believe that requiring the Query of PDMP measure beginning in CY 2020 promotes specific HHS priorities. These priorities include encouraging the increased use of PDMPs to reduce prescription drug abuse and diversion, improving patient outcomes and allowing for more informed prescribing practices. Therefore, we are finalizing this measure as proposed.

Under the final policy we are adopting, the Verify Opioid Treatment Agreement measure will be optional for both CYs 2019 and 2020 with bonus point scoring as finalized in section VIII.D.5. of the preamble of this final rule. We plan to re-evaluate the status of the Verify Opioid Treatment Agreement measure for an EHR reporting period beginning in CY 2021.

We also believe that extending the optional reporting status into CY 2020 for the Verify Opioid Treatment Agreement measure will give health care providers the additional time required to research and implement methods for verification of such agreements in practice and development of system changes and clinical workflows. We also believe the extension of the optional reporting status will provide additional time for CMS and ONC to review and assess findings from pilot studies as described in the proposed rule (83 FR 20529). We will also consider additional feedback from stakeholders and consider further advancement in developing standards. We further discuss the rationale in section VIII.D.6. of the preamble of this final rule.

Comment: Several commenters stated that certification criteria and standards should be adopted prior to finalization of the Query of PDMP and Verify Opioid Treatment Agreement measures.

Response: We agree that availability of specific mature consensus technical standards relevant to the use cases these measures represent would facilitate health IT developers' ability to offer technical solutions that enable providers both to perform the actions expected by the measures and automatically capture the data needed to calculate both of these measures. We will continue to evaluate the progress in the integration of PDMPs within providers' CEHRT, additional advances toward development of standards and are finalizing exclusion criteria as noted below.

For the Query of PDMP measure, in the proposed rule (83 FR 20528), we proposed that in order to meet the measure, eligible hospitals and CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3) and 170.315(a)(10)(ii), therefore, certification and standards criteria would be associated with this measure. We stated in the proposed rule that there were no current exact certification and standards criteria available for querying a PDMP but believe the use of structured data in CEHRT could support querying through broader use of health IT (83 FR 20528). As previously stated, health care providers would have the flexibility to query the PDMP in any manner allowed as legal and practicable under their State law (83 FR 20527) which we believe provides more flexibility for health care providers to successfully demonstrate meaningful use and be able to report on this measure beginning in CY 2020.

In the proposed rule (83 FR 20530), we proposed that in order to meet the Verify Opioid Treatment Agreement measure eligible hospitals and CAHs must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3), 170.315(a)(10) and 170.205(b)(2), however, there are no current exact standards for identification or exchange of treatment agreements. As we noted in the proposed rule (83 FR 20529 through 20530), there are a variety of standards available within CEHRT that may be able to support the electronic exchange of opioid abuse related treatment data such as the Consolidated Clinical Document Architecture (C–CDA) care plan template.

For these reasons, we are finalizing the Query of PDMP as proposed and the Verify Opioid Treatment Agreement measure as optional for CYs 2019 and CY 2020. For more information, we refer readers to the discussion in section VIII.D.6. of the preamble of this final rule. In addition, we intend to propose specific certification criteria and standards in separate future rulemaking for the Query of PDMP and the Verify Opioid Treatment Agreement measures.

We are finalizing the definition of opioids as Schedule II controlled substances under 21 CFR 1308.12 as proposed.

We are finalizing the proposal to apply the same policies for the existing e-Prescribing measure under § 495.24(e)(5)(iii) to the Query of PDMP measure and Verify Opioid Treatment Agreement measure, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy, except that unlike the e-Prescribing measure, eligible hospitals and CAHs must include Schedule II opioid prescriptions in the numerator and denominator of the Query of PDMP and Verify Opioid Treatment Agreement measures if they choose to report on them.

In addition, we are finalizing that an eligible hospital or CAH that qualifies for the e-Prescribing measure exclusion is excluded from reporting on the Query of PDMP measure beginning in CY 2020.

(1) Measure: Query of Prescription Drug Monitoring Program (PDMP)

A PDMP is an electronic database that tracks prescriptions of controlled substances at the State level and play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking the prescribed controlled substances and improving prescribing practices. The intent of the Query of PDMP measure is to build upon the current PDMP initiatives from Federal partners focusing on prescriptions generated and dispensing of opioids.

Proposed Measure Description: For at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.

We proposed that the query of the PDMP for prescription drug history

must be conducted prior to the electronic transmission of the Schedule II opioid prescription and that eligible hospitals and CAHs would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law.

We proposed to include in this measure all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter and that multiple Schedule II opioid prescriptions prescribed on the same date by the same eligible hospital or CAH would not require multiple queries of the PDMP. In the proposed rule, we requested comment on whether we should further refine the measure to limit queries of the PDMP to once during a hospital stay regardless of whether multiple eligible medications are prescribed during this time.

CMS and ONC worked together to define the following:

Denominator: Number of Schedule II opioids electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period.

Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law.

Exclusion: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period.

We proposed that the exclusion criteria would be limited to prescriptions of controlled substances as the measure action is specific to prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions.

We stated that if we finalized the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, an additional exclusion would be available beginning in 2020 for eligible hospitals and CAHs that could not report on this measure in accordance with applicable law.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20528), we stated that we understood PDMP integration is not currently in widespread use for CEHRT, and many eligible hospitals and CAHs may require additional time and workflow changes at the point of care before they can meet this measure without experiencing significant burden and that manual data entry and manual calculation of the measure may be necessary. We also acknowledged that there are no existing certification criteria for the query of a PDMP but we believed the use of structured data captured in the CEHRT, could support querying a PDMP through the broader use of health IT. In the proposed rule, we sought public comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.

We sought public comment especially from health care providers and health IT developers on whether they believe use of the NCPDP SCRIPT 2017071 standard for e-prescribing could support eligible hospitals and CAHs seeking to report on this measure, and whether HHS should encourage use of this standard through separate rulemaking.

In the proposed rule, we sought public comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden.

In including EPCS as a component of the measure we proposed, we acknowledged and sought input on perceived and real technological barriers as part of its effective implementation including but not limited to input on two-factor authentication and on the effective and appropriate uses of technology, including the use of telehealth modalities to support established patient provider relationships subsequent to in-person visit(s) and for prescribing purposes.

In the proposed rule, we also requested comment on limiting the exclusion criteria to electronic prescription for controlled substances and whether there are circumstances which may justify any additional exclusions for the Query of PDMP measure and what those circumstances might be.

We noted that under the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, measures would not have required thresholds for reporting. Therefore, if the proposed scoring methodology and this measure were finalized, this measure would not have a reporting threshold. We proposed a threshold of at least one prescription for this measure if we did not finalize the proposed scoring methodology as varying State laws related to integration of a PDMP into CEHRT can lead to differing standards for querying.

We also proposed that in order to meet this measure, an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3) and 170.315(a)(10)(ii).

We proposed to codify the Query of PDMP measure at § 495.24(e)(5)(iii)(B).

Comment: A commenter indicated that CMS should work with stakeholders to determine feasibility and testing of EPCS measures prior to finalizing.

Response: We agree that there should be testing of the measures prior to requiring them as part of the Promoting Interoperability Programs. We note that we are finalizing the Query of PDMP measure as proposed which is discussed in the section VIII.D.5. of the preamble of this final rule. The optional reporting for this measure in CY 2019 allows additional time for expansion of PDMP integration into EHRs, implementation of system changes and workflows and for health IT developers to work with health care providers on additional methods for CEHRT to capture and calculate actions specific to the PDMP query.

Comment: Several commenters agreed with the addition of the Query of PDMP measure indicating it was important for reducing inappropriate prescriptions and improving patient outcomes.

Response: We thank the commenters for their support and feedback of the proposed new measure. We believe that PDMPs currently provide valuable information on prescribed controlled substances including dosages, quantity and combinations of prescriptions. In addition, we believe PDMPs will continue to progress to achieve full integration on a widespread scale resulting in more informed prescribing practices, reduced inappropriate prescribing of opioids, and improved patient outcomes while reducing workflow and time needed for querying.

Comment: Several commenters supported the Query of PDMP measure but stated standards should be developed due to varying integration efforts across the nation. Another comment stated that CMS should collaborate with the DEA on standards and capabilities including use of mobile devices for cost control and increased flexibility.

One commenter indicated that standards should include PDMP onboarding, interstate access agreements, improved access to PDMPs via national brokers, support for patient and user ID matching between CEHRT and PDMPs. One commenter stated that

costs and incentives associated with onboarding should be a priority consideration.

Response: We thank the commenters for their support of the Query of PDMP measure and recognize that integration efforts are in various stages. While a number of these comments raise issues outside the scope of this rule, we appreciate the feedback on challenges and barriers relevant to effectively implementing the measure, which we requested in the proposed rule. This input will help to inform our future work as we continue collaborating with our colleagues across HHS, and with other public-and private-sector partners as appropriate, as we all work to advance the maturity and capabilities of America's health information infrastructure to seamlessly integrate with CEHRT and efficient clinician workflows. This is important not only for PDMP query functionality but for also other relevant tools, such as automated clinical decision support, that facilitate more informed prescribing practices and improved patient outcomes.

Our goal on burden reduction also includes consideration of costs associated with meeting the Promoting Interoperability Programs requirements. We will continue to listen to stakeholders on concerns related to costs and work to mitigate burdens whenever practicable within our programs' responsibilities and authorities.

Comment: One commenter indicated that health care providers should be able to continue to use a health information exchange to access Schedule II opioid prescription drug history in order to earn points for the Query of PDMP measure.

Response: Neither of the proposed measures, including the Query of PDMP measure specifies whether providers' CEHRT connects to PDMPs directly or through HIEs. Therefore, use of HIEs to access Schedule II opioid prescription drug history is acceptable.

Comment: One commenter also requested consideration for use of an open API by PDMPs to enable EHR access to Schedule II opioid prescription drug history.

Response: Noting that we understand ''open API'' to mean an API for which the PDMP has made freely and publicly available the specific business and technical documentation necessary to interact with the API, we agree that implementing such an API is a step PDMPs can take to make it easier for providers to connect their CEHRT to PDMPs. We are aware of some States having already taken this step to support efforts to integrate PDMP with health IT used by prescribers and pharmacists in the course of their clinical work.

Comment: A commenter stated that CMS should remove the requirement to use the capabilities and standards of CEHRT for querying the PDMP due to the absence of technology and infrastructure supporting electronic querying.

Response: We thank the commenter for this suggestion. However, we disagree that the Query of PDMP measure should not include a requirement to use the capabilities and standards of CEHRT. We proposed that, in order to report on the Query of PDMP and receive a score, eligible hospitals and CAHs must use the capabilities and standards at 45 CFR 170.315(b)(3) for electronic prescribing and 170.315(a)(10)(ii) for drug formulary checks which are required under the e-Prescribing measure. In the proposed rule (83 FR 20527), we proposed that the query of PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. The certification criteria at 45 CFR 170.315(b)(3) would allow a health care provider to create a new prescription, change a prescription, cancel a prescription, refill a prescription, request fill status notifications and request and receive medication history information which we believe could support the query for a prescription drug history of the patient.

In addition, 45 CFR 170.315(a)(10)(ii) drug formulary checks are most useful when performed in combination with e-prescribing which could increase the efficiency and safety of care and lower costs. We believe that the use of capabilities and standards at 45 CFR 170.315(b)(3) for electronic prescribing for Query of PDMP, which include the ability of the user to reconcile a patient's active medication list, medication allergy list, and problem list, are key to system interoperability. This reconciliation will allow for the seamless flow of medication history data between disparate systems to help prescribers and pharmacists improve patient outcomes. As noted in the proposed rule and elsewhere in this final rule, given the variance in State level requirements and actions used to perform the query, health care providers have flexibility to satisfy this measure by querying the PDMP in any manner legal and practicable in their State.

Comment: A few commenters stated that the Query of PDMP measure should not be finalized as part of the Promoting Interoperability Programs, and the integration of the PDMP with health information technology should remain as part of State requirements only.

Response: We believe finalizing the Query of PDMP measure would be instrumental in furthering widespread implementation of PDMP query capabilities within EHRs. We noted in the proposed rule that several Federal agencies have had integral roles in the expansion of PDMPs with health information technology systems and we believe that this measure will encourage continued progress on integrating PDMP queries into EHR work flows, and reinforce the importance of prescribers seeking and using PDMP information where it is relevant to making more informed opioid prescribing decisions.

Comment: A few commenters supported the use of NCPDP Script Standard Implementation Guide Version 2017071 medication history transactions for PDMP queries and response. One commenter proposed convergence on the use of HL7 FHIR such as CDS Hooks for other consumer facing apps to more extensively connect EHRs and consumer facing apps with PDMPs as a long term goal.

Response: We appreciate the commenters' views. In partnership with colleagues across HHS, we encourage and applaud advances in standards and their use to deliver innovative, interoperable solutions that will seamlessly integrate PDMP query functionality and other relevant tools, such as automated clinical decision support, into clinician-friendly, patient-centered CEHRT-enabled workflows that facilitate safer, more informed prescribing practices and improved patient outcomes.

Comment: One commenter requested an additional exclusion for the Query of PDMP measure specific to States that do not have a Statewide PDMP. Another commenter requested exclusion criteria for hospitals whose States do not allow direct integration with an API as workflows that are not interoperable will increase reporting burden.

Response: We decline to finalize additional exclusion criteria, as recommended by the commenters. We stated that health care providers may query the PDMP in any manner that is allowed by their State, which we believe would reduce the burden of instituting new workflows. In addition, we are adopting exclusion criteria below for hospitals not able to report on this measure in accordance with applicable law when the measure is required beginning in CY 2020. We will continue to monitor health care provider use and querying of PDMPs and consider whether additional exclusion criteria

are necessary in future rulemaking, as the measure is optional for CY 2019.

We decline to finalize exclusion criteria for eligible hospitals and CAHs whose States do not allow for direct integration through an API. We believe that finalization of exclusion criteria such as this would enable a significant number of health care providers to avoid reporting on the measure, even though they would have the ability to query a PDMP through other means. In addition, we believe that although additional time and workflow changes may be necessary in order for health care providers to meet the measure, it is still possible without direct integration as long as it is conducted using CERHT in accordance with applicable State law.

Comment: One commenter stated that CMS should work with State and other Federal agencies to develop a common set of formulary schedules, common data set and common set of interoperability standards that can easily work at an interstate level.

Response: We recognize that there is work to be done to resolve various real and perceived barriers to achieving the full potential of interoperable health IT and health information exchange to improve patient care and outcomes. We plan to continue collaborating with our colleagues across HHS, including ONC, on standards and requirements specific to the Promoting Interoperability Programs. We believe that the pilots and projects discussed in the proposed rule at (83 FR 20527) which include collaboration between the agencies of ONC, SAMHSA, DOJ and CDC for example, have had integral roles in the progression of health IT as related to the opioid crisis. Likewise, the ONC and CDC have been integral in development of Promoting Interoperability Program requirements, including interoperability standards and certification criteria; therefore, we will continue to work with our colleagues on future requirements specific to interoperability standards, data sets and formulary schedules.

Comment: One commenter stated that PDMP view-only access is insufficient and data exchange that can enable clinical decision support to assist health care providers is needed.

Response: We understand where PDMP query is implemented in a way that does not return data in a computable format consistent with standards the CEHRT supports, providers and their patients will not be able to benefit from advanced capabilities of EHRs, such as clinical decision support.

We agree that the ability to automate real-time clinical decision support informed by a patient's complete prescription drug history would be helpful to providers. We believe that as the measure is more widely implemented, and concurrently as advanced CDS functionalities become more widely available to providers via their CEHRT, both are vital to successfully combating the opioid crisis. To that end, we will continue to work across HHS and with our stakeholders to develop the necessary standards and complementary resources that will support such use. This will include further development of technical interoperability standards and may include revisions to this measure in future rulemaking.

Comment: One commenter stated that the Query of PDMP measure should be prescription-based for simplicity, not evaluating medications administered during the admission or presentation to the ED. Another commenter stated the denominator should reference discharged patients during the EHR reporting period not the number of opioids prescribed during the EHR reporting period, and recommended the denominator be changed to ''Discharges where Schedule II medications were prescribed.''

Response: The denominator for the measure is based on the Schedule II opioids that are electronically prescribed using CEHRT during the EHR reporting period rather than medications administered as the intent is to identify multiple provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. In addition, we decline to revise the denominator of the measure as it could include prescriptions upon discharge as well as electronic prescriptions generated during the admission.

Comment: One commenter stated that the numerator definition does not follow typical workflow for PDMP queries as some States require logging into an external portal making data capture and measure calculation difficult.

Response: We understand that for PDMPs that do not currently allow for integration with EHR systems, prescribers may be required to take additional actions to complete the query, such as logging into an external portal. We acknowledged in the proposed rule that due to the varying integration of PDMPs into EHR systems, additional time, workflow changes and manual data capture and calculation would be needed to complete the query and could contribute to overall reporting burden. Therefore, this measure allows health care providers the flexibility to query the PDMP using CEHRT in any manner legal and practicable in their State.

Comment: A few commenters stated that CERHT should also be able to support workflow integration such as querying the PDMP on demand. Another commenter indicated there are challenges associated with non-consolidated responses, which present a patient-centric view of all prescribing activities.

Response: It is our understanding that PDMP query integration with prescriber workflow can be accomplished with CEHRT on the market today. However, we acknowledge that it may not be an automatic capability of CEHRT and may not be possible in all States due to variations in laws and technical approaches. As the measure will be required beginning in CY 2020, we will review those variations over the next year and consider whether additional exclusion criteria would be necessary.

Comment: One commenter requested clarification on whether hospitals must query multiple registries if the hospital's location is close to a State border.

Response: We are not requiring eligible hospitals and CAHs to query multiple registries if the location is close to the State border, as we believe this would serve to increase the burden by requiring additional workflows and time requirements. We defer to the hospital and/or prescriber on whether multiple queries should be performed based on clinical relevance in specific circumstances.

In addition, next year we intend to propose in rulemaking that EHR-integrated PDMP querying would be required beginning in CY 2020 as part of this measure. In connection with that proposed requirement, we also intend to propose an additional exclusion for providers in States where integration with a Statewide PDMP is not yet feasible or not yet widely available. This exclusion would require confirmation from the State acknowledging that PDMP integration of EHRs is not yet in place. We will seek comment and suggestions in future rulemaking to ascertain if additional exclusions are needed for eligible hospitals or CAHs located in one of the States where PDMPs are not integrated into EHRs. We understand the lack of certification criteria and standards that are currently available as it relates to the Query of PDMP measure, but believe that this measure is essential to ensuring that we are working to combat the opioid crisis. We will continue to collaborate with our Federal partners to advance the capabilities, standards and

functionalities for querying PDMPs as well as to facilitate more informed prescribing practices and improvement of patient outcomes.

After consideration of the public comments we received, we are finalizing the Query of PDMP measure as proposed.

We are finalizing that in order to meet this measure, an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3) and 170.315(a)(10)(ii).

We are codifying the Query of PDMP measure at § 495.24(e)(5)(iii)(B).

We are adopting the measure as follows:

Query of PDMP

Measure Description: For at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.

Denominator: Number of Schedule II opioids electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period.

Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law.

Exclusions beginning with an EHR reporting period in CY 2020: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and

Any eligible hospital and CAH that could not report on this measure in accordance with applicable law.

(2) Measure: Verify Opioid Treatment Agreement

The intent of this measure is for eligible hospitals and CAHs to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days. We believe seeking to identify an opioid treatment agreement will further efforts to coordinate care between health care providers and foster a more informed review of patient therapy.

In the proposed rule (83 FR 20529), we stated that we understood there are varied opinions regarding opioid treatment agreements amongst health care providers. Because of the debate among practitioners, we requested comment on the challenges this proposed measure may create for health care providers, how those challenges might be mitigated, and whether this measure should be included as part of the Promoting Interoperability Program. We also acknowledged challenges related to prescribing practices and multiple State laws, which may present barriers to the uniform implementation of this proposed measure. In the proposed rule, we sought public comment on the challenges and concerns associated with opioid treatment agreements and how they could impact the feasibility of the proposal.

Proposed Measure Description: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into CEHRT.

We proposed this measure would include all Schedule II opioids prescribed for a patient electronically using CEHRT by the eligible hospital or CAH during the EHR reporting period, as well as any Schedule II opioid prescriptions identified in the patient's medication history request and response transactions during a 6 month look-back period, where the total number of days for which a Schedule II opioid was prescribed for the patient is at least 30 days.

In the proposed rule, we acknowledged in part, that completing the Verify Opioid Treatment Agreement measure might prove burdensome to health care providers as it could be difficult to identify an existing treatment agreement. Attempting to identify whether there is a treatment agreement in place would likely require additional time and changes to existing workflows. In the proposed rule, we sought public comment on pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning.

We proposed that the 6-month look-back period would begin on the date on which the eligible hospital or CAH electronically transmits its Schedule II opioid prescription using CEHRT.

We proposed a 6-month look-back period in order to identify more egregious cases of potential overutilization of opioids and to cover timeframes for use outside the EHR reporting period. We proposed that the 6-month look-back period would utilize at a minimum the industry standard NCDCP SCRIPT v10.6 medication history request and response transactions codified at 45 CFR 170.205(b)(2).

In the proposed rule, we did not propose to define an opioid treatment agreement as a standardized electronic document; nor did we propose to define the data elements, content structure, or clinical purpose for a specific document to be considered a ''treatment agreement.'' We sought public comment on what characteristics should be included in an opioid treatment agreement and incorporated into CEHRT, such as clinical data, information about the patient's care team, and patient goals and objectives, as well as which functionalities could be utilized to accomplish the incorporation of this information. In the proposed rule, we also sought public comment on methods or processes for incorporation of the treatment agreement into CEHRT, including which functionalities could be utilized to accomplish this. We sought public comment on whether there are specific data elements that are currently standardized that should be incorporated via reconciliation and if the ''patient health data capture'' functionality could be used to incorporate a treatment plan that is not a structured document with structured data elements.

Denominator: Number of unique patients for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient's medication history request and response transactions during a 6-month look-back period.

Numerator: The number of unique patients in the denominator for whom the eligible hospital or CAH seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT.

Exclusions: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic

prescriptions for controlled substances at the start of its EHR reporting period.

We proposed that the exclusion criteria would be limited to prescriptions of controlled substances as the measure action is specific to electronic prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions and that an additional exclusion would be available beginning in 2020 for eligible hospitals and CAHs that could not report on this measure in accordance with applicable law under the proposed scoring methodology in the proposed rule. We requested public comment on limiting the exclusion criteria to electronic prescriptions for controlled substances and whether there are circumstances which may require an additional exclusion for the Verify Opioid Treatment Agreement measure and what those circumstances might be.

We stated in the proposed rule that if the proposed scoring methodology and measure were finalized, this measure would not have a reporting threshold. We also proposed that if we did not finalize the proposed scoring methodology, but we finalized this proposed measure, that there would be a threshold of at least one unique patient for this new measure. We also noted there are medical diagnoses and conditions that could necessitate prescribing Schedule II opioids for a cumulative period of more than 30 days.

We also proposed that, in order to meet this measure, an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3), 170.315(a)(10) and 170.205(b)(2).

Lastly, we requested comment on whether we should explore adoption of a measure focused only on the number of Schedule II opioids prescribed and the successful use of EPCS for permissible prescriptions electronically prescribed. We sought public comment about the feasibility of such a measure, and whether stakeholders believe this would help to encourage broader adoption of EPCS.

We proposed to codify the Verify Opioid Treatment Agreement measure at § 495.24(e)(5)(iii)(C).

Comment: A few commenters supported the Verify Opioid Treatment Agreement measure and indicated that it was an important measure for reducing inappropriate prescriptions.

Response: We thank the commenters for their support of the measure. We believe the Verify Opioid Treatment Agreement measure could have some benefit for promoting care coordination between health care providers. We also agree that this measure will help in reducing inappropriate prescribing practices. In addition, we believe there are merits to combatting the opioid crises through various means including health care providers verifying if there is an opioid treatment agreement in place before prescribing.

However, we also have considered the lack of standards and agreement on the effectiveness of opioid treatment agreements. Therefore, we are finalizing the Verify Opioid Treatment Agreement measure as optional for 2019 and 2020. We will reevaluate the status of the measure for an EHR reporting period beginning in CY 2021.

Comment: Many commenters requested that CMS not finalize the Verify Opioid Treatment Agreement measure due to the lack of defined data elements, structure, and standards and certification criteria. Some of those commenters indicated the measure would be administratively burdensome as most patients are discharged with no more than a week's prescription of schedule II controlled substances.

In addition, a few commenters were concerned that finalization of this measure may result in unintended negative consequences such as a decline of pain management therapies and treatment for patients who are post-surgical or recovering from acute illnesses, reluctance of patients to seek treatment or health care related to pain or reluctance on part of health care providers to prescribe short term opioids when appropriate.

Another commenter stated there are no current standards for exchange of opioid treatment agreements, they are not usually based on clinical information, and are primarily provider requested. One commenter stated there is no evidence that opioid treatment agreements improve patient outcomes. One commenter stated opioid treatment agreements are more commonly used by outpatient programs where use of CEHRT is limited.

Response: We understand the concerns voiced by the commenters and acknowledged the lack of defined data elements, structure, standards and criteria. We also understand the concerns of the commenters that discussed the unintended consequences and the potential administrative burden associated with this measure. We also are well aware of the varying evidence regarding the efficacy of the opioid treatment agreements. All of these concerns voiced by commenters were acknowledged in the proposed rule (83 FR 20528 through 20530). However, we believe there are health care providers who are already verifying if there is an opioid treatment agreement in place before prescribing opioids. We also believe it is important to continue to improve prescribing practices for controlled substances using currently available methods, and that this particular measure can help lead to improvement in prescribing practices.

As noted in the proposed rule (83 FR 20529), there are a number of ways certified health IT may be able to support the electronic exchange of opioid abuse related treatment data, such as use of the C–CDA care plan template that is currently optional in CEHRT. This template contains information on health concerns, goals, interventions, health status evaluation & outcomes sections that could support the development of an opioid treatment agreement. In addition, the ''patient health data capture'' functionality which is part of the 2015 Edition (45 CFR 170.315(e)(3)) could be used to incorporate a treatment plan that is not a structured document with structured data elements.

We disagree that this measure will result in unintended consequences, such as the decline of pain management therapies. As we discussed in the proposed rule (83 FR 20530), we are only including patients where the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period. We also believe this measure could encourage discussion and additional treatment options between health care providers and patients. In addition, this measure would help to rule out issues related to pain management therapies for certain post-surgical patients and those recovering from acute illnesses. We also understand that certain medical conditions and diagnoses could necessitate prescribing for over 30 days, including some terminal illnesses, recovery from some surgeries or their underlying conditions, and other diagnoses that cause pain requiring alleviation by opioids. It is not our intention to be a barrier to the most effective and clinically appropriate pain alleviating therapies available to patients in need, or to impose an undue burden on health care providers. Our goal is to work on improving patient outcomes and we do believe that this measure has merits, as the opioid treatment agreement can be an integral part of clinically effective, patient-empowering pain management plans developed and implemented in the course of shared decision-making by a clinical team and a patient with serious, chronic pain.

Opioid treatment agreements may be more commonly used by outpatient

programs where use of CEHRT is limited, however we believe their verification in other care settings such as hospitals would improve prescribing practices through identification of overutilization of controlled substances.

Finally, we reiterate that this measure will be optional for hospitals in 2019 and 2020. We acknowledge many providers may not find this measure applicable for their setting, and believe it is most likely to be adopted by those providers already engaged in treatment scenarios where the verification of an Opioid Treatment Agreement would be beneficial, such as providers offering treatment for substance use disorders, or providers closely integrated with behavioral health treatment facilities.

Comment: One commenter stated that the measure could present challenges in the context of Part 2 programs as data sharing restrictions complicate feasibility of the measure.

Response: We do understand that 42 CFR part 2 protects the confidentiality for substance use disorder patient records. However, we note that the disclosure of such information may be possible under certain conditions, including upon patient consent or request for the disclosure of such information.

Comment: One commenter requested an additional exclusion for Verify Opioid Treatment Agreement measure to include patients with certain diagnoses or settings including but not limited to terminal or end stage conditions, cancer and hospice settings.

One commenter disagreed with use of medication history transaction for the measure denominator as this does not support the concept of prescription days but uses a duration, which has no start or stop date.

Response: We decline to add an additional exclusion as this measure is optional for CY 2019 and 2020. We are not finalizing the proposed exclusion criteria (83 FR 20530) as we are finalizing this measure as optional for both CY 2019 and 2020.

Moreover, as we discuss in more detail in reference to the preceding comment, we do not believe that confirming an opioid treatment agreement is inconsistent with sound clinical practices for developing and implementing holistic, patient-centered pain management plans for patients affected by conditions causing pain for which opioid treatment for more than 30 days is a clinically appropriate component of an effective overall treatment approach.

We decline to the modify the denominator for this measure as we indicated that we are seeking the cumulative days for an opioid prescription over a 6 month look back period to identify egregious cases (83 FR 20529). We understand that each prescription would include a quantity based on the number of doses allowed. However, the intent is to also look at prescriptions from other health care providers as well for episodes of prescription shopping. As we indicated in the proposed rule (83 FR 20529), the 6 month look back would begin on the date in which the eligible hospital or CAH electronically transmits its Schedule II Opioid prescription using CEHRT.

Comment: A few commenters stated that this measure may not be possible to calculate as the NCPDP 10.6 Medication History query does not contain a field for prescription days and relies on third party data that may not be discrete.

Response: We recognize that the capabilities to which health IT must be certified in order for it to meet the minimum requirements for CEHRT under this program do not include the ability to automatically track prescriber behaviors addressed by this measure. However, we disagree that this measure cannot be implemented at this time, and believe that some health care providers are currently verifying if there is an opioid treatment agreement in place before they prescribe. As we noted that in the proposed rule (83 FR 20529), the adoption of the NCPDP 10.6 standard does not preclude developers from also incorporating and using technology standards or services not required by regulation in their health IT product which could result in development of a workflow which more closely resembles types that health care provider are currently using. However we do understand the limitations for those health care providers that have chosen not to implement such standards and functionalities beyond the minimum to which their CEHRT is required to be certified to meet the requirements of this program.

We also recognize that a provider's attempt to verify whether a treatment agreement is in place may be difficult to capture in an automated fashion in cases where a machine readable treatment agreement cannot be queried. While we believe some providers do currently have the ability to query for an electronic treatment agreement, which could support machine capture of this data, we recognize that for most health care providers this will require additional workflow steps.

As a result of these issues, we are also finalizing this measure as optional for CYs 2019 and 2020, and expect this measure is likely to be adopted by a limited set of providers in treatment arrangements that already possess the infrastructure to support capture and calculation of this measure. We intend to revisit this measure along with the necessary data elements in future rulemaking.

Comment: A few commenters stated that the measure would contain unreliable data and suspect calculations as it would be possible for CEHRT to receive duplicative medication history data from various systems. One commenter requested information on how the EHR would machine calculate duplicative data and cumulative days.

One commenter stated the patient's medical history is not clearly laid out in external prescription history and may require manual calculation with no system ability to determine if users are identifying applicable patients or not.

Response: We recognize that this measure would be technically complex and potentially burdensome for providers to implement. However, we believe that some health care providers may be able to verify if there is an opioid treatment agreement in place through various means such as C–CDA based information exchange. We understand that there is a potential for duplicative medication history data but believe that the reconciliation burden this currently poses for clinicians not only in context of prescribing long-term opioid therapy but a variety of more general clinical situations and thus is one that the market should already be working to address.

Moreover, as the clinical practice this measure tracks is more widely adopted, we believe health care providers and their health IT vendors will develop innovative solutions to accurately capture needed data elements and calculate the measure while reducing workflow complexity and inconvenience to prescribers and other personnel involved in the care and/or measurement process. Therefore, we are taking into account these limitations and are finalizing this measure as optional for CYs 2019 and 2020 and will reevaluate the status of the measure for an EHR reporting period beginning in CY 2021.

After consideration of the comments we received, and for the reasons stated above, we are finalizing the Verify Opioid Treatment Agreement measure as proposed with the modification discussed in section VIII.D.6. of the preamble of this final rule, that the measure will be optional in CYs 2019 and 2020. We are codifying the measure at § 495.24(e)(5)(iii)(C). In addition, we are finalizing that, in order to meet this measure, an eligible hospital or CAH

must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3), 170.315(a)(10) and 170.205(b)(2).

We are adopting the measure as follows:

Verify Opioid Treatment Agreement

Measure Description: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into CEHRT.

Denominator: Number of unique patients for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient's medication history request and response transactions during a 6-month look-back period.

Numerator: The number of unique patients in the denominator for whom the eligible hospital or CAH seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT.

c. Final Policy for the Health Information Exchange (HIE) Objective

The Health Information Exchange measures for eligible hospitals and CAHs hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. However, through our review of existing measures, we determined that we could potentially improve the measures to further reduce burden and better focus the measures on interoperability in provider to provider exchange. Such modifications would address a number of concerns raised by stakeholders including:

- Supporting the implementation of effective health IT supported workflows based on a specific organization's needs;
- Reducing complexity and burden associated with the manual tracking of workflows to support health IT measures; and
- Emphasizing within these measures the importance of using health IT to support closing the referral loop to improve care coordination.

The Health Information Exchange objective currently includes three measures under § 495.24(c)(7)(ii) (in the proposed rule (83 FR 20530) we inadvertently referred to § 495.24(e)(6)(ii)), and we believe we can potentially improve each to streamline measurement, remove redundancy, reduce complexity and burden, and address stakeholders' concerns about the focus and impact of the measures on the interoperable use of health IT.

As discussed in section VIII.D.6.a. of the preamble of the proposed rule, we proposed to remove the exclusions from all three of the measures associated with the Health Information Exchange objective under § 495.24(c)(7)(iii), as reflected in the two measures proposed under § 495.24(e)(6). However, we stated that if we finalized the new scoring methodology we proposed, eligible hospitals and CAHs would be able to claim an exclusion under the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure.

We proposed several changes to the current measures under the Stage 3 Health Information Exchange objective. First, we proposed to change the name of Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. We also proposed to remove the current Stage 3 Clinical Information Reconciliation measure and combine it with the Request/Accept Summary of Care measure to create a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. This proposed new measure would include actions from both the current Request/Accept Summary of Care measure and Clinical Information Reconciliation measure and focus on the exchange of the health care information while reducing the administrative burden of reporting on two separate measures.

We stated that if we did not finalize the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, we would maintain the current Health Information Exchange objective, associated measures and exclusions under § 495.24(c)(7) as described in section VIII.D.5. of the preamble of the proposed rule and as outlined in the table in that section which describes Stage 3 objectives and measures if new scoring methodology is not finalized.

Comment: One commenter suggested retaining the previous names of the Request/Accept Summary of Care and Clinical Information Reconciliation measures for consistency and to prevent confusion with the HIPAA electronic transaction for ''Referrals'' which also uses the terminology ''loops.''

Response: We respectfully decline to retain the previous name of the measures Request/Accept Summary of Care and Clinical Information Reconciliation as the overall intent is to combine the functionalities and actions of both measures to reduce the burden of having to report on two separate measures thereby simplifying reporting. We noted in the proposed rule that the separate Clinical Information Reconciliation measure does not include the exchange of health care information nor use of CEHRT to successfully complete the measure action and is redundant in the action to incorporate summary of care records with the Request/Accept Summary of Care measure. As previously indicated in the proposed rule and this final rule, the focus of the program is on reducing burden, increasing interoperability, exchange of health care information and the advanced use of CEHRT.

We disagree the measure name will create undue confusion with the HIPAA electronic transaction as both fall under separate programs and are associated with differing actions.

Comment: A few commenters agreed with use of any C–CDA document templates available within the C–CDA which contains the most clinically relevant information that may be required by the recipient of the transition or referral. The commenters stated this proposal supports increased flexibility, enables increased information sharing between care providers, and will help providers better understand their patient's history.

Response: We appreciate the feedback by the commenter and agree that this proposal will provide further flexibility for health care providers to focus on clinically relevant information and decrease burden associated with reporting requirements.

Comment: A few commenters requested that CMS allow for flexibility to use any HL7 C–CDA formats available to meet the HIE measures to create and electronically send summary of care records. A few commenters stated all CEHRT does not support every document types within the HL7 C–CDA nor are they applicable in every setting.

One commenter stated that since other document types/templates for the 2015 Edition are not required, availability and delivery within the suggested timeframe for implementation of the 2015 Edition may be unlikely; therefore, healthcare providers should not be limited to the three document types as part of the 2015 Edition.

Another commenter stated that CEHRT should be tested for the ability to generate and send the needed C–CDA template as well as the ability to receive and accept any C–CDA template; therefore, standard templates should be required.

Response: We appreciate commenters' support for the proposal to allow use of any document template within the C–CDA standard for purposes of the measures under the Health Information Exchange objective. We believe this proposal will provide further flexibility for health care providers to focus on clinically relevant information. We note that CEHRT supports the ability to send and receive C–CDA documents according to Releases 1.1 and 2.1 to support interoperability and exchange. The 2015 Edition transitions of care certification criterion at § 170.315(b)(1) requires Health IT Modules support the Continuity of Care Document, Referral Note, and (inpatient settings only) Discharge Summary document templates.

At a minimum, all CEHRT will be able to support exchange of those three document types therefore, testing should not be necessary. However, that does not preclude developers of CEHRT in supporting additional document templates.

While eligible hospitals' and CAHs' CEHRT must be capable of sending the full C–CDA upon request, we believe this additional flexibility will help support clinicians efforts to ensure the information supporting a transition is relevant. We note that in the use of a document template beyond those available in the certification program, the provider would need to work with their developer to determine appropriate technical workflows and implementation.

Comment: One commenter stated that C–CDA standards used for referrals should be required to include data to link a referral request to consult report, a universal referral tracking or index number, better patient identity matching and use of common titles for the document.

Response: We appreciate the comment and encourage the commenter to participate in the standards development-enhancement process of HL7, the steward of the HL7 Implementation Guide for CDA Release 2.

Comment: A commenter recommended support for the widespread availability of patient identifiers for the health information exchange measures in the Promoting Interoperability Programs.

Response: We appreciate the comment and will consider the recommendation for future rulemaking to the extent permissible by law.

(1) Modifications To Send a Summary of Care Measure

In the proposed rule (83 FR 20531), we proposed to change the name of the Send a Summary of Care measure at 42 CFR 495.24(c)(7)(ii)(A) to Support Electronic Referral Loops by Sending Health Information at 42 CFR 495.24(e)(6)(ii)(A), to better reflect the emphasis on completing the referral loop and improving care coordination. We proposed to change the measure description only to remove the previously defined threshold from Stage 3, in alignment with our proposed implementation of a performance-based scoring system, to require that the eligible hospital or CAH create a summary of care record using CEHRT and electronically exchange the summary of care record for at least one transition of care or referral.

Proposed name and measure description: Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

We stated in the proposed rule that if an eligible hospital or CAH is the recipient of a transition of care or referral, and subsequent to providing care the eligible hospital or CAH transitions or refers the patient back to the referring provider of care, this transition of care should be included in the denominator of the measure for the eligible hospital or CAH.

We proposed that eligible hospitals and CAHs may use any document template within the C–CDA standard for purposes of the measures under the Health Information Exchange objective. While eligible hospitals' and CAHs' CEHRT must be capable of sending the full C–CDA upon request, we believe this additional flexibility will help support efforts to ensure the information supporting a transition is relevant.

For instance, when the eligible hospital or CAH is referring to another health care provider, the recommended document is the ''Referral Note,'' which is designed to communicate pertinent information from a health care provider who is requesting services of another health care provider of clinical or nonclinical services. When the receiving health care provider sends back the information, the most relevant C–CDA document template may be the ''Consultation Note,'' which is generated by a request from a clinician for an opinion or advice from another clinician. However, eligible hospitals and CAHs may choose to utilize other documents within the C–CDA to support transitions, for instance the ''Discharge Summary'' document.

We noted that if the new scoring methodology and measure were finalized, this measure would not have a reporting threshold and if we did not finalize the proposed scoring methodology, we would maintain the current Stage 3 requirements finalized in previous rulemaking. Therefore, eligible hospitals and CAHs would be required report on the Stage 3 Send a Summary of Care measure under the Health Information Exchange objective codified at § 495.24(c)(7)(ii)(A).

Comment: A few commenters supported the name change to Supporting Electronic Referral Loops by Sending Health Information. A few commenters agreed with the focus on patient outcomes with this measure. These commenters believed that the measure focuses on ensuring that the patient's health data is accurately shared between health care providers thereby improving care coordination and patient outcomes.

Response: We appreciate the support for the name change and focus and believe this reflects our emphasis on improving care coordination and communication between health care providers, as it relates to completing the referral loop. We believe that the emphasis on closing the referral loop will positively influence patient outcomes due to improved exchange of clinically relevant patient health information for care performed by other parties.

Comment: One commenter voiced concerned that many providers do not have interoperable EHRs and sending a summary of care to these providers should not be counted towards meeting requirements under the Promoting Interoperability Program.

Response: We thank the commenter for its feedback. We are committed to the use of certified health IT to effectively support the interoperable electronic exchange across the care continuum. While we recognize that not all of the provider types to whom a hospital or CAH might send a care summary currently use technology certified under the ONC Health IT Certification Program, we believe that it is important that eligible hospitals and CAHs are including these workflows in their everyday practice. Since the

beginning of the EHR Incentive Program, hospital efforts to engage in and expand health information exchange across the care continuum have helped to build and evolve health IT infrastructure across the nation. We note that eligible hospitals have achieved near-universal adoption of certified health IT, with 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals having adopted certified EHRs with the capability to electronically export a summary of clinical care as of 2015. We also note that there may be many cases where this information is valuable to health care providers even if they are not capable of receiving and incorporating the information when it is transmitted from interoperable health IT according to applicable interoperability standards.

After consideration of the public comments we received, we are finalizing the name change of Send a Summary of Care to Support Electronic Referral Loops by Sending Health Information and codifying this measure at 42 CFR 495.24(e)(6)(ii)(A).

We are finalizing that eligible hospitals and CAHs may use any document template within the C–CDA standard for purposes of the measures under the Health Information Exchange objective.

We are adopting the measure description as proposed, in alignment with the scoring methodology in section VIII.D.5. of the preamble of this final rule:

Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

We are finalizing the proposal to remove the exclusion from this measure.

(2) Removal of the Request/Accept Summary of Care Measure

In the proposed rule (83 FR 20531), we proposed to remove the Request/Accept Summary of Care measure at § 495.24(c)(7)(ii)(B) under the proposed § 495.24(e)(6). Our analysis of the existing measure and stakeholder input indicated the measure specification does not effectively identify when health care providers are engaging with other providers of care or care team members to obtain up-to-date patient health information and to subsequently incorporate relevant data into the patient record, resulting in unintended consequences where health care providers implement either:

- A burdensome workflow to document the manual action to request or obtain an electronic record, for example, clicking a check box to document each phone call or similar manual administrative task, or
- A workflow which is limited to only querying internal resources for the existence of an electronic document.

Further, stakeholder feedback highlights the fact that the requirement to incorporate data is insufficiently clear regarding what data must be incorporated.

In addition, as indicated in the proposed rule, stakeholders noted that when approached separately, the incorporate portion of the Request/Accept Summary of Care measure is both inconsistent with and redundant to the Clinical Information Reconciliation measure which causes unnecessary burden and duplicative measure calculation.

Comment: One commenter stated that the removal of this measure would not reduce burden as the Request/Accept Summary of Care measure would be included in the Support Electronic Referral Loops By Receiving and Incorporating Health Information which was thought to be a more complex measure to calculate.

Several commenters disagreed with the new Support Electronic Referrals Loops By Receiving and Incorporating Health Information measure as they believed it is too burdensome under one measure and does not align with their current workflows creating a potential for errors.

A few commenters stated this measure would be more complex and difficult to calculate as it includes multiple actions under one measure. One commenter stated there was not enough time allowed for implementation since it is a new measure and requires testing and certification.

Response: We disagree that removing this measure would not reduce burden. We believe that the current separation of the Request/Accept Summary of Care measure from the Clinical Information Reconciliation measure is burdensome and redundant in the action of incorporation of the summary of care record. In addition, stakeholder concerns indicated the separate Request/Accept Summary of Care and Clinical Information Reconciliation measures were not reflective of clinical and care coordination workflows.

For instance, under the prior Request/Accept Summary of Care measure, a provider receiving a transition of care was required to obtain the patient's record (if not already received via a Direct message), through querying for the record or a manual request (such as a phone call). Once received, the provider was then required to ''incorporate'' this information into the patient's record. Each individual action in this process, from querying and requesting to incorporating, had to be tracked for each individual use case in order to calculate the measure. Under the Clinical Information Reconciliation measure, the provider was required to review a record received electronically or by other means, or capture information through verbal discussion with the patient, and then use this information to reconcile the medications, medication allergies, and problem list within the record. As with the Request/Accept Summary of Care measure, each of these actions had to be tracked in order to calculate the measure.

The combined measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information, significantly simplifies these actions, specifying that upon receipt of an electronic record, the provider must reconcile information regarding medications, medication allergies, and problem list. Rather than tracking individual actions as required by existing measures, this new measure would instead focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record. We believe that moving away from the actions requiring manual or other tracking in the existing measures will reduce burden for providers and developers and more closely align with provider workflows.

In addition, with regard to the commenter's concerns about implementation timing, we are establishing an exclusion to this measure for 2019. We believe that all eligible hospitals and CAHs should be able to perform the actions required by this measure by 2020. We also note that this measure aligns with our goals to have a truly interoperable system which includes the free flow of health information between EHR systems.

After consideration of the public comments we received, we are finalizing the removal of the Request/Accept Summary of Care measure as proposed.

(3) Removal of the Clinical Information Reconciliation Measure

In the proposed rule (83 FR 20532), we proposed to remove the Clinical Information Reconciliation measure at

§ 495.24(c)(7)(ii)(C) from the new measures at proposed § 495.24(e)(6) to reduce redundancy, complexity, and provider burden.

As discussed in the proposed rule, we believe the Clinical Information Reconciliation measure is redundant in regard to the requirement to ''incorporate'' electronic summaries of care in light of the requirements of the Request/Accept Summary of Care measure. In addition, the measure is not fully health IT based as the exchange of health care information is not required to complete the measure action and the measure specification is not limited to only the reconciliation of electronic information in health IT supported workflows. In addition, feedback from hospitals, clinicians, and health IT developers indicates that because the measure is not fully based on the use of health IT to meet the measurement requirements, eligible hospitals and CAHs must engage in burdensome tracking of manual workflows.

Comment: Multiple commenters supported the removal of this measure and stated the removal of this measure would reduce burden.

Response: We appreciate the support and agree that it will help to reduce provider burden and refocus on the use of health IT to meet the measure requirements.

After consideration of the public comments we received, we are finalizing the removal of the Clinical Information Reconciliation measure as proposed.

(4) New HIE Measure: Support Electronic Referral Loops by Receiving and Incorporating Health Information

In the proposed rule (83 FR 20532 through 20533), we proposed to add the following new measure for inclusion in the Health Information Exchange objective at § 495.24(e)(6)(ii)(B): Support Electronic Referral Loops by Receiving and Incorporating Health Information. This measure would build upon and replace the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures.

Proposed measure name and description: Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list.

We proposed to combine two existing measures, the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure, in this new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to focus on the exchange of health care information as the current Clinical Information Reconciliation measure is not reliant on the exchange of health care information nor use of CEHRT to complete the measure action. We did not propose to change the actions associated with the existing measures; rather, we proposed to combine the two measures to focus on the exchange of the health care information, reduce administrative burden, and streamline and simplify reporting.

CMS and ONC worked together to define the following for this measure:

Denominator: Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.

Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

We proposed the denominator would increment on the receipt of an electronic summary of care record after the eligible hospital or CAH engages in workflows to obtain an electronic summary of care record for a transition, referral or patient encounter in which the health care provider has never before encountered the patient and the numerator would increment upon completion of clinical information reconciliation of the electronic summary of care record for medications, medication allergies, and current problems. The eligible hospital or CAH would no longer be required to manually count each individual non-health-IT-related action taken to engage with other providers of care and care team members to identify and obtain the electronic summary of care record. Instead, the measure would focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record. We believe this approach would allow eligible hospitals and CAHs to determine and implement appropriate workflows supporting efforts to receive the electronic summary of care record consistent with the implementation of effective health IT information exchange at an organizational level.

Finally, we proposed to apply our existing policy for cases in which the eligible hospital or CAH determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the eligible hospital or CAH may count the reconciliation in the numerator without completing a redundant or duplicate update to the record. We sought public comment on methods by which this specific action could potentially be electronically measured by the provider's health IT system—such as incrementing on electronic signature or approval by an authorized provider—to mitigate the risk of burden associated with manual tracking of the action.

In addition, we sought public comment on methods and approaches to quantify the reduction in burden for eligible hospitals and CAHs implementing streamlined workflows for this proposed measure. We also sought public comment on the impact these proposals may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes. Specifically, we sought public comment on whether ONC should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification. Finally, we sought public comment on whether this proposed new measure that combines the Request/Accept Summary of Care and Clinical Information Reconciliation measures should be adopted, or whether either or both of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures should be retained in lieu of this proposed new measure.

We stated if we finalize the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, an exclusion would be available for eligible hospitals and CAHs that could not implement the Support Electronic Referral Loops by Receiving and Incorporating Health

Information measure for an EHR reporting period in CY 2019.

We proposed that we would maintain the current Stage 3 requirements finalized in previous rulemaking if we did not finalize the new scoring methodology proposed in section VIII.D.5. of the preamble of the proposed rule. Therefore, eligible hospitals and CAHs would be required report on the Stage 3 Request/Accept Summary of Care measure and Clinical Information Reconciliation measures under the Health Information Exchange objective codified at § 495.24(c)(7)(ii)(B) and (C).

We also proposed that, in order to meet this measure, an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(1) and (b)(2).

Comment: One commenter supported the exclusion for Support Electronic Referrals Loops by Receiving and Incorporating Health Information.

Response: We appreciate the support and believe the exclusion will benefit health care providers who are unable to implement the measure for an EHR reporting period in 2019 due to additional time needed to perform necessary updates and workflow changes.

Comment: A few commenters requested that CMS not finalize this measure and maintain the Request/Accept Summary of Care information and Clinical Information Reconciliation measures separately. These commenters believed that clinical information reconciliation presents many challenges including partially automated reconciliation and functionalities for problem list, which require some manual actions. These commenters suggested that the actions required for the combined measure would create a complex workflow and would not result in improved interoperability.

Response: We believe that the current separation of the measures is burdensome and redundant in the action of incorporation of the summary of care record. In addition, we listened to stakeholder concerns regarding the separate Request/Accept Summary of Care and Clinical Information Reconciliation measures, which indicated that the separation between receiving and reconciling patient health information is not reflective of clinical and care coordination workflows and the incorporation aspect is redundant to both measures. We agree the process of clinical information reconciliation includes both automated and manual reconciliation to allow the receiving health care provider to work with both the electronic data provided with any necessary review, and to work directly with the patient to reconcile their health information. We also indicated in previous rulemaking (80 FR 62861) that if no update is necessary, the process of reconciliation may consist of simply verifying that fact or reviewing a record received on referral and determining that such information is merely duplicative of existing information in the patient record, which we believe would reduce burden. In addition, we believe that combining the measures of Request/Accept Summary of Care and Clinical Information Reconciliation retains the focus on interoperability and exchange of health information as opposed to the separation of the measures where health information exchange and interoperability was not a focus for clinical information reconciliation.

Comment: One commenter stated that health care providers should not be held accountable for performance scores that depend on actions of another health care provider to receive credit.

One commenter stated that health care providers are querying for external data but not consistently ''closing the referral loop'' by sending information back, and recommended automating a closed loop referral workflow process.

Response: We disagree with the commenter's concern regarding being accountable for another health care provider's actions. We stated in the proposed rule (83 FR 20516) that we were moving to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. The Health Information Exchange measures focus on interoperability and coordination of care. Therefore, we do not believe health care providers are being held accountable for the actions of another health care provider, rather, we are focusing on improving interoperability and patient outcomes through exchange of health care information. In addition, we note that the denominator language includes ''the number of summary of care records received using CEHRT,'' therefore, an eligible hospital or CAH would not increment the denominator if a summary of care record was not received; however, we encourage the eligible hospital or CAH to make a reasonable effort to acquire the summary of care, such as a request to the referring provider and a query of any HIE or service. To that end, we believe that if information is not received after a referral, the eligible hospital or CAH who referred the patient should also make a reasonable effort to acquire the summary of care from the referral. We believe this will effectively improve closing the referral loop after a referral. We believe that in order to have an interoperable system, EHRs should have a free flow of data between systems. We also note that this measure takes into account the entire cycle of care and helps to foster agreement among healthcare providers.

Similarly, we believe that it is up to the referring provider to ensure that they are taking into account the care of their patients in order to make necessary and relevant clinical decisions. We believe that this consolidated measure gets to that end.

We appreciate the commenter's support for efforts to improve processes and technology solutions around closing referral loops. We believe that the measures finalized in this rule will help incentivize further innovation around interoperable exchange of information to support these processes. We also encourage providers to work with health IT developers to pursue products that deliver greater automation around key care coordination functions.

We will continue to collaborate with ONC in future rulemaking on possible functionalities which could support an automated processes for closing the referral loop.

Comment: One commenter stated that there should be a model for incorporation of health information including attachment/incorporation into the record, parse and group. The commenter further added that it should at least require data domains for the summary of care record (Medications, Medication Allergies, Problem Lists) with the ability to compare for duplication and advance informatics analytics against all data from all sources.

Response: Health IT certified to the ONC 2015 Edition criteria at § 170.315(b)(2) will have the model capabilities recommended by the commenter. The ONC 2015 Edition includes requirements for health IT to be capable of the reconciliation and incorporation of health information from multiple sources. Health IT certified to the 2015 Edition must demonstrate that a transition of care/referral summary artifact received by a system can be properly matched to the correct patient, and then simultaneously display (in a single view) the data from at least two sources. The certified health IT must enable a user to create a single reconciled list of each of the following: Medications; medication allergies; problems; enable a user to review and validate the accuracy of a final set of data, and with the user's confirmation, automatically update the list, and

incorporate the reconciled data. The 2015 Edition requirement is codified at § 170.315(b)(2) (Clinical information reconciliation and incorporation).

Comment: A commenter requested clarification on the definition of a new patient.

Response: As we stated in the proposed rule (83 FR 20532), this measure refers to patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.

After consideration of the public comments we received, we are finalizing the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as proposed and codifying this measure at § 495.24(e)(6)(ii)(B). We are finalizing the proposal to apply the existing policy for cases in which the eligible hospital or CAH determines no update or modification is necessary within the patient record based on the electronic clinical information received, and the eligible hospital or CAH may count the reconciliation in the numerator without completing a redundant or duplicate update to the record.

We are finalizing an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(1) and (b)(2).

We are adopting the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as follows:

Measure Description: Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, mediation allergy, and current problem list.

Denominator: Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.

Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

We are finalizing an exclusion for eligible hospitals and CAHs that could not implement the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure for an EHR reporting period in CY 2019.

d. Final Policy for the Provider to Patient Exchange Objective

The Provider to Patient Exchange objective for eligible hospitals and CAHs builds upon the goal of improved access and exchange of patient health information, patient centered communication and coordination of care using CEHRT. In section VIII.D.5. of the preamble of the proposed rule, we proposed to rename the Patient Electronic Access to Health Information objective to Provider to Patient Exchange, remove the Patient Specific Education measure and rename the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information. In addition, we proposed to remove the Coordination of Care through Patient Engagement objective and all associated measures. The existing Stage 3 Patient Electronic Access to Health Information objective includes two measures under § 495.24(c)(5)(ii) and the existing Stage 3 Coordination of Care through Patient Engagement objective includes three measures under § 495.24(c)(6)(ii).

We reviewed the existing Stage 3 requirements and determined that the proposals for the Patient Electronic Access to Health Information objective and Coordination of Care through Patient Engagement objective could reduce program complexity and burden and better focus on leveraging the most current health IT functions and standards for patient flexibility of access and exchange of health information. We proposed the Provider to Patient Exchange objective would include one measure, the existing Stage 3 Provide Patient Access measure, which we proposed to rename to Provide Patients Electronic Access to Their Health Information. In addition, we proposed to revise the measure description for the Provide Patients Electronic Access to Their Health Information measure to change the threshold from more than 50 percent to at least one unique patient in accordance with the proposed scoring methodology proposed in section VIII.D.5. of the preamble of the proposed rule. As discussed in section VIII.D.6.a. of the preamble of the proposed rule, we proposed to remove the exclusion for the Provide Patients Electronic Access to Their Health Information measure.

We proposed that if we finalized the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, we would remove all of the other measures currently associated with the Patient Electronic Access to Health Information objective and the Coordination of Care through Patient Engagement objective.

We stated that if we did not finalize the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, we would maintain the existing Stage 3 requirements finalized in previous rulemaking as outlined in the table in that section which describes Stage 3 objectives and measures if new scoring methodology is not finalized. Therefore, we would retain the existing Patient Electronic Access to Health Information objective, associated measures and exclusions under § 495.24(c)(5) and the existing Coordination of Care through Patient Engagement objective, associated measures and exclusions under § 495.24(c)(6).

(1) Modifications To Provide Patient Access Measure

In the proposed rule (83 FR 20534), we proposed to change the name of the Provide Patient Access measure at 42 CFR 495.24(c)(5)(ii)(A) to Provide Patients Electronic Access to Their Health Information at proposed 42 CFR 495.24(e)(7)(ii) (in the proposed rule (83 FR 20534), we inadvertently referred to 42 CFR 495.24(e)(7)(ii)(A)) to better reflect the emphasis on patient engagement in their health care and patient's electronic access of their health information through use of APIs. We proposed to change the measure description only to remove the previously established threshold from Stage 3, in alignment with our proposed implementation of a performance-based scoring methodology, to require that the eligible hospital or CAH provide timely access for viewing, downloading or transmitting their health information for at least one unique patient discharged using any application of the patient's choice.

Proposed name and measure description: Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged

from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

- The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and
- The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT.

We proposed to change the measure name to emphasize electronic access of patient health information as opposed to use of paper based actions in accordance with the 2015 EHR Incentive Programs final rule policy for Stage 3 to discontinue inclusion of paper based formats and limit the focus to only health IT solutions to encourage adoption and innovation in use of CEHRT (80 FR 62783 through 62784). In addition, we are committed to promoting patient engagement with their health care information and ensuring access in an electronic format upon discharge from the eligible hospital or CAH.

We noted that under the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, measures would not have required thresholds for reporting. Therefore, if the new scoring methodology and measure were finalized, this measure would not have a reporting threshold. We stated that if we did not finalize the proposed scoring methodology, we would maintain the existing Stage 3 requirements finalized in previous rulemaking. Therefore, eligible hospitals and CAHs would be required report on the Stage 3 Provide Patient Access measure under the Patient Electronic Access to Health Information objective codified at § 495.24(c)(5)(ii)(A).

Comment: Several commenters supported the renaming of the measure as proposed.

Response: We thank the commenters for their support and believe the name change effectively focuses the electronic aspect of the measure and our focus on leveraging advanced used of health IT.

Comment: One commenter indicated concern over the current software available for this objective, which results in difficult and burdensome record submission and patient access. The commenter recommended vendor-specific regulations to address the software concern that does not increase costs for health care providers.

Response: We appreciate the commenter's feedback and have emphasized increasing interoperability, burden reduction and improving patient's electronic access to their health information. We believe that the new functionalities of the 2015 Edition such as the health care provider's ability to make patient data accessible through an API to other third party applications, will increase interoperability as well as communication and information between providers and patients. We will continue to review program requirements and work with our partners to focus on burden reduction.

Comment: One commenter recommended that eligible hospitals and CAHs should be required to share all results with patients through the use of API functionality and that failure to do so should be considered to be information blocking. One commenter felt that eligible hospitals and CAHs should not be able to turn off any API functionality which could limit patient access to their health care information.

Response: Patients should be able to access their health information on demand, and we encourage health care providers to maintain the appropriate functionalities for patient access to their health information at all times unless the system is undergoing scheduled maintenance, which should be limited to the least amount of time necessary to perform the maintenance. Furthermore, we noted in previous rulemaking (80 FR 62779) that the actions and workflows that support the requirements of the EHR Incentive Programs are intended to be in effect continuously, not enabled and implemented for only 90 days.

Comment: One commenter supported no longer including paper-based methods in measure calculations.

Response: We thank the commenter for the support and believe the removal of paper-based actions in part supports the discontinuation of manual paper-based calculation and chart abstraction and leverages the advanced use of CEHRT.

Comment: A commenter recommended an exclusion for the Provide Patients Electronic Access to Their Health Information measure for eligible hospitals and CAHs that cannot successfully identify an app that meets the security needs of their system.

Response: We decline to implement exclusion criteria for the Provide Patients Electronic Access to Their Health Information measure as we believe eligible hospitals and CAHs should work with their health IT vendors to identify applications that meet their security needs.

Comment: A commenter requested that the definition of ''timely'' should be increased to 72 hours from 36 hours.

Response: We decline to change the definition of ''timely'' and note that providing patients access to their health information is a top priority for the program and we have not received compelling evidence to indicate that 36 hours is not feasible. We continue to believe that 36 hours is a reasonable timeframe because it allows for immediate access and a reasonable amount of time for health care providers to review any information necessary before it is made available to the patient as provided in previous rulemaking (80 FR 62813 through 62814).

Comment: A commenter requested that CMS provide privacy language and guidance that health care providers can use to present to patients who choose to access their health information via an API.

Response: A resource titled ''Key Privacy and Security Considerations for Healthcare Application Programming Interfaces (APIs)'' dated December 2017 is available on ONC's *https://www.HealthIT.gov* website and includes information on this issue. We refer readers to additional resources that may be useful from the HHS Office for Civil Rights through the ''HIPAA for Individuals'' selection under the ''HIPAA—Health Information Privacy'' selection at the *https://www.hhs.gov/* website.

Comment: One commenter requested that CMS address parental/guardian proxy rights related to a child's personal health information, privacy rights, and adolescent confidentiality. The commenter also requested clarification on the definition of ''timely access'' specific to pediatric providers.

Response: We did not make specific proposals related to parental/guardian proxy rights, privacy rights, and adolescent confidentiality, and we encourage the commenter to consult existing sources of applicable law with regard to these topics. We did not propose to change the definition of ''timely access'' to health care information under this rule and the definition will remain within 36 hours as finalized in the 2015 EHR Incentive Programs final rule (80 FR 62813 through 62814).

Commenter: One commenter stated electronic connectivity for sharing of records is optimal but not always possible—and never will be. The commenter further stated that even while there is movement to a more efficient, interoperable system, there will still be myriad situations from frontier health care delivery to computer

failure that require a ''paper'' alternative and that many of these situations are critical for the patient involved.

Response: We appreciate the commenter's concerns and understand that health care providers have an obligation to do their best to serve patients even during times of minor disruptions, such as a computer downtime or failure, or in major dislocations, such as those that may result from natural disasters. Therefore, contingency planning is prudent for continuity of all essential aspects of health care services, including the electronic health record. One available resource to assist with this issue is the ONC Safety Assurance Factors for EHR Resilience (SAFER) Guides (*https://www.healthit.gov/topic/safety/safer-guides*), specifically the Contingency Planning Guide (*https://www.healthit.gov/sites/default/files/safer/guides/safer_contingency_planning.pdf*). This guide identifies recommended safety practices associated with planned or unplanned EHR unavailability—instances in which clinicians or other end users cannot access all or part of the EHR and provides useful recommendations from backup procedures for potential clinical or administrative data loss to recommendations around use of paper forms to replace key EHR functions during downtimes.

Comment: Multiple commenters requested that the measure should allow health care providers to offer access to at least one application or limit applications to ones deemed secure by the healthcare provider rather than any application configured to meet the technical specifications of the API in the CEHRT.

Response: It was not our intent to imply that eligible hospitals and CAHs and their technology suppliers would not be permitted to take reasonable steps to protect the privacy and security of their patients' information. Such measures might include vetting application developers prior to allowing their applications to connect to the API functionality of the provider's health IT. We also remind stakeholders that even in the case where a health care provider or its CEHRT developer/vendor chooses not to vet application developers, any application would not have unmitigated access to data in the health care provider's CEHRT. To the contrary, each application should be registered and thus be identifiable so that the health care provider, or their CEHRT developer/vendor that supplies the API technology to the provider, can deactivate any application's access if the application functions in anomalous or malicious ways (for example, denial of service attack). We also anticipate that a patient seeking access to their data using any application may need to authenticate (using credentials previously issued by a healthcare provider or trusted source) and authorize the application to connect to the API server. In addition, the measure does not require that the eligible hospital or CAH provide an application for its patients' use.

Comment: A few commenters requested that CMS slow the implementation and requirements for use of APIs secondary to risks for systems security and confidentiality of health information.

Response: We believe that we are moving along with the current implementation of APIs and as a result are revising elements of the Promoting Interoperability Programs to take into account the new innovations. In addition, we believe that we are providing ample time for health care providers to incorporate the necessary system securities and confidentiality provisions.

Comment: A commenter recommended creation of a site, list or address where health care providers may report and obtain information on suspicious applications.

Response: We appreciate the commenter's recommendation, and we refer readers to the Health IT Feedback submission mechanism, at: *https://www.healthit.gov/form/healthit-feedback-form*.

Comment: A few commenters requested additional guidance on how information blocking requirements would be viewed in relation to security of systems with use of APIs, specifically that health care provider determination of an unsecure API should not fall under information blocking.

Response: We thank the commenters for the input and will continue to consider how any policy related to information blocking should treat issues involving the use of APIs.

Comment: One commenter stated that CMS should work with ONC to specify required standards for API access to promote evolution of relevant patient facing applications.

Response: We thank the commenter for the input and will continue to work across HHS and with partners on API standards to support patient access to their electronic health information.

After consideration of the public comments we received, we are finalizing the Provide Patients Electronic Access to Their Health Information measure as proposed and codifying this measure at 42 CFR 495.24(e)(7)(ii).

We are finalizing the measure description in alignment with the scoring methodology in section VIII.D.5. of the preamble of this final rule:

Measure description: Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

- The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and
- The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT.

(2) Removal of the Patient Generated Health Data Measure

In the proposed rule (83 FR 20534), we proposed to remove the Patient Generated Health Data (PGHD) measure at 42 CFR 495.24(c)(6)(ii)(C) at proposed § 495.24(e)(7) to reduce complexity and focus on the goal of using advanced EHR technology and functionalities to advance interoperability and health information exchange.

As finalized in the 2015 EHR Incentive Programs final rule (80 FR 62851), the measure is not fully health IT based as we did not specify the manner in which health care providers would incorporate the data received. Instead, we finalized that health care providers could work with their EHR developers to establish the methods and processes that work best for their practice and needs. We indicated that this could include incorporation of the information using a structured format (such as an existing field in the EHR or maintaining an isolation between the data and the patient record such as incorporation as an attachment, link or text reference which would not require the advanced use of CEHRT. We note that although this measure requires use of the 2015 Edition, it does not require key updates to functions and standards of health IT, therefore, it does not align with the current program goals of improving interoperability, prioritizing actions completed electronically and use of advanced CEHRT functionalities.

Comment: Several commenters supported the removal of the measure indicating the standards and processes were immature.

Response: We agree that the Patient Generated Health Data did not focus on the advanced use of CEHRT as it was not fully health IT-based nor were the actions associated with the measure fully electronic and may have included paper-based actions, which did not align with the focus of Stage 3 to remove paper based actions. In addition, stakeholder feedback we received through correspondence and listening sessions indicated there was confusion related to the types of data that would be applicable and the situations in which the patient data would apply. We also believe removal of this measure will decrease reporting burden as it could require aspects of manual processes to incorporate the data and did not focus on the advanced use of CEHRT.

Comment: One commenter requested that CMS retain the functionality of this measure if removed due to the benefits of receiving patient generated health data.

Response: We have previously stated to healthcare providers in rulemaking (80 FR 62786) that functions and standards related to measures that are no longer required for the Promoting Interoperability Programs could still hold value for some healthcare providers and may be utilized as best suits their practice and the preferences of their patient population. The removal of measures is not intended to discourage the use of the standards, the implementation of best practices, or conducting and tracking the information for providers' own quality improvement goals.

After consideration of the public comments we received, we are finalizing the removal of this measure as proposed.

(3) Removal of the Patient-Specific Education Measure

In the proposed rule (83 FR 20534), we proposed to remove the Patient-Specific Education measure at § 495.24(c)(5)(ii)(B) at proposed § 495.24(e)(7) as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from health care providers' progress on current program priorities.

We believe that the Patient-Specific Education measure does not align with the current emphasis of the Medicare Promoting Interoperability Program to increase interoperability, leverage the most current health IT functions and standards or reduce burden for eligible hospitals and CAHs. For example, the Patient-Specific Education measure's primary focus is on use of CEHRT for patient resources specific to their health care and diagnosis as well as patient centered care. However, the education resources do not need to be maintained within or generated by CEHRT. Therefore, even though the CEHRT identifies the patient educational resources, the process to generate them could take additional time and interrupt health care provider's workflows. In addition, there could be redundancy in providing educational materials based on resources identified by the CEHRT as CEHRT identifies educational resources using the patient's medication list and problem list but can also include other elements as well. If there are no changes to a patient's health status or treatment based on his or her health care information, there would likely be many resources and materials that present the same type of information and could increase burden to the health care provider in seeking additional resources to provide.

Comment: A few commenters recommended keeping the Patient-Specific Education measure as research conducted indicates the measure improves patient outcomes and improves quality of care, and reduces costs through patient knowledge of their health conditions. In addition, the commenters indicated the Patient-Specific Education measure instantly produces materials for patients increasing efficiency and lowering costs associated with manual procurement of those materials.

Response: We disagree that the Patient-Specific Education measure should be retained as a required measure. While we believe that there are merits to the Patient-Specific Education measure, we affirm our position that the Patient-Specific Education measure does not align with the current emphasis of the Medicare Promoting Interoperability Program which aims to increase interoperability, leverage the most current health IT functions and standards and reduce burden for eligible hospitals and CAHs. In addition, as we stated in the proposed rule (83 FR 20525), although the measure would no longer be required for reporting, eligible hospitals and CAHs may continue to use the standards and functions of those measures no longer required for successful demonstration of meaningful use if they are beneficial for them. We believe that if health care providers find value in the Patient-Specific Education measure, they will continue to use the standards and functions, even if not required.

Comment: A few commenters supported the removal of the Patient-Specific Education measure, but stated that CMS should encourage use of its functionality.

Response: We thank the commenters for their support of the removal. As we indicated in the preceding response, providers may choose to continue to use the functionalities that support the measure even if the measure is no longer required.

After consideration of the public comments we received, we are finalizing the removal of this measure as proposed.

(4) Removal of the Secure Messaging Measure

In the proposed rule (83 FR 20534 through 20535), we proposed to remove the Secure Messaging measure at § 495.24(c)(6)(ii)(B) at proposed § 495.24(e)(7) as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from health care providers' progress on current program priorities.

Secure Messaging was finalized as a Stage 3 measures for eligible hospitals and CAHs in the 2015 EHR Incentive Programs final rule with the intent to build upon the Stage 2 policy goals of using CEHRT for provider-patient communication (80 FR 62841 through 62849). As mentioned above, we believe that Secure Messaging does not align with the current emphasis of the Medicare Promoting Interoperability Program to increase interoperability or reduce burden for eligible hospitals and CAHs.

In addition, we believe there is burden associated with tracking secure messages, including the unintended consequences of workflows designed for the measure rather than for clinical and administrative effectiveness. We believe that because this measure is not required under Modified Stage 2, removal would not negatively impact patient engagement nor care coordination and serve to decrease burden.

In addition, after further review, we believe that this measure may not be practical for eligible hospitals and CAHs as the patient would likely receive follow up care from another health care provider such as the patient's primary care physician, a rehabilitation facility, or home health after discharge. The patient would communicate with those health care providers instead of the hospital for information related to their health post-discharge.

Comment: A few commenters supported the removal of the secure messaging measure, indicating it would be burdensome to eligible hospitals and CAHs as follow up should be conducted

with the health care provider the patient is transitioning to.

Response: We thank the commenters for their support. We agree this measure would detract from health care providers' progress on current program priorities and follow up after discharge should be with the health care provider to whom the patient's care is transitioned such as the patient's primary care provider, a rehabilitation facility, or home health provider. The patient would communicate with those health care providers instead of the hospital for information related to their health post-discharge.

After consideration of the public comments we received, we are finalizing the removal of this measure as proposed.

(5) Removal of the View, Download or Transmit Measure

In the proposed rule (83 FR 20535), we proposed to remove the View, Download or Transmit measure at § 495.24(c)(6)(ii)(A) at proposed § 495.24(e)(7) as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from eligible hospitals and CAHs progress on current program priorities.

We received health care provider and stakeholder feedback through correspondence, public forums, and listening sessions indicating there is ongoing concern with measures which require patient action for successful attestation. We have noted that data analysis on the patient action measures supports stakeholder concerns regarding the barriers that exist, which impact a provider's ability to meet the measure. We note that we have heard from these stakeholders that certain demographics of their patient populations which may include low-income, patients in rural areas, and an aging population, all contribute to the barriers of not having access to computers, internet and/or email. These barriers have resulted in certain patient actions measures being outside of the purview and control of the health care provider. They have also noted that this particular population is concerned with having their health information online. After additional review, we note that successful attestation predicated solely on a patient's action has inadvertently created burdens to health care providers and detracts from progress on the Promoting Interoperability Program's measure goals of focusing on patient care, interoperability and leveraging advanced used of health IT. Therefore, we proposed to remove the View, Download or Transmit measure.

Comment: Many commenters supported removal of the View, Download or Transmit measure as proposed.

Response: We appreciate support for removal of the measure. Previous stakeholder feedback through correspondence, public forums, and listening sessions indicated there is ongoing concern with measures which require health care providers to be accountable for patient actions such as VDT. We further understand that there are barriers which could negatively impact an eligible hospital or CAHs ability to successfully meet a measure requiring patient action, such as location in remote, rural areas and access to technology including computers, internet and/or email. As the issues described contribute to reporting burden and could negatively impact an eligible hospital or CAHs successful demonstration in the Promoting Interoperability Programs, we agree that removing the patient action measures will allow for focus on program goals of increasing interoperability and patient access to their health information.

After consideration of the public comments we received, we are finalizing the removal of this measure as proposed.

e. Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

In connection with the new scoring methodology we proposed in section VIII.D.5. of the preamble of proposed rule (83 FR 20535 through 20536), we proposed changes to the Public Health and Clinical Data Registry Reporting objective and six associated measures under 42 CFR 495.24(c)(8)(ii)(A) through (F) in proposed 42 CFR 495.24(e)(8) (in the proposed rule (83 FR 20535), we inadvertently referred to 42 CFR 495.24(e)(7)). We believe that public health reporting through EHRs will extend the use of electronic reporting solutions to additional events and care processes, increase timeliness and efficiency of reporting and replace manual data entry.

We proposed to change the name of the objective to Public Health and Clinical Data Exchange. Under the new scoring methodology proposed in section VIII.D.5. of the preamble of the proposed rule, in aligning with our goal to increase flexibility, improve value, and focus on burden reduction, we proposed that eligible hospitals and CAHs would be required to attest to the Syndromic Surveillance Reporting measure and at least one additional measure from the following options: Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting.

We proposed to require the Syndromic Surveillance Reporting measure under the Public Health and Clinical Data Exchange objective because the CDC indicates the primary source of data for syndromic surveillance comes from EHRs in emergency care settings. Typically, EHR data transmitted from health care facilities to public health agencies for syndromic surveillance are not filtered or categorized. As a result, public health agencies can use the same data that support delivery of care for an all-hazards surveillance approach.

In addition, syndromic surveillance reporting via CEHRT leverages the wealth and depth of clinical information that has not been captured before to study emerging health conditions like the rising opioid overdose epidemic. The data will also provide a unique opportunity to examine rare conditions and new procedures.

While we believe that it is important to leverage health IT through advanced use of CEHRT, for public health and clinical data registries reporting, we also want to reduce burden. Through stakeholder feedback, we understand that some of the existing active engagement requirements are complicated and confusing, and contributed to unintended burden due to issues related to readiness or onboarding for electronic exchange with registries. Therefore, under the new scoring methodology proposed in section VIII.D.5. of the preamble of the proposed rule, we proposed to require attestation to only two measures under the Public Health and Clinical Data Exchange objective instead of three, which is currently required under Stage 3.

In addition, we stated that we intend to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022, and sought public comment on whether hospitals will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective and measures are removed, as well as other policy levers outside of the Promoting Interoperability Program that could be adopted for continued reporting to public health and clinical data registries, if necessary. Therefore, we are also interested in identifying other appropriate venues in which reporting to public health and clinical data registries could be reported. We sought public comment on the role that

each of the public health and clinical data registries should have in the future of the Promoting Interoperability Programs and whether the submission of this data should still be required when the incentive payments for meaningful use of CEHRT will end in 2021.

Lastly, we sought public comment on whether the Promoting Interoperability Programs are the best means for promoting the sharing of clinical data with public health entities.

In the proposed rule, we stated that if we did not finalize the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule, we would maintain the existing Stage 3 requirements finalized in previous rulemaking and outlined in the table in that section which describes Stage 3 objectives and measures. Therefore, we would retain the existing Public Health and Clinical Data Registry Reporting objective and associated measures and exclusions under § 495.24(c)(8).

Comment: Many commenters requested that eligible hospitals and CAHs be able to report on any two measures to meet the Public Health and Clinical Data Exchange objective, and disagreed with the proposed requirement to report on the Syndromic Surveillance Reporting measure and one other measure because they indicated not all eligible hospitals can report on the Syndromic Surveillance Reporting measure because some States do not accept Syndromic Surveillance files.

Response: We understand the concerns of the commenters and are committed to reducing provider burden while increasing flexibility. We believe the ability to report on any two measures associated with the objective would promote flexibility in reporting and enables eligible hospitals and CAHs to focus on the measures that are most relevant to them and their patient population. In addition, we understand that some eligible hospitals and local jurisdictions are not able to send and receive Syndromic Surveillance files, including Oklahoma, Iowa, Minnesota and some counties in Colorado. With the ability to report on any two measures, eligible hospitals and CAHs will not have to claim an exclusion if they are unable to report on the Syndromic Surveillance Reporting measure. Rather, they will be able to select measures they have the ability to report on and therefore not claim exclusions, unless necessary. For these reasons, we are finalizing our proposal with the modification to allow eligible hospitals and CAHs to choose any two measures associated with the Public Health and Clinical Data Exchange objective to report. We will continue to monitor the ability of health care providers to report on Syndromic Surveillance Reporting measures and consider requiring Syndromic Surveillance reporting in future rulemaking.

Comment: One commenter agreed with the Public Health and Clinical Data Exchange reporting requirements proposed, stating it would continue to advance interoperability and improve early detection of outbreaks as well as promote population health strategies.

Response: We appreciate the supportive comments and reiterate that our priority is to improve the flexibility of the Promoting Interoperability Programs, reducing the reporting burden and promoting interoperability between health care providers and health IT systems.

Comment: A few commenters inquired why the Syndromic Surveillance Reporting measure was proposed as a required measure.

Response: We worked in conjunction with the CDC and ONC to identify public health reporting requirements that would be valuable to eligible hospitals and CAHs. As discussed in the proposed rule (83 FR 20535 through 20536), the CDC indicated the primary source of syndromic surveillance data comes from EHRs in emergency care settings and reporting via CEHRT has been instrumental in the capture and study of emerging health conditions such as the opioid overdose epidemic. In addition, syndromic surveillance reporting has improved data collection efforts resulting in the ability of public health agencies to more closely monitor trends in emergency department visits with greater precision and allowing communities to respond to emerging health threats more expeditiously.

Comment: One commenter stated that changes to the reporting requirements has resulted in less emphasis on Immunization Registry Reporting.

Response: We disagree that changes to the reporting requirements have resulted in less emphasis on immunization reporting. Instead, EHR data has improved efficiencies of reporting from health care providers to immunization registries. For example providers no longer have to duplicate data entry into a website for the IIS and their EHR system as the data is directly sent from the EHR to the registry. Although we proposed to reduce reporting from three measures to two measures with Syndromic Surveillance Reporting being required as one of the measures, eligible hospitals and CAHs would have the ability to select Immunization Registry Reporting as the other measure. In addition, eligible hospitals and CAHs may attest to additional Public Health and Clinical Data Exchange measures; however, reporting on additional measures would not increase their score.

Comment: A few commenters requested that CMS retain or increase the current public health reporting requirements for eligible hospitals and CAHs of attesting to at least three public health measures or as many as four as they believe reducing the amount of required measures de-emphasizes this objective.

One commenter requested CMS limit the Public Health and Clinical Data Exchange measure reporting requirements to one measure to further reduce reporting burden.

Response: We decline to increase the reporting requirements for the Public Health and Clinical Data Exchange objective. As we had stated in the proposed rule (83 FR 20535), our goals include increasing flexibility, improving value and reducing burden to providers. In addition, based on stakeholder feedback, we understand the active engagement requirements were complicated or confusing, therefore we are reducing provider burden through requiring attestation to only two measures. We reiterate that eligible hospitals and CAHs may attest to additional measures under the Public Health and Clinical Data Exchange objective; however it would not increase their score.

We decline to reduce the required number of measures for reporting to one Public Health and Clinical Data Exchange measure. While we are focusing on increasing flexibility, improving value and reducing burden to providers, we also want to balance those goals with maintaining communication and value in public health registry and bidirectional data exchange between providers and public health agencies and clinical data registries.

Comment: Many commenters strongly opposed CMS intent to remove public health measures in the future of the program as they believed that interoperability of public health data is still evolving and incentivizes health care providers to share data with public health agencies.

Response: We appreciate the feedback and understand the importance of reporting to public health and clinical data registries. We are continuing to focus on burden reduction as well as other platforms and venues for reporting data to public health and clinical data registries outside of the Promoting Interoperability Programs. We will

continue to monitor the data we compile specific to the public health reporting requirements and take the commenters' concerns into consideration related to future actions.

Comment: One commenter indicated that the Public Health and Clinical Data Exchange objective should include additional methods for data capture or reporting.

Response: Certification criteria and standards that support the Public Health and Clinical Data Exchange measures are established by ONC and we will work with them on future considerations for the Promoting Interoperability Programs.

Comment: A few commenters requested clarification on whether claiming an exclusion would count toward meeting the objective. A few commenters requested clarification regarding whether a health care provider needed to select another measure to report on if claiming an exclusion.

Response: For the Public Health and Clinical Data Exchange objective, health care providers are only required to attest to two measures total, regardless of whether an exclusion is claimed. Therefore, for example, a health care provider could attest to the Immunization Registry Reporting measure and claim an exclusion for the Electronic Case Reporting measure and meet the requirements for the objective. Providers may attest to additional Public Health and Clinical Data Exchange measures if they choose to; however, it would not increase their overall score for the objective. For additional information on the reporting and scoring methodology, we refer readers to section VIII.D.6. of the preamble of this final rule.

Comment: One commenter requested that the public health measures should change from a yes/no response to reporting on the number of times a health care provider shares unique patient clinical data with public health entities regarding each of the six measures within the Public Health and Clinical Data exchange objective.

Response: We decline to revise the attestation response for the Public Health and Clinical Data Exchange objective. We believe changing the attestation response would cause confusion and possibly increase burden to health care providers who are familiar with the current attestation process.

After consideration of the public comments we received, we are finalizing the Public Health and Clinical Data Exchange objective proposals as proposed with the following modification, as discussed above.

We are finalizing the objective name change from Public Health and Clinical Data Registry Reporting to Public Health and Clinical Data Exchange and to codify this change at 42 CFR 495.24(c)(8)(ii)(A) through (F).

We are modifying our proposed policy and finalizing that eligible hospitals and CAHs must report on any two Public Health and Clinical Data Exchange measures of their choice.

f. Request for Comment—Potential New Measures for HIE Objective: Health Information Exchange Across the Care Continuum

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20536 through 20537), we sought public comment on a potential concept for two additional measure options for the Health Information Exchange objective for eligible hospitals and CAHs who refer or transition care of patients to health care providers in long-term care and postacute care settings, skilled nursing facilities, and behavioral health settings. Many current Promoting Interoperability Program participants are now engaged in bi-directional exchange of patient health information with these health care providers and settings of care and many more sought to incorporate these workflows as part of efforts to improve care team coordination or to support alternative payment models.

For these reasons, we sought public comment on two potential new measures for inclusion in the program to enable eligible hospitals and CAHs to exchange health information through health IT supported care coordination across a wide range of settings.

New Measure Description for Support Electronic Referral Loops by Sending Health Information Across the Care Continuum: For at least one transition of care or referral to a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH creates a summary of care record using CEHRT; and electronically exchanges the summary of care record.

New Measure Denominator: Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transitioning or referring provider to a provider of care other than an eligible hospital or CAH.

New Measure Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created and exchanged electronically using CEHRT.

New Measure Description for Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum: For at least one electronic summary of care record received by an eligible hospital or CAH from a transition of care or referral from a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH conducts clinical information reconciliation for medications, mediation allergies, and problem list.

New Measure Denominator: The number of electronic summary of care records received for a patient encounter during the EHR reporting period for which an eligible hospital or CAH was the recipient of a transition of care or referral from a provider of care other than an eligible hospital or CAH.

New Measure Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation was completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

We sought public comment on whether these two measures should be combined into one measure so that an eligible hospital or CAH that is engaged in exchanging health information across the care continuum may include any such exchange in a single measure. We sought public comment on whether the denominators should be combined to a single measure including both transitions of care from a hospital and transitions of care to a hospital. We also sought public comment on whether the numerators should be combined to a single measure including both the sending and receiving of electronic patient health information. We sought public comment on whether the potential new measures should be considered for inclusion in a future program year or whether stakeholders believe there is sufficient readiness and interest in these measures to adopt them as early as 2019. For the purposes of focusing the denominator, we sought public comment regarding whether the potential new measures should be limited to transitions of care and referrals specific to long-term and postacute care, skilled nursing care, and behavioral health care settings. We also sought public comment on whether additional settings of care should be considered for inclusion in the denominators and if a provider should

be allowed to limit the denominators to a specific type of care setting based on their organizational needs, clinical improvement goals, or participation in an alternative payment model. Finally, we sought public comment on the impact the potential new measures may have for health IT developers to develop, test, and implement a new measure calculation for a future program year.

Comment: Many commenters opposed the addition of this type of measure as they believed that the current measures in the Health Information Exchange objective accurately capture the exchange of health information to other settings such as long term care facilities and an additional measure such as this would be redundant. Other commenters requested that CMS to convene stakeholder discussions with health care providers who would be included in this type of measure to identify what data elements are most valuable for them. Some commenters provided feedback that adoption of CERHT in postacute care settings could be a slow process. One commenter recommended that CMS focus on adoption of CEHRT in postacute care settings under the PFS rulemaking.

In addition, commenters asked specific follow up questions regarding what providers of care would be included, and how CMS would develop the care setting elements into the measure.

Response: We thank the commenters and we will consider their views as we develop future policy regarding the potential new measures that focus on health information exchange across the care continuum.

7. Application of Final Scoring Methodology and Measures Under the Medicaid Promoting Interoperability Program

As indicated in sections VIII.D.5. and VIII.D.6. of the preamble of the proposed rule (83 FR 20518 through 20537), we did not propose to require States to adopt the new scoring methodology and measures that we proposed. Instead, we proposed to give States the option to adopt the new scoring methodology we proposed in section VIII.D.5. of the preamble of the proposed rule together with the measures proposals included in section VIII.D.6. of the preamble of the proposed rule for their Medicaid Promoting Interoperability Programs. Any State that wishes to exercise this option must submit a change to its State Medicaid HIT Plan (SMHP) for CMS' approval, as specified in § 495.332. If a State chooses not to submit such a change, or if the change is not approved, the objectives, measures, and scoring would remain the same as currently specified under § 495.24. We believe that States are unlikely to choose this option due to concerns with burden, time constraints and costs associated with implementing updates to technology and reporting systems, as very few eligible hospitals will be eligible to receive an incentive payment under the Medicaid Promoting Interoperability Program in 2019 and subsequent years. However, our proposal to extend this option to States would allow them flexibility to benefit from the improvements to meaningful use scoring outlined in the proposed rule, if they so choose. Similarly, in the proposed rule, we also requested public comment on whether we should modify the objectives and measures for eligible professionals (EPs) in the Medicaid Promoting Interoperability Program in order to encourage greater interoperability for Medicaid EPs. In the proposed rule, we stated that we are interested in policy options that should be considered, including the benefits of greater alignment with the Merit-Based Incentive Payment System requirements for eligible clinicians. We also invited comments on the burdens and hurdles that such policy changes might create for EPs and States.

In connection with these proposals regarding the scoring methodology and measures, we proposed to require under § 495.40(b)(2)(vii) ''dual-eligible'' eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use, and are also eligible to earn a Medicaid incentive payment for meaningful use) to demonstrate meaningful use for the Promoting Interoperability Program to CMS, and not to their respective State Medicaid agency, beginning with the EHR reporting period in CY 2019. This includes all attestation requirements, including the objectives and measures of meaningful use, in addition to reporting clinical quality measures. In the past, we have generally adopted a common definition of meaningful use under Medicare and Medicaid (for example, 77 FR 44324 through 44326). If we adopt the proposals made in the proposed rule, there would not be a common definition of meaningful use, unless a State chooses to exercise the option described above and receives approval from CMS. In light of these changes, we believe it would be more efficient and straightforward in terms of program administration and operations if all dual-eligible eligible hospitals and CAHs demonstrate meaningful use to CMS. If a dual-eligible eligible hospital or CAH instead demonstrates meaningful use to its State Medicaid agency, it would only qualify for an incentive payment under Medicaid (assuming it meets all eligibility and other program requirements), and it would not qualify for an incentive payment under Medicare and/or avoid the Medicare payment reduction. The proposals in the proposed rule would not change the deeming policy under the definition of meaningful EHR user under § 495.4, under which an eligible hospital or CAH that successfully demonstrates meaningful use to CMS would be deemed a meaningful EHR user for purposes of the Medicaid incentive payment.

We also proposed to amend the requirements for State reporting to CMS under the Medicaid Promoting Interoperability Program under § 495.316(g), so that States would not be required to report, for program years after 2018, provider-level attestation data for each eligible hospital that attests to the State to demonstrate meaningful use.

Comment: One commenter requested clarification on whether States have only two options: (1) Continue with the existing meaningful use measures, or (2) adopt the Medicare QPP measures. The commenter supported having only two options, and stated that anything beyond those options creates confusion and burden for all stakeholders.

Response: We confirm that the commenter is correct in describing the two options proposed for States. There is no option to adopt some of the revisions to the hospital scoring system, but not others.

Comment: One commenter expressed concern that requirements around APIs are less stringent for Medicaid EPs compared to the MIPS program.

Response: While the requirements differ across different programs, we are committed to promoting API access. For example, Medicaid EPs have the opportunity to use APIs to meet Stage 3, EP Objective 6, Measure 1 (View, download or transmit). In addition, we expressly support States' use of open APIs in their Medicaid enterprise architecture in 42 CFR 433.112.

Comment: Several commenters stated that the Medicaid Stage 3 requirements are too stringent and suggested that these requirements be aligned with those for Medicare clinicians under MIPS. In addition, one commenter suggested that CMS allow providers to attest to Meaningful Use Modified Stage

2 Objectives, using 2015 Edition CEHRT, through the end of the Promoting Interoperability Program (CY 2021).

Response: We thank the commenters for their input about the program requirements. However, we did not propose any changes to Stage 3 or for EPs in the proposed rule, but did ask for comments on ways we can align and reduce the burden for EPs who also participate in MIPS. We will take these comments into consideration for future rulemaking. As for CEHRT, the 2015 Edition does not have the capability to meet the Modified Stage 2 meaningful use objectives and measures.

After consideration of the public comments we received, we are finalizing the our proposals as proposed.

8. Promoting Interoperability Program Future Direction

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20537 through 20538), we sought comments on the future direction of the Promoting Interoperability Program. In future years of the Promoting Interoperability Program, we will continue to consider changes which support a variety of HHS goals, including: Reducing administrative burden; supporting alignment with the Quality Payment Program; advancing interoperability and the exchange of health information; and promoting innovative uses of health IT. We believe a focus on interoperability and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery. One strategy we are exploring is creating a set of priority health IT activities that would serve as alternatives to the traditional EHR Incentive Program measures.

We specifically sought public comments on the following questions:

- What health IT activities should CMS consider recognizing in lieu of reporting on objectives that would most effectively advance priorities for nationwide interoperability and spur innovation? What principles should CMS employ to identify health IT activities?
- Do stakeholders believe that introducing health IT activities in lieu of reporting on measures would decrease burden associated with the Promoting Interoperability Programs?
- If additional measures were added to the program, what measures would be beneficial to add to promote our goals of care coordination and interoperability?
- How can the Promoting Interoperability Program for eligible hospitals and CAHs further align with the Quality Payment Program (for example, requirements for eligible clinicians under MIPS and Advanced APMs) to reduce burden for health care providers, especially hospital-based MIPS eligible clinicians?
- What other steps can HHS take to further reduce the administrative burden associated with the Promoting Interoperability Program?

Comment: Many commenters expressed support for introducing health IT activities in lieu of reporting on measures and indicated an approach such as this would reduce provider burden associated with these reporting activities. The commenters also noted that supporting improved interoperability through this approach is an important goal.

Some commenters requested clarification on how interoperability is defined and requested that CMS work with stakeholders on identification of benchmarks and have a reasonable and predictable pathway for changing Health IT policies. Other commenters indicated a single set of standards by the Federal government is needed to ensure all health care providers are exchanging data in a uniform manner.

Some commenters disagreed with introducing health IT activities in lieu of reporting on measures as this approach could create additional burden if its required additional documentation to validate that the provider had performed the activity. Some commenters also recommended that such an approach should be left optional, as many providers may not be able to perform the activities identified. Finally, commenters expressed concerns regarding specific potential activities, for instance, one commenter expressed concern about whether participation in the Trusted Exchange Framework and Common Agreement (TEFCA) would be available by the time this approach was finalized.

Some commenters supported participation in the TEFCA and indicated it should be considered a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective.

Some commenters suggested CMS realign efforts with ''Patient Centered'' interoperability.

A few commenters indicated CMS should include a measure for data quality based on the USCDI which would set expectations for content, not just exchange of data.

Some commenters indicated the 2015 CEHRT needs to be updated to support integration of SNOMED, LOINC and RxNorm (and other terminology standards) into a single system.

Response: We thank the commenters for their input and we will consider their views as we develop future policy regarding the future direction of the Promoting Interoperability Program.

9. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the Medicare and Medicaid Promoting Interoperability Programs

a. Background and Current CQMs

Under sections 1814(l)(3)(A), 1886(n)(3)(A), and 1903(t)(6)(C)(i)(II) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (referred to as CQMs or eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid Promoting Interoperability Programs.

The table below lists the 16 CQMs available for eligible hospitals and CAHs to report under the Medicare and Medicaid Promoting Interoperability Programs beginning in CY 2017 (81 FR 57255).

CQMs for Eligible Hospitals and CAHs Beginning With CY 2017

Short name	Measure name	NQF No.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
ED–3	Median Time from ED Arrival to ED Departure for Discharged ED Patients	0496
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	(+)
ED–1	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354

CQMS FOR ELIGIBLE HOSPITALS AND CAHS BEGINNING WITH CY 2017—Continued

Short name	Measure name	NQF No.
PC–01	Elective Delivery (Collected in aggregate, submitted via web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding*	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	(+)
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

+ NQF endorsement has been removed.
* Measure name has been shortened. We refer readers to annually updated measure specifications on the CMS eCQI Resource Center web page for further information at: *https://www.healthit.gov/newsroom/ecqi-resource-center*.

b. CQMs for Reporting Periods Beginning With CY 2020

As we have stated previously in rulemaking (82 FR 38479), we plan to continue to align the CQM reporting requirements for the Promoting Interoperability Programs with the Hospital IQR Program. In order to move the program forward in the least burdensome manner possible, while maintaining a set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, we stated the we believe it is appropriate to propose to remove certain eCQMs at this time to develop an even more streamlined set of the most meaningful eCQMs for hospitals. To align with the Hospital IQR Program, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20539), we proposed to reduce the number of eCQMs in the Medicare and Medicaid Promoting Interoperability Programs eCQM measure set from which eligible hospitals and CAHs report, by proposing to remove eight eCQMs (from the 16 eCQMs currently in the measure set) beginning with the reporting period in CY 2020. The eight eCQMs we proposed to remove are:

- Primary PCI Received Within 90 Minutes of Hospital Arrival (NQF #0163) (AMI–8a);
- Home Management Plan of Care Document Given to Patient/Caregiver (CAC–3);
- Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF #0495) (ED–1);
- Hearing Screening Prior to Hospital Discharge (NQF #1354) (EHDI–1a);
- Elective Delivery (NQF #0469) (PC–01);
- Stroke Education (STK–08) (adopted at 78 FR 50807;
- Assessed for Rehabilitation (NQF #0441) (STK–10); and
- Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF 0496) (ED–3).

We note that the first seven eCQMs on this list are currently included in the Hospital IQR Program, and in section VIII.A.5.b.(9) of the preamble of the proposed rule, we proposed to remove them from the Hospital IQR Program beginning in CY 2020. For more information on the first seven eCQMs selected for removal, we refer readers to section VIII.A.5.b.(9) of the preambles of the proposed rule and this final rule.

We believe that a coordinated reduction in the overall number of eCQMs in both the Hospital IQR Program and Medicare and Medicaid EHR Promoting Interoperability will reduce certification burden on hospitals, improve the quality of reported data by enabling eligible hospitals and CAHs to focus on a smaller, more specific subset of CQMs while still allowing eligible hospitals and CAHs some flexibility to select which eCQMs to report that best reflect their patient populations and support internal quality improvement efforts. With respect to the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure (NQF 0496) (ED–3), this is an outpatient measure and is not included as an eCQM in the Hospital IQR Program. We proposed to remove it so the eCQMs would align completely between the two programs in order to reduce burden and enable eligible hospitals and CAHs to easily report electronically through the Hospital IQR Program submission mechanism.

As we stated in section VIII.A.5.b.(9) of the preambles of the proposed rule and this final rule, with regard to the Hospital IQR Program proposal for the CY 2020 reporting period and subsequent years, we also considered proposing to remove these eCQMs one year earlier, beginning with the CY 2019 reporting period/FY 2021 payment determination. In establishing our eCQM policies, we must balance the needs of eligible hospitals and CAHs with variable preferences and capabilities. Overall, across the range of capabilities and resources for eCQM reporting, stakeholders have expressed that they want more time to prepare for eCQM changes.

We recognize that some hospitals and health IT vendors may prefer earlier removal in order to forgo maintenance on those eCQMs proposed for removal. In preparation for the proposed rule, we weighed the relative burdens associated with removing these measures beginning with the CY 2019 reporting period or beginning with the CY 2020 reporting period. In the event we finalize our proposal to remove these eCQMs, we intend to align the timing of the removal for the Medicare and Medicaid Promoting Interoperability Programs with the Hospital IQR Program.

We invited public comment on our proposal, including the specific measures proposed for removal and the timing of removal from the Medicare and Medicaid Promoting Interoperability Programs.

Comment: Several commenters supported the reduction in the number of eCQMs stating that it would create a streamlined measure set. The majority of commenters addressed the reduction in the number of eCQMs in general and not specifically related to the Promoting Interoperability Program.

Response: We thank the commenters for their support and refer readers to section VIII.A.5.b. of the preamble of this final rule for more information on the eCQM proposals and for additional comments and responses. We are committed to staying in alignment with the Hospital IQR Program policies to the greatest extent feasible.

Comment: One commenter supports the use of eCQMs to measure quality of

care. In addition, the commenter suggests that proposed e-measures be carefully validated by EHR vendors in advance to determine if data elements are readily available, to eliminate documentation and burden redundancies.

Response: We appreciate the commenter's position that e-measures should carefully validated prior to implementation. Our goal is to closely align the Promoting Interoperability Programs with the Hospital IQR Program, while reducing the burden on hospitals. By focusing on a smaller subset of measures, the eligible hospitals and CAHs will have some flexibility regarding eCQMs they choose to report best reflect their patient population and support internal quality improvement efforts.

We encourage eligible hospitals and CAHs to submit measures during the Annual Call for measures. This process reinforces our commitment to engaging stakeholders to process reinforces our commitment to engaging with stakeholders to further advance meaningful use of CEHRT by eligible hospitals and CAHs participating in the Promoting Interoperability Programs.

Comment: One commenter disagreed with the proposed reduction in the number of eCQMs available for reporting, indicating this would be very limiting in selection and creates additional costs, especially for small hospitals with a limited daily census.

Response: While we understand this concern, we believe that is important to align the eCQM requirements for the Promoting Interoperability Programs with those of the Hospital IQR Program. The removal of these measures is consistent with CMS' commitment to using a smaller set of more meaningful measures. CMS is focusing on measures that provide opportunities to reduce both paperwork and reporting burden on health care providers and patient-centered outcome measures, rather than process measures. For further discussion of our policy reasons for eliminating these eCQMs for the Hospital IQR Program, which we believe also apply in the context of the Promoting Interoperability Programs, we refer readers to section VIII.A.5.b. of the preamble of this final rule.

After consideration of the public comments we received, we are adopting our proposal as proposed.

c. CQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CY 2019

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20539 through 20540), for CY 2019, we proposed the same CQM reporting periods and criteria as established in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38479 through 38483) for the Medicare and Medicaid EHR Incentive Programs in CY 2018, which would be as follows:

For CY 2019, for eligible hospitals and CAHs that report CQMs electronically, we proposed the reporting period for the Medicare and Medicaid Promoting Interoperability Programs would be one, self-selected calendar quarter of CY 2019 data, and the submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the calendar year, ending February 29, 2020. For eligible hospitals and CAHs that report CQMs by attestation under the Medicare Promoting Interoperability Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid Promoting Interoperability Program, we previously established a CQM reporting period of the full CY 2019 (consisting of 4 quarterly data reporting periods) (80 FR 62893). We also established an exception to this full-year reporting period for eligible hospitals and CAHs demonstrating meaningful use for the first time under their State's Medicaid EHR Incentive Program. Under this exception, the CQM reporting period is any continuous 90-day period within CY 2019 (80 FR 62893). We proposed that the submission period for eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program would be the 2 months following the close of the CY 2019 CQM reporting period, ending February 29, 2020. In regard to the Medicaid EHR Incentive Program, we provide States with the flexibility to determine the method of reporting CQMs (attestation or electronic reporting) and the submission periods for reporting CQMs, subject to prior approval by CMS.

For the CY 2019 reporting period, we proposed that the reporting criteria under the Medicare and Medicaid Promoting Interoperability Program for eligible hospitals and CAHs reporting CQMs electronically would be as follows: For eligible hospitals and CAHs participating only in the Promoting Interoperability Program, or participating in both the Promoting Interoperability Program and the Hospital IQR Program, report on at least 4 self-selected CQMs from the set of 16 available CQMs listed in the table above.

We proposed the following reporting criteria for eligible hospitals and CAHs that report CQMs by attestation under the Medicare Promoting Interoperability Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid Promoting Interoperability Program, for the reporting period in CY 2019—report on all 16 available CQMs listed in the table in section VIII.D.9.a. of the preamble of the proposed rule.

Comment: A few commenters supported the proposed self-selected calendar quarter of CY 2019 data for CQM reporting as it aligns to the proposed 90-day EHR reporting period for the objectives and measures of the Promoting Interoperability Program.

Response: We appreciate the support for our proposal and agree that reporting periods of similar length may help simplify data submission and reduce burden.

After consideration of the public comments we received, we are adopting our proposal as proposed.

d. CQM Reporting Form and Method for the Medicare Promoting Interoperability Program in CY 2019

As we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 49760), for the reporting periods in 2016 and future years, we are requiring QRDA–I for CQM electronic submissions for the Medicare EHR Incentive (now Promoting Interoperability) Program. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49760), States would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

The form and method of electronic submission are further explained in sub-regulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS Implementation Guide for QRDA; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the eCQI Resource Center web page at: *https://ecqi.healthit.gov/*. For further information on CQM reporting, we refer readers to the EHR Incentive Program (now Promoting Interoperability Program) website where guides and tip sheets are located at: *http://www.cms.gov/ehrincentiveprograms*.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20540), for the reporting period in CY 2019, we

proposed the following for CQM submission under the Medicare Promoting Interoperability Program:

- Eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program (single program participation)—electronically report CQMs through QualityNet Portal.
- Eligible hospital and CAH options for electronic reporting for multiple programs (that is, Promoting Interoperability Program and Hospital IQR Program participation)—electronically report through QualityNet Portal.

As noted in the 2015 EHR Incentive Programs final rule (80 FR 62894), starting in 2018, eligible hospitals and CAHs participating in the Medicare EHR Incentive Program must electronically report CQMs where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible. For the Medicaid Promoting Interoperability Program, States continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

For CY 2019, we proposed to continue our policy regarding the electronic submission of CQMs, which requires the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. For the CY 2019 electronic reporting of CQMs, this means eligible hospitals and CAHs are required to use the Spring 2017 version of the CQM electronic specifications and any applicable addenda available on the eCQI Resource Center web page at: *https://ecqi.healthit.gov/*. In addition, we proposed that eligible hospitals or CAHs must have their EHR technology certified to all 16 available CQMs listed in the table above. As discussed in section VIII.D.3. of the preamble of the proposed rule, eligible hospitals and CAHs are required to use 2015 Edition CEHRT for the Medicare and Medicaid Promoting Interoperability Programs in CY 2019. We reiterate that an EHR certified for CQMs under the 2015 Edition certification criteria does not have to be recertified each time it is updated to a more recent version of the CQMs (82 FR 38485).

We did not receive any comments on these proposals and we are adopting our proposal as proposed.

e. Request for Comment

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20540 through 20541), we requested comments on a number of issues regarding eCQMs. Specifically, we invited comment on the following:

- What aspects of the use of eCQMs are most burdensome to hospitals and health IT vendors?
- What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM burden?
- What are the most significant barriers to the availability and use of new eCQMs today?
- What specifically would stakeholders like to see us do to reduce burden and maximize the benefits of eCQMs?
- How could we encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?
- How could we encourage hospitals and health IT vendors to engage in testing new eCQMs?
- Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?
- What ways could we incentivize or reward innovative uses of health IT that could reduce burden for hospitals?
- What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?

We received numerous comments in response to our request for comment.

Comment: Several commenters supported the goals of using EHRs to reduce the burden of quality reporting and use of the data to support their quality improvement initiatives. Several commenters supported the following improvements in quality measurement: Uniform calculation of eCQMs across various CEHRT systems and practices; addressing misalignment between the eCQM reporting requirements and availability of eCQMs by vendors; improved methods of reporting to support the needs of the program participants; development of strategies to apply the Meaningful Measures framework to eCQMs; development of metrics that inform readiness of eCQM data for public reporting; and increased opportunities for eligible hospitals and CAHs to participate in eCQM testing using processes, methods and/or innovated use of health IT. A few commenters suggested rewarding hospitals who already implemented innovative quality improvement programs and processes using health IT. A few commenters indicated that future eCQMs should be based on data elements that are already captured within CEHRT.

A few commenters indicated that burdens related to use of eCQMs included exclusions and data availability and many eCQMs are not developed based on data available or created during routine care. A few commenters indicated it is burdensome to test eCQMs due to time, effort and resource requirements. A few commenters requested simplification of the measure development process which would include strict selection criteria and endorsement processes as the current development process was noted to create significant barrier related to availability and use.

A few commenters suggested CMS work with stakeholders to establish research and pilot programs to reduce quality measurement burden and leverage data captured by all members of the care team, other electronic means or by the patients themselves.

Response: We thank the commenters and we will consider their views as we develop future policy regarding eCQMs.

10. Participation in the Medicare Promoting Interoperability Program for Subsection (d) Puerto Rico Hospitals

a. Background

In the Stage 1 final rule (77 FR 44448), we noted that subsection (d) Puerto Rico hospitals as defined in section 1886(d)(9)(A) of the Act were not ''eligible hospitals'' as defined in section 1886(n)(6)(B) of the Act, and therefore were not eligible for the incentive payments for the meaningful use of CEHRT under section 1886(n) of the Act. Section 602(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) subsequently amended section 1886(n)(6)(B) of the Act to include subsection (d) Puerto Rico hospitals in the definition of ''eligible hospital,'' which made subsection (d) Puerto Rico hospitals eligible for the incentive payments under section 1886(n) of the Act for hospitals that are meaningful EHR users and subject to the payment reductions under section 1886(b)(3)(B)(ix) of the Act for hospitals that are not meaningful EHR users. In order to take into account delays in implementation, section 602(d) of the Consolidated

Appropriations Act, 2016 adjusted the existing timelines for the incentive payments by five years and payment reductions by seven years for subsection (d) Puerto Rico hospitals, as further discussed in the sections below.

As authorized under section 602(c) of the Consolidated Appropriations Act, 2016, we have previously elected to implement the amendments made by section 602 as applied to subsection (d) Puerto Rico hospitals through program instruction. In doing so we have sought to align the policies for subsection (d) Puerto Rico hospitals with our existing policies for eligible hospitals under the Medicare Promoting Interoperability Program to the greatest extent possible, while taking into account the unique circumstances applicable to hospitals on Puerto Rico. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20541 through 20542), we proposed to codify the program instructions we have issued to subsection (d) Puerto Rico hospitals and to amend our regulations under Parts 412 and 495 such that the provisions that apply to eligible hospitals would include subsection (d) Puerto Rico hospitals unless otherwise indicated.

b. Definitions

(1) Eligible Hospital: Subsection (d) Puerto Rico Hospitals

We proposed to define a ''Puerto Rico eligible hospital'' under § 495.100 as a subsection (d) Puerto Rico hospital as defined in section 1886(d)(9)(A) of the Act.

We proposed to amend the definition of ''eligible hospital'' under § 495.100 to include Puerto Rico eligible hospitals unless otherwise indicated.

We proposed to amend the general provisions under § 412.200 as related to prospective payment rates for inpatient operating costs for subsection (d) Puerto Rico hospitals.

We did not receive any comments on these proposals and are finalizing our proposals as proposed.

(2) EHR Reporting Period: Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that for subsection (d) Puerto Rico hospitals, FY 2016 is the first payment year under section 1886(n)(2)(G)(i) of the Act for which an incentive payment could be made to a hospital that is a meaningful EHR user. The definition of ''EHR reporting period'' under § 495.4 specifies for eligible hospitals for the FY 2016 payment year an EHR reporting period of any continuous 90-day period in CY 2016, which is consistent with the program instructions we issued to subsection (d) Puerto Rico hospitals, so we do not believe any amendment is necessary. We proposed to amend the definition of ''EHR reporting period'' under § 495.4 to specify for Puerto Rico eligible hospitals for the FY 2017 payment year an EHR reporting period of a minimum of any continuous 14-day period in CY 2017, which is consistent with the program instructions we issued to subsection (d) Puerto Rico hospitals. We allowed for a 14-day EHR reporting period in CY 2017 to acknowledge and account for the devastation to Puerto Rico caused by Hurricane Maria. We have not issued program instructions to subsection (d) Puerto Rico hospitals concerning the EHR reporting periods for the payment years after FY 2017. For the FY 2018, 2019, and 2020 payment years, we proposed an EHR reporting period of a minimum of any continuous 90-day period in CYs 2018, 2019, and 2020 respectively for Puerto Rico eligible hospitals, and we proposed corresponding amendments to the definition of ''EHR reporting period'' under § 495.4.

Comment: Several commenters supported the proposed codification of the policies for subsection (d) Puerto Rico hospitals for the Promoting Interoperability Program. One commenter expressed gratitude for the reduction of the EHR reporting period from 90 days to 14 days in CY 2017 after Hurricane María as the commenter indicated it helped hospitals in Puerto Rico demonstrate meaningful use and find relief within the difficult situation.

Response: We appreciate the commenters' support.

After consideration of the public comment we received, we are finalizing our proposals as proposed.

(3) EHR Reporting Period for a Payment Adjustment Year for Eligible Hospitals: Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that the payment reductions under section 1886(b)(3)(B)(ix) of the Act would apply beginning with FY 2022 for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for the applicable EHR reporting period for the payment adjustment year. Because Puerto Rico eligible hospitals would be considered eligible hospitals, the EHR reporting periods for payment adjustment years and related policies, including deadlines and requests for significant hardship exceptions, that we establish for eligible hospitals would also apply to Puerto Rico eligible hospitals beginning with the FY 2022 payment adjustment year.

We did not receive any comments on this topic.

(4) Payment Year for Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that for subsection (d) Puerto Rico hospitals, FY 2016 is the first payment year under section 1886(n)(2)(G)(i) of the Act for which an incentive payment could be made to a hospital that is a meaningful EHR user. We proposed to amend the definition of ''payment year'' under § 495.4 to specify for Puerto Rico eligible hospitals, payment year means a Federal FY beginning with 2016.

We did not receive any comments on this proposal and are finalizing our proposal as proposed.

(5) Payment Adjustment Year for Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that the payment reductions under section 1886(b)(3)(B)(ix) of the Act will apply beginning with FY 2022 for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for the applicable EHR reporting period for the payment adjustment year. We proposed to amend the definition of ''payment adjustment year'' under § 495.4 to specify for Puerto Rico eligible hospitals, payment adjustment year means a Federal fiscal year beginning with 2022.

We did not receive any comments on this proposal and are finalizing our proposal as proposed.

c. Duration and Timing of Incentive Payments for Subsection (d) Puerto Rico Hospitals—Transition Periods and Transition Factors

Section 602(d) of the Consolidated Appropriations Act, 2016 provides for a phase down under section 1886(n)(2)(E)(ii) of the Act for subsection (d) Puerto Rico hospitals whose first payment year is after 2018. We proposed to amend § 495.104(b) to specify the following years for which Puerto Rico eligible hospitals may receive incentive payments under section 1886(n) of the Act:

- Puerto Rico eligible hospitals whose first payment year is FY 2016 may receive such payments for FYs 2016 through 2019.
- Puerto Rico eligible hospitals whose first payment year is FY 2017 may receive such payments for FYs 2017 through 2020.
- Puerto Rico eligible hospitals whose first payment year is FY 2018 may receive such payments for FYs 2018 through 2021.

• Puerto Rico eligible hospitals whose first payment year is FY 2019 may receive such payments for FY 2019 through 2021.

• Puerto Rico eligible hospitals whose first payment year is FY 2020 may receive such payments for FY 2020 through 2021.

We proposed to amend § 495.104(c)(5) to specify the following transition factors under section 1886(n)(2)(E)(i) of the Act for Puerto Rico eligible hospitals:

PROPOSED TRANSITION FACTORS FOR SUBSECTION (D) PUERTO RICO HOSPITALS

	First payment year (FY)				
	2016	2017	2018	2019	2020
2016	1.00				
2017	0.75	1.00			
2018	0.50	0.75	1.00		
2019	0.25	0.50	0.75	0.75	
2020		0.25	0.50	0.50	0.50
2021			0.25	0.25	0.25

We did not receive any comments on these proposals and are finalizing our proposals as proposed.

d. Market Basket Adjustment for Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that the payment reductions under section 1886(b)(3)(B)(ix) of the Act would apply beginning with FY 2022 for subsection (d) Puerto Rico hospitals. We proposed for a subsection (d) Puerto Rico hospital that is not a meaningful EHR user for the EHR reporting period for the FY, three-quarters of the applicable percentage increase otherwise applicable for such FY shall be reduced by 33⅓ percent for FY 2022, 66⅔ percent for FY 2023, and 100 percent for FY 2024 and each subsequent FY. We proposed to amend § 412.64(d)(3) to reflect these proposed reductions.

We did not receive any comments on these proposals and are finalizing our proposals as proposed.

11. Modifications to the Medicare Advantage Promoting Interoperability Program

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20542 through 20543), we proposed several modifications to the Medicare Advantage Promoting Interoperability Program.

a. Participation in the Medicare Advantage Promoting Interoperability Program for Subsection (d) Puerto Rico Hospitals

Section 1853(m) of the Act provides for incentive payments to qualifying Medicare Advantage (MA) organizations for certain affiliated eligible hospitals (as defined in section 1886(n)(6)(B)) that meaningfully use certified EHR technology, and for application of downward payment adjustments to qualifying MA organizations for their affiliated hospitals that are not meaningful users of certified EHR technology, beginning in FY 2015. As noted in section VIII.D.8. of the preamble of the proposed rule, section 602(a) of the Consolidated Appropriations Act, 2016 amended section 1886(n)(6)(B) of the Act to include subsection (d) Puerto Rico hospitals in the definition of ''eligible hospital.'' We note that the definition of ''qualifying MA-affiliated hospital'' in § 495.200 means an eligible hospital under section 1866(n)(6) that meets certain other criteria. Therefore, the amendment to section 1866(n)(6) by the Consolidated Appropriations Act to include subsection (d) Puerto Rico hospitals renders such hospitals potentially eligible as qualifying MA-affiliated hospitals for purposes of the Medicare Advantage Promoting Interoperability incentives and payment adjustments. We proposed certain changes to our regulations under 42 CFR part 495 so that the incentive payment and payment adjustment provisions that apply to MA-affiliated eligible hospitals are applicable to MA-affiliated eligible hospitals in Puerto Rico.

b. Definitions

(1) Payment Year for MA-Affiliated Eligible Hospitals in Puerto Rico

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that for subsection (d) Puerto Rico hospitals, FY 2016 is the first payment year for which an EHR incentive payment could be made to an eligible hospital that is a meaningful EHR user. We proposed, under section 1871 of the Act and to implement that amendment to the EHR provisions, to amend the definition of ''payment year'' under § 495.200 to specify that, with respect to MA-affiliated eligible hospitals in Puerto Rico, payment year means a Federal FY beginning with 2016 and ending with FY 2021.

We did not receive any comments on this proposal so we are adopting the amendments to the definition of ''payment year'' in § 495.200 as proposed to be consistent with the statute.

(2) MA Payment Adjustment Year for MA-Affiliated Eligible Hospitals in Puerto Rico

Section 602(d) of the Consolidated Appropriations Act, 2016 provides for payment reductions to subsection (d) Puerto Rico hospitals that are not meaningful EHR users for the applicable EHR reporting period for the payment adjustment year, beginning with FY 2022. We proposed to amend the definition of ''MA payment adjustment year'' under § 495.200 to specify that, for qualifying MA organizations that first receive an MA EHR incentive payment for at least 1 payment year for an MA-affiliated eligible hospital in Puerto Rico, payment adjustment year means a calendar year starting with 2022.

We solicited feedback on whether we should amend the definition of ''MA payment adjustment year'' to specify that the duration of the reporting period for MA-affiliated eligible hospitals for purposes of determining whether a qualifying MA organization is subject to a payment adjustment should be other than the full Federal fiscal year ending in the MA payment adjustment year. We also requested comments on an alternative approach under which we would use the same reporting period that is used for the Medicare Promoting Interoperability Program.

We did not receive any comments on this proposal so we are finalizing the amendment to the definition of ''MA payment adjustment year'' under § 495.200 as proposed.

c. Payment Adjustments Effective for 2015 and Subsequent MA Payment Years With Respect to MA-Affiliated Eligible Hospitals

Under § 495.211, beginning for MA payment adjustment year 2015, payment adjustments set are made to prospective payments (issued under section 1853(a)(1)(A) of the Act) of qualifying MA organizations that previously received incentive payments under the MA EHR Incentive (now Promoting Interoperability) Program, if all or a portion of the MA-affiliated eligible hospitals that would meet the definition of qualifying MA-affiliated eligible hospitals (but for their demonstration of meaningful use) are not meaningful EHR users. Section 495.211(e) sets forth the formula for calculating payment adjustments for 2015 and subsequent years with respect to MA-affiliated eligible hospitals. We proposed to amend paragraph (e) by adding a new subparagraph (4), which specifies that, prior to payment adjustment year 2022, subsection (d) Puerto Rico hospitals are neither qualifying nor potentially qualifying MA-affiliated eligible hospitals for purposes of applying the payment adjustments under § 495.211.

We solicited comment on whether further regulatory amendments are necessary or appropriate so that the EHR incentive payment and payment adjustment provisions that apply to MA-affiliated eligible hospitals are applicable to MA-affiliated eligible hospitals in Puerto Rico in a manner that is consistent with the Consolidated Appropriations Act, 2016.

Comment: One commenter requested that the Medicare Advantage benchmarks be updated so that the 2019 Medicare Advantage benchmark payments can reflect any payment updates in fee for service resulting from 2019 FFS payment rules.

Response: The request for CMS to immediately conform MA benchmarks to reflect payment updates in FFS Medicare is outside the scope of the proposed rule. We address updates to MA benchmarks through the annual Advance Notice and Rate Announcement process.

After consideration of the public comment we received, we are finalizing the amendment to § 495.211(e) (that is, adding paragraph (e)(4)) as proposed.

12. Modifications to the Medicaid Promoting Interoperability Program

In section VIII.E.12. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20543 through 20544), we proposed modifications to the Medicaid Promoting Interoperability Program. The policies proposed in that section would apply only in the Medicaid EHR Incentive (now Promoting Interoperability) Program.

Comment: One commenter stated that changing the program name from the Medicaid EHR Incentive Program to the Medicaid Promoting Interoperability Program would create confusion and lead to lower participation rates.

Response: The program name change was announced in the proposed rule. The name change was intended to highlight the efforts within CMS to promote interoperability between patients, health care providers and health insurers. We are working to educate stakeholders that the name change does not signal an end to Medicaid incentive payments for meaningful use prior to the deadlines finalized in this final rule and to alleviate any potential confusion regarding the name change.

a. Requirements Regarding Prior Approval of Requests for Proposals (RFPs) and Contracts in Support of the Medicaid Promoting Interoperability Program

Section 1903(a)(3)(F)(ii) of the Act establishes an enhanced Federal matching rate of 90 percent for State expenditures related to the administration of Medicaid Promoting Interoperability Program payments. On July 28, 2010, in the Stage 1 final rule (75 FR 44313, 44507), we established prior approval requirements for State funding, planning documents, proposed budgets, project schedules, and certain implementation activities that a State may wish to pursue in support of the Medicaid Promoting Interoperability Program, as a condition of receipt of the 90 percent FFP available to States under section 1903(a)(3)(F)(ii) of the Act. To minimize the burden on States, we designed the prior approval conditions and prior approval process to mirror what was at the time used in support of acquiring automated data processing (ADP) equipment and services in conjunction with development and operation of States' Medicaid Management Information Systems (MMIS), which are the States' automated mechanized claims processing and information retrieval systems approved by CMS. Specifically, at § 495.324(b)(2) we established that, as a condition of receiving 90 percent FFP for administration of their Medicaid Promoting Interoperability Programs, States must receive prior approval for requests for proposals and contracts used to complete activities under 42 CFR part 495, subpart D, unless specifically exempted by HHS, before release of the request for proposal or execution of the contract. This was consistent with the requirement then in place for MMIS at 45 CFR 95.611(a)(2). At § 495.324(b)(3) we established that unless specifically exempted by HHS, States must receive prior approval for contract amendments involving contract cost increases exceeding $100,000 or contract time extensions of more than 60 days, prior to execution of the contract amendment. This was consistent with the requirement then in place at 45 CFR 95.611(b)(2)(iv).

Subsequently, in the final rule titled ''State Systems Advance Planning Document (APD) Process'' (75 FR 66319, October 28, 2010), HHS amended 45 CFR 95.611(b)(2)(iii) to establish a $500,000 threshold for prior HHS approval of acquisition solicitation documents and contracts for ADP equipment or services for which States would seek enhanced Federal matching funds (75 FR 66331). In the same rule, HHS also established at 45 CFR 95.611(b)(2)(iv) a $500,000 prior approval threshold for contract amendments for which States would seek enhanced Federal match (75 FR 66324). In the final rule titled ''Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems (90/10)'' (80 FR 75817, 75836 through 75837, December 4, 2015), 45 CFR 95.611(a)(2) was amended to establish a $500,000 threshold for prior approval of acquisitions related to ADP equipment and services matched at the enhanced rate for MMIS authorized under 42 CFR part 433, subpart C. There was previously no threshold dollar amount for prior approvals related to such acquisitions in 45 CFR 95.611(a)(2).

In the proposed rule, we proposed to amend 42 CFR 495.324(b)(2) and 495.324(b)(3) to align with current prior approval policy for MMIS and ADP systems at 45 CFR 95.611(a)(2)(ii), and (b)(2)(iii) and (iv), and to minimize burden on States. Specifically, we proposed that the prior approval dollar threshold in § 495.324(b)(3) would be increased to $500,000, and that a prior approval threshold of $500,000 would be added to § 495.324(b)(2). We also proposed minor amendments to the language of 495.324(b)(2) and (3) to better align it with the language of 45 CFR 95.611(b)(2)(iii) and (iv). In addition, in light of these proposed changes, we proposed a conforming amendment to amend the threshold in § 495.324(d) for prior approval of justifications for sole source acquisitions to be the same $500,000 threshold. That threshold is currently aligned with the $100,000 threshold in

current § 495.324(b)(3). We explained that we believe that amending § 495.324(d) to preserve alignment with § 495.324(b)(3) would reduce burden on States and maintain the consistency of our prior approval requirements. This proposal would not affect the other requirements that States must comply with when making acquisitions in support of the Medicaid Promoting Interoperability Program under the Federal provisions contained in 42 CFR part 495, subpart D, and specifically 42 CFR 495.348, regardless of conditions for prior approval.

We explained in the proposed rule that we believe that this proposal would reduce burden on States by raising the prior approval thresholds and generally aligning them with the thresholds for prior approval of MMIS and ADP acquisitions costs.

We did not receive any comments on this proposal and are finalizing the proposal as proposed.

b. Funding Availability to States To Conclude the Medicaid Promoting Interoperability Program

Under section 1903(a)(3)(F) and (t) of the Act, State Medicaid programs may receive FFP in expenditures for incentive payments to certain Medicaid providers to adopt, implement, upgrade, and meaningfully use CEHRT. In addition, FFP is available to States for reasonable administrative expenses related to administration of those incentive payments as long as the State meets certain conditions. Specifically, section 1903(a)(3)(F)(i) of the Act establishes 100 percent FFP to States for incentive payments to eligible Medicaid providers (described in section 1903(t)(1) and (2) of the Act) to adopt, implement, upgrade, and meaningfully use CEHRT. Section 1903(a)(3)(F)(ii) of the Act establishes 90 percent FFP to States for administrative expenses related to administration of the incentive payments.

In § 495.320 and § 495.322, we provide the general rule that States may receive: (1) 100 percent FFP in State expenditures for EHR incentive payments; and (2) 90 percent FFP in State expenditures for administrative activities in support of implementing incentive payments to Medicaid eligible providers. Section 495.316 establishes State monitoring and reporting requirements regarding activities required to receive an incentive payment. Subject to § 495.332, the State is responsible for tracking and verifying the activities necessary for a Medicaid EP or eligible hospital to receive an incentive payment for each payment year, as described in § 495.314.

To date, we have not established a date beyond which 90 percent FFP is no longer available to States for their expenditures related to administering the Medicaid Promoting Interoperability Program. In the Stage 1 final rule (75 FR 44319), we established that, in accordance with sections 1903(t)(4)(A)(iii) and (5)(D) of the Act, in no case may any Medicaid EP or eligible hospital receive an incentive payment after 2021 (42 CFR 495.310(a)(2)(v) and 495.310(f)).

Because December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability incentive payments to Medicaid EPs and eligible hospitals (other than pursuant to a successful appeal related to 2021 or a prior year), we believe it is reasonable for States to conclude most administrative activities related to the Medicaid Promoting Interoperability Program, including submitting final required reports to CMS, by September 30, 2022. Therefore, we proposed to amend § 495.322 to provide that the 90 percent FFP for Medicaid Promoting Interoperability Program administration would no longer be available for most State expenditures incurred after September 30, 2022.

We proposed a later sunset date for the availability of 90 percent enhanced match for State administrative costs related to Medicaid Promoting Interoperability Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities. States have a responsibility to conduct audits of the payments made to Medicaid providers participating in the Medicaid Promoting Interoperability Program, in accordance with § 495.368, in order to combat fraud and abuse, and States also must provide a process for EHR incentive payment appeals in accordance with § 495.370. We expect that these activities will require administration for some time after, but at most a year, beyond September 30, 2022. Because provider incentive payments could be disbursed up until December 31, 2021, we anticipate that States would need additional time to review provider risk factors, select samples, and conduct audits. Once post-payment audits are completed, States would also need time to work with any providers who choose to appeal their audit findings. Collectively, the post-payment audit process and/or appeals process could take several months, and in some cases might take more than one year. Therefore, we proposed that the 90 percent FFP would continue to be available for State administrative expenditures related to Medicaid Promoting Interoperability Program audit and appeals activities until September 30, 2023. States would not be able to claim any Medicaid Promoting Interoperability Program administrative match for expenditures incurred after September 30, 2023.

States should be aware that under this proposal, they would need to incur the expenditures for which they would claim the 90 percent FFP for Medicaid Promoting Interoperability Program administrative activities no later than the sunset dates of September 30, 2022 or September 30, 2023, as applicable. This means that for States to claim the 90 percent FFP for goods and services related to Medicaid Promoting Interoperability Program administrative activities, States would have to ensure that the goods and services are provided no later than close of business September 30, 2022 or close of business September 30, 2023, as applicable. Thus, for example, if an amount that is related to administration of a Medicaid Promoting Interoperability Program audit or appeal has been obligated by September 30, 2023, but the good or service has not yet been furnished by that date, then the expenditure could not be claimed at the enhanced 90 percent FFP.

We invited public comments on this proposal, especially on whether the timelines proposed provide States with a reasonable amount of time to wind down their Medicaid Promoting Interoperability Programs.

Comment: Many commenters expressed concerns about the December 31, 2021 deadline for disbursing all incentive payments for the Medicaid Promoting Interoperability Program, particularly that it would be burdensome for States to issue incentive payments by December 31, 2021 for Program Year 2021, and that EPs and eligible hospitals would not have time for a full reporting period before the attestation deadline. Several commenters suggested extending the December 31, 2021 deadline.

Response: Under sections 1903(t)(4)(A)(iii) and (5)(D) of the Act, all Medicaid Promoting Interoperability Program incentive payments must be made by December 31, 2021. Because this is a statutory deadline, we do not have the authority to change it. We note that in the ''Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, Medicare Shared Savings Program Requirements; Quality Payment Program, and Medicaid Promoting

Interoperability Program'' proposed rule, we are seeking comment on proposed flexibilities to the EHR reporting period and eCQM reporting period for the Medicaid Promoting Interoperability Program in CY 2021 (83 FR 35872 through 35873). This proposed rule is available at: *https://www.federalregister.gov/documents/2018/07/27/2018-14985/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions*.

Comment: Several commenters suggested that 90 percent administrative FFP for HIE activities be extended beyond the proposed deadline.

Response: Consistent with section 1903(a)(3)(F) and (t) of the Act, enhanced administrative FFP under the Medicaid Promoting Interoperability Program for HIE must be directly correlated to the Medicaid EHR Incentive Program. That is, enhanced administrative FFP for HIE must be directly tied to promoting EPs' and eligible hospitals' adoption and meaningful use of CEHRT. Once the deadline for making incentive payments (December 31, 2021) has passed, we are concerned that there would be no basis for continuing enhanced administrative FFP for HIE consistent with section 1903(a)(3)(F)(ii) of the Act. We intend to issue information regarding incurring expenditures that could be matched at enhanced administrative FFP under section 1903(a)(3)(F)(ii) of the Act for HIE under the Medicaid Promoting Interoperability Program. However, we are committed to promoting interoperability, and we are continuing to look for ways for Medicaid to support HIE initiatives.

For additional information on FFP for State administrative expenses related to pursuing initiatives to encourage the adoption of CEHRT to promote health care quality and the exchange of health care information, we refer readers to State Medicaid Director letters #10–016, 11–004, and #16–003. We understand the ongoing importance of HIE to State Medicaid programs, but again, we are concerned that we do not have the authority to extend the availability of enhanced administrative FFP under section 1903(a)(3)(F)(ii) of the Act for HIE beyond the December 31, 2021 deadline for making incentive payments.

Comment: One commenter suggested that CMS allow continued 90 percent FFP for States to complete administrative work, such as annual and quarterly reporting to CMS, beyond December 31, 2021.

Response: We note that we proposed and are finalizing that FFP is available at 90 percent for administrative activities in support of implementing incentive payments to Medicaid eligible providers only for expenditures incurred on or before September 30, 2022, except for expenditures related to audit and appeal activities, which must be incurred before September 30, 2023 to qualify for FFP at 90 percent. There are two sets of reports that are required from States for the Medicaid Promoting Interoperability Program, the annual report at § 495.316(c) and quarterly reports at § 495.352. As we approach 2021 and 2022, we will take the deadlines we are finalizing in this final rule into consideration as we set reporting requirements and deadlines for 2021 and 2022, so that States will be able to conclude administrative activities by the September 30, 2022 in a manner that will allow them to claim 90 percent FFP.

Comment: Several commenters supported the deadline of September 30, 2023 for incurring expenditures related to audit and appeals activities that can be matched at 90 percent FFP, including directly-related technical assistance and administrative activities. A few commenters suggested extending that September 30, 2023 deadline by another year.

Response: We thank the commenters for their input. We acknowledge that some States are several years behind their auditing targets. However, we believe that timely auditing is important and encourage those States to accelerate their auditing timelines. We note that hiring additional auditing staff or contractors would be eligible for enhanced FFP. In addition, we note that any expenditures related to audits and appeals, will be eligible for enhanced administrative FFP until September 30, 2023.

After consideration of the public comments we received, we are finalizing the proposed policies as proposed. We are amending § 495.322 to provide that the 90 percent FFP for Medicaid Promoting Interoperability Program administration would no longer be available for most State expenditures incurred after September 30, 2022.

The availability of 90 percent match for State administrative costs related to Medicaid Promoting Interoperability Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities, will continue until September 30, 2023. States would not be able to claim any Medicaid Promoting Interoperability Program administrative match for expenditures incurred after September 30, 2023.

States should be aware that under this final rule, they will need to incur the expenditures for which they would claim the 90 percent FFP for Medicaid Promoting Interoperability Program administrative activities no later than the sunset dates of September 30, 2022 or September 30, 2023, as applicable. This means that for States to claim the 90 percent FFP for goods and services related to Medicaid Promoting Interoperability Program administrative activities, States will have to ensure that the goods and services are provided no later than close of business September 30, 2022 or close of business September 30, 2023, as applicable.

IX. Revisions of the Supporting Documentation Required for Submission of an Acceptable Medicare Cost Report

A. Background

Sections 1815(a) and 1833(e) of the Act provide that no Medicare payments will be made to a provider unless it has furnished the information, as may be requested by the Secretary, to determine the amount of payments due the provider under the Medicare program. In general, providers submit this information through annual cost reports [410] that cover a 12-month period of time. Under the regulations at 42 CFR 413.20(b) and 413.24(f), providers are required to submit cost reports annually, with the reporting period based on the provider's accounting year. For cost years beginning on or after October 1, 1989, section 1886(f)(1) of the Act and § 413.24(f)(4) of the regulations require hospitals to submit cost reports in a standardized electronic format, and the same requirement was later imposed for other types of providers.

All providers participating in the Medicare program are required under § 413.20(a) to maintain sufficient

[410] There are currently nine Medicare cost reports: the Hospital and Health Care Complex Cost Report, Form CMS–2552, OMB No. 0938–0050; the Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report, Form CMS–2540, OMB No. 0938–0463; the Home Health Agency Cost Report, Form CMS–1728, OMB No. 0938–0022; the Outpatient Rehabilitation Provider Cost Report, Form CMS–2088, OMB No. 0938–0037; the Independent Rural Health Clinic and Freestanding Federally Qualified Health Center Cost Report (prior to October 1, 2014), Form CMS–222, OMB No. 0938–0107; the Federally Qualified Health Center Cost Report (beginning on or after October 1, 2014), Form CMS–224, OMB No. 0938–1298; the Organ Procurement Organizations and Histocompatibility Laboratory, Form CMS–216, OMB No. 0938–0102; the Independent Renal Dialysis Facility Cost Report, Form CMS–265, OMB No. 0938–0236; and the Hospice Cost and Data Report, Form CMS–1984, OMB No. 0938–0758.

financial records and statistical data for proper determination of costs payable under the program. Moreover, providers must use standardized definitions and follow accounting, statistical, and reporting practices that are widely accepted in the hospital and related fields. Upon receipt of a provider's cost report, the Medicare Administrative Contractor (herein referred to as ''contractor'') reviews the cost report to determine its acceptability in accordance with § 413.24(f)(5). Each cost report submission by a provider to its contractor, including an amended cost report, is considered to be a separate cost report submission under § 413.24(f)(5). Each cost report submission requires the supporting documentation specified in § 413.24(f)(5)(i). A cost report submitted without the required supporting documentation is rejected under § 413.24(f)(5)(i). Under § 413.24(f)(5)(iii), when the cost report is rejected, it is deemed an unacceptable submission and treated as if it had never been filed.

Several provisions in the regulations requiring supporting documentation for the Medicare cost report to be acceptable need to be updated to reflect current practices, to improve the accuracy of these reports, and to facilitate more efficient contractor review of cost reports. The regulations at § 413.24(f)(5)(i) provides that a provider's cost report is rejected if the provider does not complete and submit the Provider Cost Reimbursement Questionnaire (a questionnaire independent of the cost report, OMB No. 0938–0301, also known as Form CMS–339). The Form CMS–339 requires the provider to submit supporting documents, as applicable, for items such as Medicare bad debt, approved educational activities, and cost allocation from a home office or chain organization.

Beginning in 2011, as cost report forms were updated for various provider types, the Form CMS–339 was incorporated as a worksheet in the Medicare cost report (the worksheet title and placement within the cost report vary by provider type), and is no longer submitted as a separate supporting document. The Form CMS–339 has been incorporated into all Medicare cost reports except for the Organ Procurement Organization (OPO) and Histocompatibility Laboratory cost report, Form CMS–216. In section IX.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20544 through 20548), we proposed to incorporate the Form CMS–339 into the OPO and Histocompatibility cost report, Form CMS–216.

The cost report worksheet that incorporated the Form CMS–339 continues to require the provider to submit supporting documents for Medicare bad debt, approved educational activities, and certain cost allocation information from a home office or chain organization, as applicable. However, our regulations at § 413.24(f)(5)(i) do not reflect that the Provider Cost Reimbursement Questionnaire, Form CMS–339, has been incorporated into the Medicare cost report as a worksheet because the regulations require the Form CMS–339 to be submitted as a supporting document to the cost report.

Section 413.24(f)(5)(i) also provides that a cost report is rejected for a teaching hospital if a copy of the Intern and Resident Information System (IRIS) diskette is not included as supporting documentation. However, diskettes are no longer used by providers to furnish these data to contractors.

Section 413.20 of the regulations requires providers to maintain sufficient financial records and statistical data for the proper determination of costs payable under the program as well as an adequate ongoing system for furnishing records needed to provide accurate cost data and other information capable of verification by qualified auditors. In accordance with § 413.20(d), the provider must furnish such information to the contractor as may be necessary to assure proper payment. Information from the provider relating to Medicaid days used in the calculation of DSH payments, charity care charges, uninsured discounts, and home office cost allocations are necessary to assure proper payment. While our regulations require that these supporting documents be maintained by the provider and furnished to the contractor to assure proper payment, § 413.24(f)(5) does not require submission of supporting documentation for Medicaid days used in the calculation of DSH payments, charity care charges, uninsured discounts, or home office cost allocations reported on a provider's cost report for the provider to have an acceptable cost report submission. These supporting documents are often subsequently requested by the contractor, and must be submitted by the provider in order to assure proper payment, which can delay payments and prolong audits.

Our specific proposals for revising our regulations that were included in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20544 through 20548) are discussed below, along with the public comments we received and our responses and the policies that we are finalizing in this final rule.

B. Revisions to Regulations

1. Provider Cost Reimbursement Questionnaire

Section 413.24(f)(5)(i) of the regulations provides that a provider's Medicare cost report is rejected for lack of supporting documentation if it does not include the Provider Cost Reimbursement Questionnaire (also known as Form CMS–339). As discussed in section IX.A. of the preamble of the proposed rule and this final rule, beginning in 2011, as cost report forms were updated, the Provider Cost Reimbursement Questionnaire, Form CMS–339, was incorporated into all Medicare cost reports as a worksheet, except the OPO and Histocompatibility Laboratory cost report, Form CMS–216. In the FY 2019 IPPS/LTCH PPS proposed rule, we proposed to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339, into the OPO and Histocompatibility Laboratory cost report, Form CMS–216. The incorporation of the Form CMS–339 into the Form CMS–216 will complete our incorporation of the Form CMS–339 into all Medicare cost reports.

In addition, in the proposed rule, we proposed to revise § 413.24(f)(5)(i) by removing the reference to the Provider Cost Reimbursement Questionnaire so that § 413.24(f)(5)(i) no longer states that a cost report will be rejected for lack of supporting documentation if it does not include a Provider Cost Reimbursement Questionnaire (Form CMS–339). Furthermore, we proposed to add language to the first sentence of § 413.24(f)(5)(i) to clarify that a provider must submit all necessary supporting documents for its cost report. We stated in the proposed rule that we believe the proposal is consistent with the recordkeeping requirements in §§ 413.20 and 413.24.

Comment: Several commenters supported the incorporation of the Provider Cost Reimbursement Questionnaire, Form CMS–339 into the OPO and Histocompatibility Laboratory cost report, Form CMS–216 because of the ease of completing the Provider Cost Reimbursement Questionnaire as an incorporated worksheet within the Medicare cost report.

Response: We appreciate the commenters' support for our proposals.

Comment: Many commenters agreed with the proposal to add language to the first sentence of § 413.24(f)(5)(i) to clarify that a provider must submit all necessary supporting documents for its

cost report. Some commenters who were in agreement cited the need for data integrity within the Medicare cost report. However, several commenters disagreed with the proposal, citing increased burden upon providers to submit all necessary supporting documents for its cost report at the time of the cost report submission. Some commenters believed the supporting documents should only be submitted to the contractor during an audit of the cost report. Several commenters stated that the cost report should not be rejected when the provider fails to submit it with the supporting documentation.

Response: We agree with the commenters that accuracy of the data reported in the Medicare cost report is necessary. We note that many Medicare payment systems are based upon data reported in the cost report. We disagree with the commenters that submitting supporting documents with the cost report is burdensome, as these data are recorded and maintained by the provider and are available to providers at the time of completion of the Medicare cost report. This documentation that is recorded and maintained by the provider is necessary to complete the cost report and supports the amounts reported in the cost report. When a cost report is audited, the provider's records are tested for accuracy and at that point additional detailed documents may be requested. Because not all cost reports are audited, the submission of supporting documents that agree with the amounts reported in the cost report at the time of submission is necessary so that contractors can pay providers promptly and accurately.

After consideration of the public comments we received, for the reasons discussed above and in the proposed rule, we are finalizing our proposal, without modification, to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339 into the OPO and Histocompatibility Laboratory cost report, Form CMS–216, and to revise § 413.24(f)(5)(i) by removing the reference to the Provider Cost Reimbursement Questionnaire so that § 413.24(f)(5)(i) no longer states that a cost report will be rejected for lack of supporting documentation if it does not include a Provider Cost Reimbursement Questionnaire (Form CMS–339). In addition, we are finalizing the addition of language to the first sentence of § 413.24(f)(5)(i) to clarify that a provider must submit all necessary supporting documents for its cost report.

2. Intern and Resident Information System (IRIS) Data

Section 413.24(f)(5)(i) also provides that a Medicare cost report for a teaching hospital is rejected for lack of supporting documentation if the cost report does not include a copy of the Intern and Resident Information System (IRIS) diskette.

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99–272, establishes a methodology for determining payments to hospitals for the GME programs (which is currently implemented in the regulations at 42 CFR 413.75 through 413.83). To account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals, section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the IME adjustment under the IPPS for hospitals that have residents in an approved GME program. The regulation regarding the calculation of this additional payment is located at 42 CFR 412.105. (We refer readers to sections IV.E. and L. of the preamble of this final rule for additional background on IME and direct GME payments.)

In accordance with § 413.78(b) for direct GME and § 412.105(f)(1)(iii)(A) for IME, no individual may be counted as more than one full-time equivalent (FTE). A hospital cannot claim the time spent by residents training at another hospital; if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as a partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

In 1990, we established the IRIS, under the authority of sections 1886(d)(5)(B) and 1886(h) of the Act, in order to facilitate proper counting of FTE residents by hospitals that rotate their FTE residents from one hospital or nonprovider setting to another. Teaching hospitals use the IRIS to collect and report information on residents training in approved residency programs. Section 413.24(f)(5)(i) requires teaching hospitals to submit the IRIS data along with their Medicare cost reports in order to have an acceptable cost report submission. The IRIS can be downloaded from CMS' website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IRIS/index.html?redirect=/iris*. We are currently in the process of producing a new Extensible Markup Language (XML)-based IRIS file format that captures FTE resident count data consistent with the manner in which FTEs are reported on the Medicare cost report.

After receiving the IRIS data along with each teaching hospital's cost report, the contractors upload the data to a national database housed at CMS, which can be used to identify ''duplicates,'' that is, FTE residents being claimed by more than one hospital for the same rotation. Identifying duplicates allows the contractors to approach the hospitals that simultaneously claimed the same FTE, and correct the duplicate reporting on the respective hospitals' cost reports for direct GME and IME payment purposes.

Historically, we would collect the IRIS data from hospitals on a diskette, as referenced in § 413.24(f)(5)(i). Because diskettes are no longer used by providers to furnish these data to contractors, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20545 and 20546), we proposed to remove the reference in the regulations to a diskette and instead reference ''Intern and Resident Information System data.'' Specifically, we proposed to amend § 413.24(f)(5)(i) by adding a new paragraph (A) to include this proposed revised language (83 FR 20546).

In addition, to enhance the contractors' ability to review duplicates and to ensure residents are not being double-counted, we stated that we believe it is necessary and appropriate to require that the total unweighted and weighted FTE counts on the IRIS for direct GME and IME respectively, for all applicable allopathic, osteopathic, dental, and podiatric residents that a hospital may train, must equal the same total unweighted and weighted FTE counts for direct GME and IME reported on Worksheet E–4 and Worksheet E, Part A. The need to verify and maintain the integrity of the IRIS data has been the subject of reviews by the Office of the Inspector General (OIG) over the years. An August 2014 OIG report cited the need for CMS to develop procedures to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–13–01014, August 2014). More recently, a July 2017 OIG report recommended that procedures be developed to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–15–01027, July 2017).

Therefore, effective for cost reports filed on or after October 1, 2018, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20546), we proposed to add the requirement that IRIS data contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME and IME FTE residents reported in the cost report. Specifically, we proposed to specify in a new paragraph (A) of § 413.24(f)(5)(i) that, effective for cost reports filed on or after October 1, 2018, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation (83 FR 20569).

Comment: Some commenters expressed concern that the current IRIS does not calculate the total amounts of direct GME FTE and IME FTE residents, leaving teaching hospitals unable to ensure that the IRIS direct GME FTE totals and the IME FTE totals are the same as what a teaching hospital reports in its hospital cost report. The commenters suggested that the IRIS program be updated to calculate the total resident FTEs.

Response: We understand and agree with the commenters' concerns that the current IRIS program does not calculate the totals of the hospital's resident FTEs and therefore it would be difficult to require that a hospital's resident FTEs in the IRIS equate to the resident FTEs in the hospital's cost report. The number of direct GME FTE residents and IME FTE residents in the current IRIS is self-reported by the teaching hospitals from their resident data records. We believe that the IRIS data should represent the total of direct GME FTE residents, weighted and unweighted, and the total of IME FTE residents. As we noted in the proposed rule, we are in the process of producing a new XML-based IRIS that will capture FTE resident count data consistent with the manner in which FTEs are reported on the Medicare cost report. It was our intention that the new XML-based IRIS would capture both weighted and unweighted direct GME FTE and IME FTE residents and totals. It was also our intention that the new XML-based IRIS would be available by October 1, 2018 and that hospitals would be able to comply with our proposal by ensuring that the weighted and unweighted direct GME FTE and IME FTE residents and totals calculated in the new XML-based IRIS would correspond with the weighted and unweighted direct GME FTE and IME FTE residents and totals the hospital reports in its cost report. However, because of extenuating circumstances, the new XML-based IRIS will not be able to calculate the GME (weighted and unweighted) FTE counts and IME FTE counts by October 1, 2018. Therefore, due to the concerns expressed in the comments, we are not finalizing our proposal that a teaching hospital's IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation. We will consider making this proposal at a future time when the new XML-based IRIS has the capability to capture the total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents.

As we noted in the proposed rule, teaching hospitals no longer submit IRIS data on diskettes. Instead, teaching hospitals submit IRIS data with their cost reports in order to have an acceptable cost report. In this final rule, we are finalizing a change to the regulation at § 413.24 to specify that, in order for teaching hospitals to have an acceptable cost report, teaching hospitals must submit their IRIS ''data,'' given that IRIS diskettes are no longer used by providers to furnish these data to contractors.

Comment: A few commenters suggested that the goal of ensuring that resident FTEs are not double counted requires a review of all hospitals that train residents and can only be done by the contractors during the cost report review and reconciliation period.

Response: We agree that ensuring that resident FTEs are not double counted among hospitals requires a review of IRIS data for all hospitals that train residents, and the review of these data is completed by the contractors during the cost report review and reconciliation period. We believe the current IRIS can be used to ascertain duplicate counting of resident FTEs, by ensuring that the IRIS FTE counts correspond to the FTE counts reported in the teaching hospital's cost report. However, any review of these data first requires that the data reported in the hospital's cost report be accurate and correspond to what is reported in the IRIS.

Comment: One commenter requested that the hospital cost report and the IRIS have abilities to differentiate between new residents and those residents in existing resident programs as a way to account for instances when the number of a hospital's resident FTEs may exceed the hospital's FTE slots.

Response: We agree with the commenter's objective to account for instances when the number of a hospital's resident FTEs may exceed its resident FTE slots. However, there is no requirement that the cost report FTE count be limited to the number of accredited slots. There is a general rule that only residents training in accredited programs can be reported. There are times when a hospital trains more residents in a program than the number of residents the program is actually accredited for, and if they do, hospitals are supposed to inform the ACGME of such an occurrence. Therefore, even in the case where the number of FTEs exceeds the accredited slots, the FTEs represented in IRIS should equal the cost report count.

Comment: One commenter expressed concern that the Medicare Cost Report e-Filing (MCReF) program requires IRIS data as a separate upload and suggested building a functionality in MCReF that would read the IRIS uploaded data and compare the data to what is reported in the cost report and produce an immediate flag upon the cost report submission if the IRIS data do not match.

Response: We appreciate the commenter's suggestion to build a functionality in MCReF that would read the IRIS uploaded data and compare them to what is reported in the cost report. We will explore this suggestion in the future with regard to the MCReF program and the feasibility for it to interface with the new XML-based IRIS program.

Comment: One commenter asked whether providers would be required to purchase the new XML-based IRIS program.

Response: We appreciate the commenter's inquiry and assure that the new XML-based IRIS software will be available for hospitals' use at no cost. However, as we explain earlier, we are not finalizing our proposal that the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, pending development of the new XML-based IRIS file and completion of the Paperwork Reduction Act (PRA) approval process. Providers will have an opportunity to comment during the comment period that is specified in the IRIS PRA notice.

Comment: Some commenters requested clarification of the effective date of the proposed provision that the

IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation.

Response: We stated in the proposed rule that the effective date for the proposed provision that the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation, would be for cost reports filed on or after October 1, 2018. However, as explained above, because the new XML-based IRIS program is not yet available, we are not finalizing this portion of the proposal.

After consideration of the public comments we received, for the reasons discussed earlier and in the proposed rule, we are finalizing our proposals with modifications. As proposed, we are removing the reference in the regulations to an IRIS diskette and instead referencing ''Intern and Resident Information System data.'' Specifically, we are amending § 413.24(f)(5)(i) by adding a new paragraph (A) to provide that a teaching hospital's cost report is rejected for lack of supporting documentation if the cost report does not include the IRIS data. For the reasons discussed above, we are not finalizing our proposal that the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation.

3. Medicare Bad Debt Reimbursement

Under section 1861(v)(1) of the Act and the regulations at § 413.89, Medicare may reimburse a portion of the uncollectible deductible and coinsurance amounts to those entities eligible to receive reimbursement for Medicare bad debt. The Medicare Provider Reimbursement Manual (PRM–1, CMS Pub. 15–1), Chapter 3, provides guidance to providers that claim Medicare bad debt reimbursement.

Section 413.24(f)(5)(i) provides that an acceptable cost report submission requires the provider to submit a Provider Cost Reimbursement Questionnaire, Form CMS–339. The Form CMS–339, which has been incorporated into all Medicare cost reports (except the OPO and Histocompatibility Laboratory cost report, Form CMS–216, which we proposed (and are finalizing) to incorporate into the cost report, as discussed in section IX.B.1. of the preamble of the proposed rule and this final rule), requires the provider to submit supporting documentation with the cost report to substantiate its claims for Medicare bad debt reimbursement. For example, the hospital cost report, which incorporated the Form CMS–339, instructs hospitals to submit a ''completed Exhibit 2 or internal schedules duplicating the documentation requested on Exhibit 2 to support the bad debts claimed'' (Section 4004.2 of CMS Pub. 15–2). This ''completed Exhibit 2 or internal schedules duplicating the documentation requested on Exhibit 2 to support the bad debts claimed'' is also known as the Medicare bad debt listing and requires information such as the patient's name, dates of service, the beneficiary's Medicaid status, if applicable, the date that collection effort ceased, and the deductible and coinsurance amounts.

Because the Provider Cost Reimbursement Questionnaire is incorporated into the cost report as a worksheet, the bad debt listing continues to be required for an acceptable cost report under § 413.24(f)(5). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20547 and 20548), we proposed to require that the Medicare bad debt listing correspond to the bad debt amount claimed in the provider's cost report, in order for the provider to have an acceptable cost report submission under § 413.24(f)(5). We stated that this proposal is also consistent with a provider's recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, and will facilitate the contractor's review and verification of the cost report. Specifically, we proposed to amend § 413.24(f)(5)(i) by adding a new paragraph (B) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a cost report would be rejected for lack of supporting documentation if it does not include a detailed bad debt listing that corresponds to the bad debt amounts claimed in the provider's cost report.

Comment: Some commenters generally supported the proposal, while other commenters suggested that a standardized format be established and required for the submission of the bad debt listing that corresponds to the bad debt amounts claimed in the provider's cost report. One commenter suggested that the format of the bad debt list follow the format of the bad debt listing from the exhibit to the Form CMS–339.

Response: We appreciate the commenters' support and agree with the suggestion that a standardized format be required for the submission of the bad debt listing. The standardized format, that we will continue to use, for the bad debt listing is currently submitted by the provider as a required exhibit to the CMS Form-339 which, with the finalization of this rule, will be incorporated into all of the Medicare cost reports in the Provider Reimbursement Manual (PRM–2, CMS Pub. 15–2). We will continue to use the exhibit to the incorporated CMS Form-339 as the standardized format of the bad debt listing. Any amendments to the format of the bad debt listing will be published with amendments to the cost report in the PRM–2, CMS Pub. 15–2.

Comment: Some commenters cited the need to revise the bad debt listing following the submission of the cost report and suggested that cost reports be permitted to be amended for this purpose.

Response: We disagree that the bad debt listing needs to be revised following the submission of the cost report. Providers are required under § 413.20(a) to maintain sufficient financial records and statistical data for proper determination of costs payable under the program. It is our expectation that the bad debt listing providers use to complete the cost report and that they submit with the cost report is complete and accurate. The Provider Reimbursement Manual, CMS Pub. 15–1, Chapter 3, section 314, provides that uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in the reporting period in which the debts are determined to be worthless. Because, pursuant to § 413.24(f)(2)(i), cost reports are due on or before the last day of the fifth month following the close of the period covered by the report, we believe there is sufficient time for the provider to accurately report bad debts. However, pursuant to 42 CFR 405.1885(a), providers are permitted, and contractors have the discretion to grant, a reopening of a contractor determination in order to revise an item in the cost report. Also, pursuant to § 413.24(f), amended cost reports to revise cost report information that has been previously submitted by a provider may be permitted by the contractor.

Comment: Other commenters suggested that the bad debt listing be submitted only when the cost report is audited instead of being submitted with

the cost report as a supporting documentation in order to have an acceptable cost report.

Response: We disagree that the bad debt listing should only be submitted when the cost report is audited. Because not all cost reports are audited, the submission of the bad debt listing with the cost report is necessary for contractors to ensure the veracity and accuracy of the bad debts claimed in the cost report and to ensure there is no duplicate reporting of bad debts from a provider's prior fiscal year cost report.

After consideration of the public comments we received, for the reasons discussed earlier and in the proposed rule, we are finalizing our proposals without modification. Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a cost report will be rejected for lack of supporting documentation if it does not include a detailed bad debt listing that corresponds to the bad debt amounts claimed in the provider's cost report.

4. Disproportionate Share Hospital (DSH) Payment Adjustment

The DSH payment adjustment provision under section 1886(d)(5)(F) of the Act was enacted by section 9105 of COBRA and became effective for discharges occurring on or after May 1, 1986. Under section 1886(d)(5)(F) of the Act, the primary method by which a hospital qualifies for a Medicare DSH payment is based on the hospital's disproportionate patient percentage, which is determined using a statutory formula. This statutory formula incorporates the hospital's number of patient days for patients who are eligible for Medicaid, but were not entitled to benefits under Medicare Part A (''Medicaid eligible days''), which hospitals are required to submit on their cost reports.

Currently, in order for a DSH eligible hospital to have an acceptable cost report submission, there is no requirement for the hospital to also submit a listing of its Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report, as a supporting document. DSH eligible hospitals have always been required to collect and maintain these data for completion of the cost report, and to submit it when requested. However, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20547), we proposed that, in order to have an acceptable cost report submission, DSH eligible hospitals must submit these supporting data with their cost reports. We indicated that, to ensure accurate DSH payments, additional information regarding Medicaid eligible days is required in order to validate the number of Medicaid eligible days the hospital reports in its cost report. Currently, when this information regarding Medicaid eligible days is not submitted by the DSH eligible hospitals with the cost report, contractors must request it. An audit may reveal an overstatement of a hospital's Medicaid eligible days. However, we stated that an audit of these data may not take place for more than a year after the cost report has been submitted, and tentative program reimbursement payments are often issued to a provider upon the submission of the cost report. Because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit these data when requested, we stated in the proposed rule that there is not additional burden.

We explained in the proposed rule (83 FR 20547) that requiring a provider to submit, as a supporting document with its cost report, a listing of the provider's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the DSH eligible hospital's cost report would provide contractors with the DSH eligible hospital's source document listing the Medicaid eligible days claimed on its cost report and would be consistent with the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require a provider to substantiate its costs. A requirement to submit this supporting documentation also would facilitate the contractor's review and verification of the cost report without the need to request additional data from the provider. We stated in the proposed rule that this proposal would not affect a hospital's ability to submit an amended cost report, within 12 months after the hospital's cost report is due, that reflects updated information on Medicaid eligible patient days after the hospital receives updated Medicaid eligibility information from the State (CY 2016 OPPS/ASC final rule with comment period (80 FR 70560)).

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule, we proposed that, effective for cost reporting periods beginning on or after October 1, 2018, in order for a hospital eligible for a Medicare DSH payment adjustment to have an acceptable cost report submission in accordance with § 413.24(f)(5), the provider must submit a detailed listing of its Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the provider's cost report, as a supporting document with the provider's cost report. In addition, we proposed that if the provider submits an amended cost report that changes its Medicaid eligible days, an amended listing or an addendum to the original listing of the provider's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the provider's amended cost report would also need to be submitted as a supporting document with the amended cost report.

Consistent with this proposal, we proposed to amend § 413.24(f)(5)(i) by adding a new paragraph (C) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a DSH payment adjustment, a cost report will be rejected for lack of supporting documentation if it does not include a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. If the hospital submits an amended cost report that changes its Medicaid eligible days, an amended listing or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report would be required.

Comment: Some commenters pointed out that, in some instances, the State may not have made information regarding the Medicaid eligible days available to the provider at the time the cost report is submitted and that hospitals have the ability to submit an amended cost report within 12 months after the hospital's cost report is due that reflects updated information on Medicaid eligible patient days if the hospital receive updated Medicaid eligibility information from the State (CY 2016 OPPS/ASC final rule with comment period (80 FR 70560)). Commenters expressed opposition to the requirement that hospitals submit a listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report because it would require the provider to submit knowingly incomplete information with the cost report and also would require a duplication of efforts if an amended cost report is submitted with an updated listing of the Medicaid eligible days in the 12 months following the hospital's cost report due date.

Response: We disagree with the commenters' assertion that our proposal would require that the provider knowingly submit incomplete information if a hospital were to submit the cost report with a listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible

days claimed in the hospital's cost report. The proposal to require a hospital to submit a listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report does not require providers to submit incomplete information. Currently, the provider is required to submit the cost report with the known Medicaid eligible days for the hospital's fiscal year. This proposal would require hospitals to substantiate those days by requiring the hospital to also submit a listing of the hospital's Medicaid eligible days that corresponds to the days claimed in the hospital's cost report. This requirement would not change the current requirements with respect to reporting on the cost report of the Medicaid eligible days known by the hospital at the time of the cost report submission. If the Medicaid eligible days change once the hospital receives the documentation from the State, the hospital may amend its cost report. The contractor must accept the amended cost report with the amended listing of the Medicaid eligible days that substantiates the revised Medicaid eligible days reported in the amended cost report if it is submitted within 12 months after the hospital's cost report is due. As a result, the requirement that hospitals submit a listing of the Medicaid eligible days with their cost report does not require the hospital to perform any duplicative actions and, in fact, only requires that in the case where a hospital submits an amended cost report that changes its Medicaid eligible days, the hospital also submit documentation to support the additional Medicaid days.

Comment: One commenter requested that hospitals that are DSH eligible, but do not actually receive DSH, be excluded from the requirement to submit a listing of the Medicaid eligible days that substantiates the Medicaid eligible days reported in the hospital's cost report. The commenter provided sole community hospitals (SCHs) and Medicare dependent small rural hospitals (MDHs) as an example and requested that they be excluded.

Response: We agree with the commenter that the requirement to submit a listing of the Medicaid eligible days that corresponds to the Medicaid eligible days reported in the hospital's cost report is not applicable to SCHs that are paid under the hospital-specific rate and are not eligible to receive DSH payment adjustments. However, because MDHs are eligible to receive DSH payment adjustments, this proposal applies to them if they are claiming a DSH payment adjustment. Similarly, an SCH that is not paid under its hospital-specific rate and is eligible to receive a DSH payment adjustment must submit a listing of the Medicaid eligible days that corresponds to the Medicaid eligible days reported in the hospital's cost report if it is claiming a DSH payment adjustment.

After consideration of the public comments we received, for the reasons discussed earlier and in the proposed rule, we are finalizing our proposals without modification. Therefore, effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a disproportionate share payment adjustment, a cost report will be rejected for lack of supporting documentation if it does not include a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. In addition, if the hospital submits an amended cost report that changes its Medicaid eligible days, the hospital must submit an amended listing or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report. We are finalizing § 413.24(f)(5)(i)(C) as proposed to reflect these policies.

5. Charity Care and Uninsured Discounts

Section 3133 of the Affordable Care Act amended the Medicare DSH payment adjustment provision at section 1886(d)(5)(F) of the Act, and established section 1886(r) of the Act which provides for an additional payment that reflects a hospital's uncompensated care (which includes charity care and discounts given to uninsured patients who qualify under the hospital's charity care policy or financial assistance policy). In accordance with the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38208), starting in FY 2018, Worksheet S–10 of the cost report is used as a data source for calculating uncompensated care payments.

Currently there is no requirement for a DSH eligible hospital to submit supporting documentation with its cost report, to substantiate its charity care or discounts given to uninsured patients who qualify under the hospital's charity care policy or financial assistance policy, in order for its cost report submission to be acceptable in accordance with § 413.24(f)(5). Uncompensated care data reported on a hospital's cost report did not have an impact on the determination of uncompensated care payments before FY 2018 when the agency first began using Worksheet S–10 data to calculate uncompensated care payments. However, because the Worksheet S–10 data are now utilized to make uncompensated care payments to DSH-eligible hospitals, documentation to substantiate charity care or discounts given to uninsured patients who qualify under the hospital's charity care or financial assistance policy is needed to complete the cost report and to ensure there is no duplication when hospitals report Medicare bad debt, charity care, and uninsured discounts. All hospitals, including DSH eligible hospitals, have always been required to collect and maintain these data for completion of the cost report, and submit it when requested. However, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20547 and 20548), we proposed that, in order to have an acceptable cost report submission, DSH eligible hospitals must submit these supporting data with their cost reports. We stated that, to ensure accurate uncompensated care payments, additional supporting information regarding charity care and uninsured discounts is required in order to validate the amounts reported in the cost report. Currently, when the documentation to support the charity care charges and uninsured discounts is not submitted by DSH eligible hospitals with the cost report, contractors must request it. We stated that because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit these data when requested, there is no additional burden.

We stated in the FY 2019 IPPS/LTCH PPS proposed rule that we believe that requiring a DSH eligible hospital to submit, with its cost report, a detailed listing of its charity care and uninsured discounts that corresponds to the amount claimed in the hospital's cost report would be consistent with the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require a provider to substantiate its costs. We stated that this supporting documentation also would facilitate the contractor's review and verification of the cost report without the need to request additional data from the provider.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule, we proposed that, effective for cost reporting periods beginning on or after October 1, 2018, in order for hospitals reporting charity care and/or uninsured discounts to have an acceptable cost report submission under § 413.24(f)(5), the provider must submit a detailed listing of charity care and/or

uninsured discounts that contains information such as the patient name, dates of service, insurer (if applicable), and the amount of charity care and/or uninsured discount given that corresponds to the amount claimed in the hospital's cost report as a supporting document with the hospital's cost report.

Consistent with this proposal, we proposed to amend § 413.24(f)(5)(i) by adding a new paragraph (D) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for hospitals reporting charity care and/or uninsured discounts, a cost report will be rejected for lack of supporting documentation if it does not include a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the provider's cost report.

Comment: Some commenters supported the proposal while other commenters believed it was burdensome for providers to submit the supporting documentation that corresponds to the amounts claimed in the provider's cost report for charity care and/or uninsured discounts at the time of the cost report submission.

Response: We appreciate the commenters' support. We disagree that requiring hospitals that report charity care and/or uninsured discounts to submit the supporting documentation that corresponds to the amounts claimed in the provider's cost report for charity care and/or uninsured discounts is burdensome to providers. As stated in the FY 2019 IPPS/LTCH PPS proposed rule, we believe that requiring a DSH eligible hospital to submit, with its cost report, a detailed listing of its charity care and/or uninsured discounts that corresponds to the amount claimed in the hospital's cost report is consistent with the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require a provider to maintain records of its cost data and produce them to substantiate its costs. These data must be recorded and maintained by the provider and are available to providers at the time of completion of the Medicare cost report. In previous years, we have received many comments in response to IPPS proposed rules where stakeholders have requested that CMS ensure the accuracy of the amounts providers report on the Worksheet S–10, and that are used to calculate uncompensated care. Because not all cost reports are audited, the submission of supporting documents with the cost report that correspond to the amounts reported in the cost report for charity care and/or uninsured discounts is necessary so that contractors can pay providers promptly and accurately.

Comment: Some commenters suggested that CMS establish a standardized format that hospitals would be required to use when submitting the supporting documentation for the charity care and/or uninsured discounts that corresponds to the amounts claimed in their cost report. Commenters believed that including such a requirement would ensure consistency of the supporting documentation submitted by hospitals.

Response: We agree that a standardized format should be established and required for the submission of the supporting documentation for the charity care and/or uninsured discounts that corresponds to the amounts claimed in the provider's cost report. We agree that requiring this information to be submitted in a standardized format would ensure consistency of the documentation and facilitate the contractor's review and verification of the cost report. As stated in the FY 2019 IPPS/LTCH PPS proposed rule, for hospitals reporting charity care and/or uninsured discounts, we believe the documentation must include information such as the patient name, dates of service, insurer (if applicable), and the amount of the charity care and/or uninsured discount given to the patient that corresponds to the amounts reported in the hospital's cost report. We will work toward developing a standard format to include in a subsequent Paperwork Reduction Act (PRA) notice to request public comment. Until a standard format is adopted, in order to have an acceptable cost report submission, hospitals should submit a listing that includes information, such as the aforementioned data elements, with its cost report submission as necessary to support the amounts reported in their cost report.

Comment: One commenter indicated that a hospital's submission of a detailed listing of the hospital's charity care/uninsured discounts with its cost report would be time and resource intensive.

Response: We disagree that a hospital's submission of a listing of charity care/uninsured discounts that corresponds to the amount of the charity care and/or uninsured discounts reported in the hospital's cost report would be time consuming and resource intensive. As previously stated, this is information already in the possession of hospitals, developed in the normal course of hospital operations, and is already needed in order to report charity care and/or uninsured discounts on the Worksheet S–10 of the cost report. As a result, the proposal would simply require a hospital to submit this supporting documentation, which has already been developed in the normal course of hospital operations, with its cost report in order to have an acceptable cost report submission.

After consideration of the public comments we received, for the reasons discussed earlier and in the proposed rule, we are finalizing our proposed policy, without modification, that, effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a cost report will be rejected for lack of supporting documentation if it does not include a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the hospital's cost report. We are finalizing § 413.24(f)(5)(i)(D) as proposed to reflect this final policy. In addition, as discussed earlier, until a standard format is adopted, a hospital must submit a listing with its cost report submission that supports the amounts reported in its cost report including information, such as: Patient name, dates of service, insurer (if applicable), and the amount of the charity care and/or uninsured discount given to the patient.

6. Home Office Allocations

A chain organization consists of a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization (Provider Reimbursement Manual 1 (PRM–1), CMS Pub. 15–1, Chapter 21, Section 2150). Chain organizations include, but are not limited to, chains operated by proprietary organizations and chains operated by various religious, charitable, and governmental organizations. A chain organization may also include business organizations which are engaged in other activities not directly related to health care.

When a provider claims costs on its cost report that are allocated from a home office (also known as a chain home office or chain organization), the Home Office Cost Statement constitutes the documentary support required of the provider to be reimbursed for home office costs in the provider's cost report as set forth in Section 2153, Chapter 21, of the PRM–1. Section 2153 states that each contractor servicing a provider in a chain must be furnished with a detailed Home Office Cost Statement as a basis for reimbursing the provider for cost allocations from a home office or chain organization. However, many cost

reports that have home office costs allocated to them are submitted without a Home Office Cost Statement as a supporting document. In addition, there are home offices or chain organizations that are not completing a Home Office Cost Statement to support the costs they are allocating to the provider cost reports. Lack of this documentation should result in a disallowance of costs. It is our understanding that some providers paid under a PPS mistakenly believe that a Home Office Cost Statement is no longer required. However, the home office costs reported in the provider's cost report may have an impact on future rate-setting and payment refinement activities. We stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20748) that we believe that requiring a home office or chain organization to complete a Home Office Cost Statement and a provider to submit, with its cost report, a copy of the Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report, is consistent with Section 2153 of the PRM–1 and would be consistent with a provider's recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require a provider to substantiate its costs.

Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule, we proposed that, effective for cost reporting periods beginning on or after October 1, 2018, in order for a provider claiming costs on its cost report that are allocated from a home office or chain organization to have an acceptable cost report submission under § 413.24(f)(5), a Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report must be submitted as a supporting document with the provider's cost report. We stated that this proposal would facilitate the contractor's review and verification of the cost report without needing to request additional data from the provider. We stated that with our proposal, we anticipate more providers will submit the Home Office Cost Statement to support the amounts reported in their cost reports, in order to have an acceptable cost report submission. We further stated that because the existing burden estimate for a provider's cost report already reflects the requirement that providers collect, maintain, and submit these data, there is no additional burden.

Consistent with this proposal, we proposed to amend § 413.24(f)(5)(i) by adding a new paragraph (E) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization, a cost report will be rejected for lack of supporting documentation if it does not include a Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report.

Comment: A few commenters supported this proposal. However, several commenters indicated that the proposal was not feasible because a home office may have a fiscal year that differs from the fiscal year of the providers in its chain. The commenters stated that because of the possible differing fiscal years, a Home Office Cost Statement may not include all costs allocated from the home office to the provider for the time period covering a provider's cost report, requiring the provider to submit the Home Office Cost Statement that is subsequently due that covers the remaining time period of the provider's cost report.

Response: We acknowledge the commenters' concerns that where a provider and its home office have differing fiscal year ends, a Home Office Cost Statement may not be available to substantiate all of a provider's costs. For example, a provider with a fiscal year that begins on October 1, 2018 and ends on September 30, 2019, whose home office has a fiscal year that begins on January 1 and ends on December 31 of each year, may have a portion of costs allocated to it from the Home Office Cost Statement that begins on January 1, 2018 and ends on December 31, 2018 and a portion of costs allocated to it from the Home Office Cost Statement that begins on January 1, 2019 and ends on December 31, 2019. We understand the provider's concern and are revising the regulation text of proposed § 413.24(f)(5)(i)(E) to provide that when the provider and its home office have differing fiscal year ends, the provider's home office costs for a portion of the cost reporting period (as reflected on the Home Office Cost Statement) must correspond to a portion of the amount reported in the provider's cost report. When the provider and its home office have the same fiscal year end, the provider's home office costs for the same time period (as reflected on the Home Office Cost Statement) must correspond to the costs reported in the provider's cost report.

Comment: Some commenters suggested that the Home Office Cost Statement be submitted by the chain's home office on behalf of all providers in the chain instead of requiring each provider in the chain to submit a Home Office Cost Statement with its cost report, in order to ensure accuracy and reduce burden to the providers in a chain.

Response: We appreciate the commenters' concerns regarding reducing burden to the providers in a chain organization and ensuring accuracy when a provider substantiates costs allocated to it from its home office. We agree with the commenters' suggestion that the home office should instead submit the Home Office Cost Statement directly to the servicing contractors for its providers when the home office has allocated costs to its providers, instead of requiring the providers to submit the Home Office Cost Statement individually with their cost report submission. Requiring the home office to instead submit the Home Office Cost Statement to the servicing contractors of its providers will reduce burden upon the individual providers within a chain organization by not requiring each provider within the chain to submit the Home Office Cost Statement with its cost report submission. Because the Home Office Cost Statement lists the providers in the chain and each of the providers' servicing contractors, the contractors to whom the Home Office Cost Statement should be sent are known to the home office. We plan to update the PRM to reflect this policy.

Comment: One commenter suggested that requiring the Home Office Cost Statement submission with the provider's cost report will make the information contained in the Home Office cost statement subject to a Freedom of Information Act (FOIA) request as opposed to the information currently being protected and exempt from a FOIA request.

Response: We appreciate the commenters' concerns. The policy finalized in this final rule, as discussed below, does not affect whether a Home Office Cost Statement may or may not be produced in response to a FOIA request. We note that both the proposed and finalized policy requires that the provider substantiate costs allocated to it from its home office in order to have an acceptable cost report.

After consideration of the public comments we received, for the reasons discussed earlier and in the proposed rule, we are finalizing our proposal with

modifications as follows: First, instead of requiring providers to submit the Home Office Cost Statement individually with their cost report submission, we are requiring instead that the home office or chain organization submit the Home Office Cost Statement directly to the servicing contractors for its providers when the home office or chain organization has allocated costs to its providers. When the home office submits its Home Office Cost Statement to its servicing contractor, the home office must also submit a copy of the Home Office Cost Statement to each of the contractors of its chain providers. For example, if a chain organization has 25 providers serviced by 2 different contractors, the home office must submit its Home Office Cost Statement to each contractor. We note that only one copy of the Home Office Cost Statement is required to be submitted by the home office to a provider's contractor, regardless of the number of providers in the chain the contractor is servicing. Second, we are applying different rules for situations where the provider and the home office have the same fiscal year end and where the provider and the home office have a different fiscal year end. Thus, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with the same fiscal year end, a cost report will be rejected for lack of supporting documentation if the home office or chain organization has not completed and submitted to the chain provider's contractor a Home Office Cost Statement that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report. Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization that has a different fiscal year end, a cost report will be rejected for lack of supporting documentation if the home office or chain organization has not completed and submitted to the chain provider's contractor a Home Office Cost Statement that corresponds to some portion of the amounts allocated from the home office or chain organization to the provider's cost report. These policies are reflected in new § 413.24(f)(5)(i)(E)(*1*) and (*2*), respectively. Thus, when the provider and its home office have differing fiscal year ends, the provider's home office costs for a portion of the cost reporting period (as reflected in the Home Office Cost Statement) must correspond to a portion of the amount reported in the provider's cost report. When the provider and its home office have the same fiscal year end, the provider's home office's cost for the same time period (as reflected in the Home Office Cost Statement) must correspond to the costs reported in the provider's cost report.

X. Requirements for Hospitals To Make Public a List of Their Standard Charges via the Internet

In the FY 2015 IPPS/LTCH proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively), we discussed the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. We noted that section 2718(e) of the Public Health Service Act, which was enacted as part of the Affordable Care Act, requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act. We reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry.

We encouraged hospitals to undertake efforts to engage in consumer friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain at the hospital, and to enable patients to compare charges for similar services across hospitals. We also stated that we expect that hospitals will update the information at least annually, or more often as appropriate, to reflect current charges. We further noted that we are confident that hospital compliance with this statutory transparency requirement will greatly improve the public accessibility of charge information. Finally, we stated that we would continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge information on the CMS website.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549), we indicated that we are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals, and patients being surprised by facility fees and physician fees for emergency department visits. We also are concerned that chargemaster data are not helpful to patients for determining what they are likely to pay for a particular service or hospital stay. In order to promote greater price transparency for patients, we stated that we are considering ways to improve the accessibility and usability of the charge information that hospitals are required to disclose under section 2718(e) of the Public Health Service Act.

Therefore, as one step to further improve the public accessibility of charge information, effective January 1, 2019, we announced the update to our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate. This could be in the form of the chargemaster itself or another form of the hospital's choice, as long as the information is in machine readable format.

We note that it was sometimes difficult to determine when certain commenters who submitted comments on the FY 2019 IPPS/LTCH PPS proposed rule were responding to the broader price transparency request for information (RFI) and when they were responding specifically to the updated guidelines. To the extent we believed that a comment addressed the updated guidelines, we summarized it below. Comments on the broader price transparency initiative and suggestions for additional future actions that we may take with the guidelines, including enforcement actions, will be addressed in future rulemaking.

Comment: Many commenters addressed the announcement of the CMS update to guidelines on price transparency. Some of these commenters supported the update and indicated that many hospitals already make their standard charges available voluntarily or under applicable State law.

Response: We appreciate the support from some commenters regarding our updated guidelines and agree that many hospitals already make their standard charges publicly available either voluntarily or under applicable State law. For example, the 2014 American

Hospital Association State Transparency Survey data indicated that 35 States required hospitals to release information on some charges and 7 States relied on voluntary disclosure of charge data (*http://www.ahacommunity connections.org/content/ 14transparency-trendwatch.pdf*). We also appreciate the public support for hospitals to undertake efforts to engage in consumer friendly communication to help patients understand what their potential financial liability might be for services they obtain at the hospital, and to enable patients to compare costs for similar services across hospitals. Improving the public accessibility to charge information is one aspect of our broader price transparency initiative.

Comment: Some commenters stated that the information contained in the chargemaster would not be useful to patients and would only increase confusion, as it would not inform them of their out-of-pocket costs for a particular service. The commenters stated that the chargemaster typically contains terms that are difficult for patients to understand, does not depict negotiated discounts with insurers, and lacks contextual information that patients would need. To the extent that such information would be published in a payer-specific manner, the commenters stated that such information is proprietary and confidential, and that publishing this information could undermine competition. Some commenters stated that certain hospitals are already providing patients with cost estimates that are specific to the payer and the patient's circumstances, and suggested that hospitals be required to provide this type of information instead. Other commenters noted programs by specific hospitals, including web-based tools, which enable patients to estimate their out-of-pocket costs. Other commenters suggested that CMS focus on ''shoppable'' health care services that can typically be scheduled in advance. Some commenters suggested that CMS conduct further research and work with stakeholders to determine the best approach to making information available to consumers.

Response: We disagree with commenters that the information contained in the chargemaster would not be useful to patients. As pointed out by commenters, many hospitals have price transparency initiatives beyond the provision of the chargemaster and we encourage hospitals to provide context surrounding the chargemaster information. We note that we are not requiring at this time that any information be published in a payer-specific manner, and we disagree that transparent charge information undermines competition. We agree that hospitals should and can provide information on ''shoppable'' health care services that can typically be scheduled in advance. However, nothing in our guidelines precludes a hospital from providing this information to patients and the public. We also agree with commenters that CMS should continue to work with stakeholders to determine the best approach to making price transparency information available to consumers and we intend to do so. One step in that process is the broad request for information from the public that CMS is currently making.

We acknowledge that providing patients with more specific information on their potential financial liability is needed and commend the hospitals that already do so. However, we believe that this more specific need does not justify a delay in the provision of chargemaster information to the public. We note that making charge information more easily accessible to patients and the public does not preclude hospitals from taking additional steps or continuing to provide the information they currently provide.

Comment: Many commenters explained that, for insured patients, payers are a better source of information about the cost of care and should be the primary source of information for out-of-pocket costs for patients. Some commenters stated that payers can provide the information that patients require without compromising competition among providers. Other commenters suggested that payers and providers work together to make this information more accessible to patients. Some commenters noted that payers can provide information as to whether patients have met the plan deductible or out-of-pocket spending limits and what their cost-sharing will be. One commenter suggested requiring insurance companies to provide cost calculators or other tools that patients can use to calculate costs specific to their situation. For uninsured patients, commenters noted that many patients receive free or discounted care through the hospital's charity care policies.

Response: With respect to the commenters who indicated that, for insured patients, payers are a better source of information about the cost of care and should be the primary source of information for out-of-pocket costs for patients, we note that nothing in our guidelines precludes hospitals and payers from working together to provide information on out-of-pocket costs for patients and to improve price transparency for patients. We also recognize that sometimes uninsured patients receive free or discounted care through a hospital's charity care policies and again commend hospitals for those policies. Nothing in our guidelines precludes a hospital from providing charity care to uninsured patients.

Comment: Several commenters expressed concern about the updated guidelines conflicting with State requirements and increasing administrative burden if hospitals are required to report charge information in multiple incongruent ways. Commenters stated that CMS should not require hospitals to duplicate or replace existing publically available resources and that the updated requirement would significantly increase provider burden to provide information that is not useful to patients. Other commenters noted that some State efforts are already providing patients with much more information than they could obtain from a chargemaster, and suggested that CMS instead encourage State level price transparency efforts.

Response: We encourage State efforts in the area of price transparency. As noted earlier, we commend the many hospitals that already make their standard charges publicly available either voluntarily or under applicable State law. This demonstrates that the disclosure of standard charges under our updated guidelines can exist in a complementary manner with State regulatory initiatives.

Comment: Some commenters stated that the definition of standard charges is unclear, as hospitals often have many negotiated rates for the same service. The commenters identified several terms, ''charges'', ''payments'', ''cost'', and ''prices'', that, according to the commenters, can have different meanings but are often used interchangeably. The commenters believed that, absent a standard definition of these terms, patients could not make accurate comparisons between hospitals.

Response: As noted earlier, we are not at this time requiring payer-specific information under our guidelines, and our updated guidelines are unchanged in this area compared to the prior guidelines. The new guidelines, when compared to the prior guidelines, merely require that this information be made available via the internet in a machine readable format and that hospitals update this information at least annually, or more often as appropriate.

Comment: A few commenters expressed concern that patients may forgo needed care if they were informed

of the charges in advance. Other commenters noted that price information in the absence of quality information can be misleading to patients in a variety of ways.

Response: We disagree that patients may forgo needed care if they were informed of the charges in advance if that information is placed in the proper context by hospitals. We agree with the commenters that price information and quality information are both important to provide to patients. We note that nothing precludes hospitals or other entities from incorporating quality information such as the publicly available CMS Hospital Compare quality information found on the website at: *https://www.medicare.gov/hospitalcompare/search.html*.

After consideration of the public comments we received, we currently do not believe there is a need to further update our guidelines beyond the updated guidelines that we previously announced would be effective January 1, 2019, which are that hospitals' list of standard charges be made available to the public via the internet in a machine readable format and that hospitals update this information at least annually, or more often as appropriate.

XI. Revisions Regarding Physician Certification and Recertification of Claims

Our Medicare regulations at 42 CFR 424.11, which implement sections 1814(a)(2) and 1835(a)(2) of the Act, specify the requirements for physician statements that certify and periodically recertify as to the medical necessity of certain types of covered services provided to Medicare beneficiaries. The regulation provision under § 424.11(c) specifies that when supporting information for the required physician statement is available elsewhere in the records (for example, in the physician's progress notes), the information need not be repeated in the statement itself. The last sentence of § 424.11(c) further provides that it will suffice for the statement to indicate where the information is to be found.

As we discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20550), as part of our ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers—and thereby free up resources that could be used to improve or enhance patient care—we have been made aware that the provisions of § 424.11(c) which state that it will suffice for the statement to indicate where the information is to be found may be resulting in unnecessary denials of Medicare claims. As currently worded, this last sentence of § 424.11(c) can result in a claim being denied merely because the physician statement technically fails to identify a specific location in the file for the supporting information, even when that information nevertheless may be readily apparent to the reviewer. We believe that continuing to require the location to be specified in this situation is unnecessary. Certifications and recertifications continue to be based on the criteria for the service being certified, and the medical record must contain adequate documentation of the relevant criteria for which the physician is providing certification or recertification, even if the precise location of the information within the medical record is not included. Moreover, the need for the precise location is becoming increasingly obsolete with the growing utilization of electronic health records (EHRs)—which, by their nature, are readily searchable. Accordingly, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20550), we proposed to delete the last sentence of § 424.11(c). In addition, we proposed to relocate the second sentence of § 424.11(c) (indicating that supporting information contained elsewhere in the provider's records need not be repeated in the certification or recertification statement itself) to the end of the immediately preceding paragraph (b), which describes similar kinds of flexibility that are currently afforded in terms of completing the required statement.

Comment: Commenters supported the proposed changes to § 424.11(c) of the regulations.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing, without modification, our proposed changes. Specifically, we are deleting the last sentence of § 424.11(c) and relocating the second sentence of § 424.11(c) to the end of the immediately preceding paragraph (b).

XII. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20550 through 20553), we included a Request for Information (RFI) related to promoting interoperability and electronic health care information exchange. We received approximately 313 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

XIII. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2018 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2019 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at: *http://www.medpac.gov*.

XIV. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We listed the IPPS-related data files that are available in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20553 through 20554).

Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20554 through 20564), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed in section IV.K.3. of the preamble of the proposed rule (83 FR 20439 through 20440) and this final rule, are not subject to the Paperwork Reduction Act, as stated in section 5506 of the Affordable Care Act.

3. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request currently approved under OMB control number 0938–1022. OMB has currently approved 3,637,282 hours of burden and approximately $133 million under OMB control number 0938–1022, accounting for information collection burden experienced by 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2020 payment determination.[411] We no longer use OMB control number 0938–0918. Below, we describe the burden changes with regards to collection of information under OMB control number 0938–1022 for IPPS hospitals due to the finalized policies in this final rule.

In section VIII.A. of the preambles of the proposed rule (83 FR 20470 through 20500) and this final rule, we discuss the following finalized policies that we expect to affect our collection of information burden estimates: (1) eCQM reporting and submission requirements for the CY 2019 reporting period/FY 2021 payment determination; (2) removal of three chart-abstracted measures beginning with the CY 2019 reporting period/FY 2021 payment determination; and (3) removal of six chart-abstracted measures beginning with the CY 2020 reporting period/FY 2022 payment determination. Details on these policies, as well as the expected burden changes, are discussed below.

This final rule also includes policies with respect to claims-based and other measures to: (1) Remove 17 claims-based measures beginning with the CY 2018 reporting period/FY 2020 payment determination; (2) remove two claims-based measures beginning with the CY 2019 reporting period/FY 2021 payment determination; (3) remove one claims-based measure beginning with CY 2020 reporting period/FY 2022 payment determination; (4) remove one claims-based measure beginning with the CY 2021 reporting period/FY 2023 payment determination; (5) remove two structural measures beginning with the CY 2018 reporting period/FY 2020 payment determination; and (6) remove seven eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination. As discussed further below, we do not expect these policies to affect our information collection burden estimates.

b. Information Collection Burden Estimate for the Removal of Chart-Abstracted Measures

(1) Information Collection Burden Estimate for the Removal of Three Chart-Abstracted Measures Beginning With the CY 2019 Reporting Period/FY 2021 Payment Determination

In section VIII.A.5.b.(8)(b) of the preamble of this final rule, we discuss our finalized proposals to remove three chart-abstracted clinical process of care measures beginning with the CY 2019 reporting period/FY 2021 payment determination:

- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) (NQF #0495);
- Influenza Immunization (IMM–2) (NQF #1659); and
- Incidence of Potentially Preventable Venous Thromboembolism (VTE–6).

We anticipate a reduction in information collection burden for all IPPS hospitals of 741,074 hours, or 225 hours per hospital, as a result of our finalized proposals to remove the ED–1 and IMM–2 chart-abstracted measures beginning with the CY 2019 reporting period/FY 2021 payment determination. This estimate was calculated by considering the previously approved information collection burden estimate for reporting the combined global population set (ED–1, ED–2, and IMM–2) of 1,599,074 hours, minus the estimated information collection reporting burden for only the ED–2 measure[412] ([15 minutes per record × 260 records per hospital per quarter × 4 quarters]/60 minutes per hour × 3,300 IPPS hospital = 858,000 hours). Through these calculations (1,599,074 hours − 858,000 hours), we estimate a reduction of 741,074 hours, or 225 hours per hospital per year (741,074 hours/3,300 hospitals) across all IPPS hospitals for the CY 2019 reporting period/FY 2021 payment determination because we are finalizing our proposals to remove the ED–1 and IMM–2 measures from the Hospital IQR Program.

We anticipate our finalized proposal to remove the VTE–6 measure will result in an information collection burden reduction of 304,997 hours for all IPPS hospitals, or 92 hours per hospital, for the CY 2019 reporting period/FY 2021 payment determination. We have previously estimated a reporting burden of 92 hours (7 minutes per record × 198 records per hospital per quarter × 4 quarters/60 minutes) per hospital per year, or 304,997 hours (92 hours per hospital × 3,300 hospitals) across all hospitals associated with abstracting and reporting VTE–6. Therefore, we estimate an information collection burden decrease of 304,997 hours for the CY 2019 reporting period/FY 2021 payment determination because we are finalizing our proposal to remove this measure from the Hospital IQR Program.

In summary, as a result of our finalized proposals in section VIII.A.5.b.(8) of the preamble of this final rule to remove IMM–2, ED–1, and VTE–6, we estimate an information collection burden reduction of 1,046,071 hours (−741,074 hours for ED–1 and IMM–2 removal + −304,997 hours for VTE–6 removal) and approximately $38.3 million (1,046,071 hours × $36.58 per hour[413]) across all

[411] The information collection burden associated with submitting data for the HCP and HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) via the CDC's NHSN system is captured under a separate OMB control number, 0920–0666. The information collection burden associated with submitting data for the HCAHPS Survey measure is captured under OMB control number 0938–0981.

[412] Estimated 15 minutes per case for reporting ED–2 measure based on average Clinical Data Abstraction Center abstraction times for 3Q 2016, 4Q 2016, and 1Q 2017 discharge data.

[413] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and

Continued

3,300 IPPS hospitals participating in the Hospital IQR Program for the CY 2019 reporting period/FY 2021 payment determination.

(2) Information Collection Burden Estimate for the Removal of Six Chart-Abstracted Measures Beginning With the CY 2020 Reporting Period/FY 2022 Payment Determination

In sections VIII.A.5.b.(2)(b) and VIII.A.5.b.(8)(b) of the preamble of this final rule, we are finalizing the removal of five chart-abstracted National Healthcare Safety Network (NHSN) hospital-acquired infection (HAI) measures [414] and one chart-abstracted clinical process of care measure beginning with the CY 2020 reporting period/FY 2022 payment determination:

- National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717);
- National Healthcare Safety Network Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138);
- National Healthcare Safety Network Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139);
- National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716);
- American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure-Specific Surgical Site Infection (SSI) Outcome Measure (Colon and Abdominal Hysterectomy SSI) (NQF #0753); and
- Admit Decision Time to ED Departure Time for Admitted Patients Measure (ED–2) (NQF #0497).

We note that as discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we proposed to remove the NHSN HAI measures beginning with the CY 2019 reporting period/FY 2021 payment determination, but are finalizing a modified version of our proposal which delays their removal until the CY 2020 reporting period/FY 2022 payment determination. Our estimates below have been updated to reflect this change. Because the burden associated with submitting data for the NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) is captured under separate OMB control number 0920–0666, we do not provide an independent estimate of the information collection burden associated with these measures for the Hospital IQR Program. Because the NHSN HAI measures will be retained in the HAC Reduction and Hospital VBP Programs, we do not anticipate a reduction in data collection and reporting burden associated with the CDC NHSN's OMB control number 0920–0666. We note, however, that we anticipate a reduction in burden associated with the Hospital IQR Program validation activities we conduct for these NHSN HAI measures, as discussed further below.

We further anticipate removing the chart-abstracted ED–2 measure will reduce the reporting burden for all IPPS hospitals by a total of 858,000 hours, or 260 hours per hospital. As discussed above, we estimate reporting the ED–2 measure takes approximately 260 hours (15 minutes per record × 260 records per hospital per quarter × 4 quarters/60 minutes = 260 hours) per hospital per year, or 858,000 hours (260 hours × 3,300 hospitals) across all IPPS hospitals. Therefore, we estimate an 858,000 hour information collection burden decrease for the CY 2020 reporting period/FY 2022 payment determination because we are finalizing our proposal to remove this measure from the Hospital IQR Program.

In summary, because we are finalizing our proposal in section VIII.A.5.b.(8)(b) of the preamble of this final rule to remove ED–2, we estimate an information collection burden reduction of 858,000 hours and approximately $31.4 million (858,000 hours × $36.58 per hour [415]) across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination.

(3) Information Collection Impacts on Data Validation Resulting From Chart-Abstracted Measure Removal

While we did not propose any changes to our validation requirements related to chart-abstracted measures, because we are finalizing our proposals with modification in section VIII.A.5.b.(2)(b) [416] and section VIII.A.5.b.(8) of the preamble of this final rule to remove five NHSN HAIs and four clinical process of care measures, we believe that hospitals will experience an overall reduction in information collection burden associated with chart-abstracted measure validation beginning with the FY 2023 payment determination.

As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49762 and 49763), we reimburse hospitals directly for expenses associated with submission of charts for clinical process of care measure data validation (we reimburse hospitals at 12 cents per photocopied page; for hospitals providing charts digitally via a rewritable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we reimburse hospitals at a rate of 40 cents per disc); we do not believe any additional information collection burden is associated with submitting this information via web portal or PDF (79 FR 50346). Therefore, because we directly reimburse, we do not anticipate any net change in burden associated with the cost of submission of validation charts as a result of our finalized proposals to remove four clinical process of care measures. Hospitals will no longer be required to submit, or be reimbursed for submitting, these data to CMS.

Because we are finalizing our proposals to remove all of the NHSN HAI measures from the Hospital IQR Program and because hospitals selected for validation currently are required to submit validation templates for the NHSN HAI measures, we anticipate a reduction in information collection burden under the Hospital IQR Program associated with the NHSN HAI data validation effort. We note that the burden associated with data collection for the NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) is accounted for under the CDC NHSN OMB control number 0920–0666. Because the NHSN HAI measures will be retained in the HAC Reduction and Hospital VBP Programs, we do not anticipate a change in data collection and reporting burden associated with this OMB control number due to our finalized proposals under the Hospital IQR Program.

The data validation activities, however, are conducted by CMS. Since

fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[414] As discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we proposed to remove the NHSN HAI measures beginning with the CY 2019 reporting period/FY 2021 payment determination, but are delaying their removal until the CY 2020 reporting period/FY 2022 payment determination.

[415] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[416] As discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we proposed to remove the NHSN HAI measures beginning with the CY 2019 reporting period/FY 2021 payment determination, but are delaying their removal until the CY 2020 reporting period/FY 2022 payment determination.

the measures were adopted into the Hospital IQR Program, CMS has validated the data for purposes of the Hospital IQR Program. Therefore, this burden has been captured under the Hospital IQR Program's OMB control number 0938–1022. We have previously estimated a reporting burden of 80 hours (1,200 minutes per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for chart-abstracted measure validation per year to submit the CLABSI and CAUTI templates, and 64 hours (960 minutes per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for chart-abstracted measure validation per year to submit the MRSA and CDI templates. Therefore, we estimate a total validation burden decrease of 43,200 hours ([−80 hours per hospital to submit CLABSI and CAUTI templates + −64 hours per hospital to submit MRSA and CDI templates] × 300 hospitals selected for validation) and approximately $1.6 million (43,200 hours × $36.58 per hour[417]) for the FY 2023 payment determination because of the removal of these measures from the Hospital IQR Program beginning with the CY 2020 reporting period/FY 2022 payment determination and the secondary effects on validation. We note that the HAC Reduction Program is finalizing the proposal to begin validation of these NHSN HAI measures as discussed in section IV.J. of the preamble of this final rule.

c. Information Collection Burden Estimate for Finalized Removal of Two Structural Measures

In sections VIII.A.5.a. and b.(1) of the preamble of this final rule, we are finalizing our proposals to remove two structural measures (Hospital Survey on Patient Safety Culture and Safe Surgery Checklist Use) beginning with the CY 2018 reporting period/FY 2020 payment determination. We anticipate removing these measures will result in a minimal information collection burden reduction for hospitals. Specifically, we do anticipate a very slight reduction in information collection burden associated with the finalized removal of the Safe Surgery Checklist measure because completion of this measure takes hospitals approximately 2 minutes each year (77 FR 53666). Similarly, we anticipate a very slight reduction in information collection burden associated with the finalized removal of the Patient Safety Checklist measure (80 FR 49762 through 49873). Consistent with previous years (80 FR 49762), we estimate a collection of information burden of 15 minutes per hospital to report all four previously finalized structural measures and to complete other forms (such as the Extraordinary Circumstances Exceptions Request Form). Therefore, our information collection burden estimate of 15 minutes per hospital remains unchanged because we believe the reduction in information collection burden associated with removing these two structural measures is sufficiently minimal that it will not substantially impact this estimate, and we want to retain a conservative estimate of the information collection burden associated with the use of our forms.

Comment: One commenter believed that the collection of information burden estimate for structural measures should take into account time hospitals spend on overall assurance that data are accurate, reported correctly, validated, and submitted.

Response: We appreciate the commenter's feedback. We note the burden estimate of 15 minutes per hospital is specific to the reporting of information for structural measures in the Hospital IQR Program, as opposed to the general work providers perform to address data collection and internal quality assurance. Further, we are finalizing our proposal to remove the two remaining structural measures from the Hospital IQR Program so that no structural measures will remain in the program, but we will take commenter's feedback into consideration should the Hospital IQR Program propose to adopt additional structural measures in the future. We refer readers to section I.K. of Appendix A of this final rule for a detailed discussion of the costs associated with the Hospital IQR Program, including costs that are not strictly information collection burden.

d. Burden Estimate for Removal of Claims-Based Measures

In section VIII.A.5.b.(2)(a), (3), (4), (6), and (7) of the preamble of this final rule, we are finalizing our proposals to remove the following 17 claims-based measures beginning with the CY 2018 reporting period/FY 2020 payment determination:

- Patient Safety and Adverse Events Composite Measure (PSI 90) (NQF #0531);
- Hospital 30-Day All-Cause Risk-Standardized Readmission Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (READM–30–AMI);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (READM–30–COPD);
- Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (READM–30–CABG);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Heart Failure Hospitalization (NQF #0330) (READM–30–HF);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization (NQF #0506) (READM–30–PN);
- 30-day Risk-Standardized Readmission Rate Following Stroke Hospitalization (READM–30–STK);
- Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1551) (READM–30–THA/TKA);
- Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization for Patients 18 and Older (NQF #0230) (MORT–30–AMI);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229) (MORT–30–HF);
- Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158);
- Cellulitis Clinical Episode-Based Payment Measure (Cellulitis Payment);
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (GI Payment);
- Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure (Kidney/UTI Payment);
- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment);
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure (Chole and CDE Payment); and
- Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment).

In addition, we are finalizing our proposals to remove two claims-based measures beginning with the CY 2019 reporting period/FY 2021 payment determination: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893); and (2)

[417] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (NQF #0468). We are also finalizing our proposal to remove one claims-based measure, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure (NQF #2558), beginning with the CY 2020 reporting period/FY 2022 payment determination, and one claims-based measure, Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty, beginning with the CY 2021 reporting period/FY 2023 payment determination.

Because these claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, we do not anticipate that removing these measures will affect information collection burden on hospitals. However, we refer readers to section VIII.A.5.b.(2)(a), (3), (4), (6) and (7) of the preamble of this final rule for a discussion of the reduction in costs associated with these measures unrelated to the information collection burden.

e. Information Collection Burden Estimate for Finalized Removal of eCQMs

In section VIII.A.5.b.(9) of the preamble of this final rule, we are finalizing our proposals to remove the following seven eCQMs from the eCQM measure set beginning with the CY 2020 reporting period/FY 2022 payment determination:

- Primary PCI Received within 90 Minutes of Hospital Arrival (AMI–8a);
- Home Management and Plan of Care Document Given to Patient/Caregiver (CAC–3);
- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) (NQF #0495);[418]
- Hearing Screening Prior to Hospital Discharge (EHDI–1a) (NQF #1354);
- Elective Delivery (PC–01) (NQF #0469);
- Stroke Education (STK–08); and
- Assessed for Rehabilitation (STK–10) (NQF #0441).

Because these eCQMs being finalized for removal were among a set of 15 eCQMs available for reporting, we believe that reducing the number of eCQMs from which hospitals choose will enable hospitals to focus on and maintain a smaller subset of measures (8 instead of 15), but this will not have an effect on the burden of submitting information to CMS. Hospitals will still be required to submit 4 eCQMs of their choice from the eCQM measure set. While the information collection burden will not change, we refer readers to section VIII.A.4.b. of the preamble of this final rule where we acknowledge that costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Hospital IQR Program requirements.

f. Information Collection Burden Estimates for the Finalized Updates to the eCQM Reporting Requirements

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361), we finalized eCQM reporting requirements, such that hospitals submit one, self-selected calendar quarter of data for 4 eCQMs in the Hospital IQR Program measure set for the CY 2018 reporting period/FY 2020 payment determination. In section VIII.A.10.d.(2) of the preamble of this final rule, we are finalizing our proposal to require that hospitals continue to submit one, self-selected calendar quarter of data for 4 eCQMs in the Hospital IQR Program measure set for the CY 2019 reporting period/FY 2021 payment determination. Therefore, we believe there will be no change to the burden estimate because the previous burden estimate of 40 minutes per hospital per year (10 minutes per record × 4 eCQMs × 1 quarter) associated with eCQM reporting requirements finalized for the CY 2018 reporting period/FY 2020 payment determination will continue to apply to the CY 2019 reporting period/FY 2021 payment determination.

g. Information Collection Burden Estimate for the Finalized Modifications to EHR Certification Requirements

In section VIII.A.10.d.(3) of the preamble of this final rule, we are finalizing our proposal to update the EHR certification requirements by requiring the use of EHR technology certified to the 2015 Edition beginning with the CY 2019 reporting period/FY 2021 payment determination, to align with the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and CAHs. We do not expect this finalized proposal to affect our information collection burden estimates because this policy does not require hospitals to submit new data to CMS. With respect to any costs unrelated to data submission, we refer readers to section I.K. of Appendix A of this final rule.

h. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate: (1) A total information collection burden reduction of 1,046,138 hours (−1,046,071 hours due to the removal of ED–1, IMM–2, and VTE–6 measures for the CY 2019 reporting period/FY 2021 payment determination and −67 hours for no longer collecting data for the voluntary Hybrid HWR measure[419]) and a total cost reduction related to information collection of approximately $38.3 million (−1,046,138 hours × $36.58 per hour[420]) for the CY 2019 reporting period/FY 2021 payment determination; (2) a total information collection burden reduction of 858,000 hours (−858,000 hours due to the removal of ED–2) and a total information collection cost reduction of approximately $31.3 million (−858,000 hours × $36.58 per hour[421]) for the CY 2020 reporting period/FY 2022 payment determination; and (3) a total information collection burden reduction of 43,200 hours (−43,200 hours due to no longer needing to validate NHSN HAI measures under the Hospital IQR Program) and a total information collection cost reduction of approximately $1.6 million (−43,200 hours × $36.58 per hour) for the CY 2021 reporting period/FY 2023 payment determination. These are the total information collection burden reduction estimates for which we are requesting OMB approval under OMB number 0938–1022.

[418] Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) is finalized for removal in both chart-abstracted and eCQM forms in sections VIII.A.5.b.(8)(b) and VIII.A.5.(b)(9)(c) of the preamble of this final rule, respectively.

[419] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized our proposal to collect data on a voluntary basis for the Hybrid HWR measure for the CY 2018 reporting period/FY 2020 payment determination. We estimated that approximately 100 hospitals would voluntarily report data for this measure, resulting in a total burden of 67 hours across all hospitals for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38504). Because we only finalized voluntary collection of data for one year, voluntary collection of this data will no longer occur, beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years, resulting in a reduction in burden of 67 hours across all hospitals.

[420] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[421] Ibid.

HOSPITAL IQR PROGRAM CY 2019 REPORTING PERIOD/FY 2021 PAYMENT DETERMINATION INFORMATION COLLECTION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for CY 2019 reporting period/FY 2021 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly finalized annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Reporting on Emergency department throughput (ED–1)/Immunizations (IMM–2)	13	4	3,300	260	225	858,000	1,599,074	−741,074
Venous thromboembolism (VTE)	7	4	3,300	198	92	0	304,997	−304,997
Voluntary HWR Reporting[422]	10	4	100	1	0.67	0	67	−67

Total Change in Information Collection Burden Hours: −1,046,138.
Total Cost Estimate: Updated Hourly Wage ($36.58) × Change in Burden Hours (−1,046,138) = −$38,267,728.

HOSPITAL IQR PROGRAM CY 2020 REPORTING PERIOD/FY 2022 PAYMENT DETERMINATION INFORMATION COLLECTION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for CY 2020 reporting period/FY 2022 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly finalized annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Reporting on Emergency department throughput (ED–2 only)	15	4	3,300	260	260	0	858,000	−858,000

Total Change in Information Collection Burden Hours:—858,000.
Total Cost Estimate: Updated Hourly Wage ($36.58) × Change in Burden Hours (−858,000) = −$31,385,640.

HOSPITAL IQR PROGRAM CY 2021 REPORTING PERIOD/FY 2023 PAYMENT DETERMINATION INFORMATION COLLECTION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for CY 2021 reporting period/FY 2023 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly finalized annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
HAI Validation Templates (CLABSI, CAUTI)	1,200	4	300	1	80	0	24,000	−24,000
HAI Validation Templates (MRSA, CDI)	960	4	300	1	64	0	19,200	−19,200

[422] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized our proposal to collect data on a voluntary basis for the Hybrid HWR measure for the CY 2018 reporting period/FY 2020 payment determination. We estimated that approximately 100 hospitals would voluntarily report data for this measure, resulting in a total burden of 67 hours across all hospitals for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38504). Because we only finalized voluntary collection of data for one year, voluntary collection of this data will no longer occur beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years resulting in a reduction in burden of 67 hours across all hospitals.

HOSPITAL IQR PROGRAM CY 2021 REPORTING PERIOD/FY 2023 PAYMENT DETERMINATION INFORMATION COLLECTION BURDEN ESTIMATES—Continued

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for CY 2021 reporting period/FY 2023 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly finalized annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Total Change in Information Collection Burden Hours: −43,200.								
Total Cost Estimate: Updated Hourly Wage ($36.58) ×Change in Burden Hours (−43,200) = −$1,580,256.								

4. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

a. Background

As discussed in sections VIII.B. of the preambles of the proposed rule (83 FR 20500 through 20510) and this final rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate. Below we discuss only changes in burden that will result from the proposals that we are finalizing in this final rule.

b. Revision of Time Estimate for Structural and Web-Based Tool Measures for the FY 2021 Program Year and Subsequent Years

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20559), we proposed to revise our burden calculation methodology. With all the parameters considered when PCHs submit data on PCHQR Program measures (training of appropriate staff members on National Healthcare Safety Network (NHSN) reporting and the CMS Web Measures Tool for the reporting of the clinical process/oncology care measures; the time required for collection and aggregation of data; and the time required for reporting of the data by the PCH's representative), we strive to achieve continuity in how we calculate and analyze burden data. In prior years, we have based our burden estimates on the notion that all 11 PCHs would report on all measures for all cases (78 FR 50958). These assumptions were made in order to be as comprehensive as possible given a lack of PCH-specific data available at the time. However, we believe it is more appropriate to use estimates developed using data available in other quality reporting programs wherever possible, because we believe these estimates will provide a more accurate estimate of burden associated with data collection and reporting. Our proposal to update the estimate the time required to collect and report data for structural measures and measures that use a web-based tool is discussed below.

We initially adopted five clinical process/cancer specific treatment measures that utilized a web-based tool for the FY 2016 program year in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50841 through 50844). In that rule, we did not specify burden estimates based on the measure type, but instead provided estimates ''for submitting all quality measure data'' (78 FR 50958). Since then, we have been able to better understand and differentiate the various levels of effort associated with data abstraction and submission for specific types of measures. Moreover, in understanding that certain measure types prove more burdensome than others (that is, chart-abstracted measures), we believe it is necessary to provide burden estimates that better reflect the type of measure being discussed.

Using historical data from its validation contractor, the Hospital IQR Program has previously estimated that it takes 15 minutes per hospital to report on four structural measures (80 FR 49762). We believe this estimate is appropriate for the PCHQR Program because data submission for measures that utilize a web-based tool is similar to the data submission for a structural measure, in that both types of measures use the same reporting mechanism, the QualityNet Secure Portal. In addition, we wish to account for the time associated with data collection and aggregation for individual measures when considering burden, and believe 15 minutes per measure is an appropriately conservative estimate for the measures submitted via a web-based tool in the PCHQR Program. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20559), we proposed to apply this burden estimate to four measures that utilize a web-based tool: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389).

We invited public comment on our proposal to utilize a burden estimate of 15 minutes per measure, per PCH, with respect to the burden estimates we discuss below for the FY 2021 program year and subsequent years.

We did not receive any public comments on this proposal. We are therefore finalizing that we will use a burden estimate of 15 minutes per measure, per PCH, with respect to the burden estimates for web-based and/or structural measures for the FY 2021 program year and subsequent years.

c. Estimated Burden of PCHQR Program Proposals for the FY 2021 Program Year

In section VIII.B.3. of the preamble of this final rule, we are finalizing our proposal to remove six measures beginning with the FY 2021 program year—four web-based, structural measures: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389), and two chart-abstracted, NHSN measures: (5) NHSN Catheter-Associated Urinary Tract Infection

(CAUTI) Outcome Measure (PCH–5/NQF #0138) and (6) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139). In addition, in section VIII.B.4.b. of the preamble of this final rule, we are finalizing our proposal to adopt one claims-based measure, 30-Day Unplanned Readmissions for Cancer Patients (NQF #3188), beginning with the FY 2021 program year. As a result of these finalized measure removals, the PCHQR Program measure set will consist of 13 measures for the FY 2021 program year.

(1) Removal of Web-Based Structural Measures

We estimate that the removal of four web-based, structural measures will reduce the burden associated with quality reporting on PCHs. We estimate a reduction of 1 hour (or 60 minutes) per PCH (15 minutes per measure × 4 measures = 60 minutes), and a total annual reduction of approximately 11 hours for all 11 PCHs (60 minutes × 11 PCHs/60 minutes per hour), due to the finalized removal of these four measures.

(2) Maintenance of Chart-Abstracted NHSN Measures

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503), we proposed to remove two NHSN measures, Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and (2) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139), from the PCHQR Program. As discussed in section VIII.B.3.b.(2) of the preamble of this final rule, we are deferring finalization of our policies regarding future use of the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) in the PCHQR Program to a future 2018 final rule, most likely in the CY 2019 OPPS/ASC final rule targeted for release no later than November 2018. We will therefore address any change in burden associated with this policy decision, most likely, in the CY 2019 OPPS/ASC final rule.

We note that we have also reconciled the burden estimates associated with the remaining NHSN measures (CLABSI, CAUTI, CDI, HCP, MRSA and Colon and Abdominal Hysterectomy SSI) included in the PCHQR Program measure, which were previously accounted for under OMB Control Number 0938–1175. The burden associated with data collection for these measures is accounted for under the CDC NHSN OMB control number 0920–0666; for this reason, we have removed the duplicative burden estimate from the PCHQR Program's OMB Control Number, 0938–1175.

(3) Adoption of 30-Day Unplanned Readmissions for Cancer Patients Measure (NQF #3188)

We do not anticipate any increase in burden on PCHs related to our finalized proposal to adopt the claims-based 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188), beginning with the FY 2021 program year, because this measure is claims-based and does not require PCHs to submit any additional data.

In summary, we estimate a total reduction of 11 hours of burden per year for all 11 PCHs (−1 hours per PCH × 11 PCHs) associated with the removal of the four web-based, structural measures beginning with the FY 2021 program year. Coupled with our estimated salary costs, we estimate that these finalized changes will result in a reduction in annual labor costs of $402 (11 hours × $36.58 hourly labor cost[423]) across the 11 PCHs beginning with the FY 2021 PCHQR Program. The burden associated with these reporting requirements is currently approved under OMB control number 0938–1175. The information collection will be revised and submitted to OMB.

5. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.I. of the preambles of the proposed rule (83 FR 20407 through 20426) and this final rule, we discuss requirements for the Hospital VBP Program. Specifically, in this final rule, with respect to quality measures, we are finalizing our proposals to remove three claims-based measures (AMI Payment, HF Payment, and PN Payment) effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. Because these claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, we do not anticipate that removing these measures will increase or decrease the reporting burden on hospitals. However, we believe removal of these measures from the Hospital VBP Program will reduce other costs associated with the program, such as: (1) Costs for health care providers and clinicians to track the confidential feedback preview reports and publicly reported information on the measures in more than one program; (2) costs for CMS to analyze and publicly report the measures' data in multiple programs; and (3) confusion for beneficiaries to see public reporting on the same measures in different programs. As discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposal to remove a fourth claims-based measure—Patient Safety and Adverse Events (Composite) (PSI 90) (NQF #0531).

In addition, in this final rule, we are finalizing our proposal to remove one chart-abstracted measure (Elective Delivery (NQF #0469) (PC–01)) beginning with the FY 2021 program year. Because this chart-abstracted measure used data required for and collected under the Hospital IQR Program (OMB control number 0938–1022), there was no additional data collection burden associated with this measure under the Hospital VBP Program. Therefore, we do not anticipate removing this measure will increase or decrease the reporting burden on hospitals. However, we believe removal of this measure from the Hospital VBP Program will reduce other costs associated with the program, such as: (1) Costs for health care providers and clinicians to track the confidential feedback preview reports and publicly reported information on the measures in more than one program; (2) costs for CMS to analyze, and publicly report the measures' data in multiple programs; and (3) confusion for beneficiaries to see public reporting on the same measures in different programs.

As discussed in section IV.I.2.c.(2) of the preamble of this final rule, we are not finalizing our proposal to remove five other chart-abstracted measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI). Because these chart-abstracted measures use data that will continue to be required for and collected under the Hospital IQR Program through the CY 2019 reporting period/FY 2021 payment determination, there is no change to the data collection burden associated with these measures under the Hospital VBP Program.

We note that we are finalizing our proposals to remove eight claims-based measures from the Hospital IQR Program, which have been finalized previously for, and will remain in, the Hospital VBP Program. However, we do not believe retaining these claims-based measures in the Hospital VBP Program will create any change in burden for

[423] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38504 through 38505), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

hospitals because the measure data will continue to be collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes.

6. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section VIII.C.5. of the preambles of the proposed rule (83 FR 20510 through 20515) and this final rule, we discuss our finalized policies to remove two measures from the LTCH QRP beginning with the FY 2020 LTCH QRP and to remove one measure from the LTCH QRP beginning with the FY 2021 LTCH QRP.

In section VIII.C.5.a. and b. of the preamble of this final rule, we are finalizing our proposals to remove two CDC NHSN measures: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure beginning with the FY 2020 LTCH QRP. LTCHs will no longer be required to submit data on these measures beginning with October 1, 2018 admissions and discharges. As a result, the burden and cost specifically for LTCHs for complying with the requirements of the LTCH QRP will be reduced. While the overall burden estimates are accounted for under OMB control number (0920–0666), to specifically account for burden reductions, the CDC provided more detailed estimates for LTCH reporting on the data for the measures we are finalizing for removal.

Based on estimates provided by the CDC, which is based on the frequency of actual reporting on such data, we estimate that the removal of the National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) will result in a 3-hour (15 minutes per MRSA submission × 12 estimated submissions per LTCH per year) reduction in clinical staff time annually to report data, which equates to a decrease of 1,260 hours (3 hours burden per LTCH per year × 420 total LTCHs) in burden for all LTCHs. Given 10 minutes of registered nurse time at $69.40 per hour, and 5 minutes of medical records or health information technician time at $39.86 per hour, for the submission of MRSA data to the NHSN per LTCH per year, we estimate that the total cost of complying with the requirements of the LTCH QRP will be reduced by $178.66 per LTCH annually, or $75,037.20 for all LTCHs annually.

Applying the same approach on burden reduction estimations, we estimate that the removal of the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP will result in a 4.4 hour (22 minutes per VAE submission × 12 estimated submissions per LTCH per year) reduction in clinical staff time to report data, which equates to a decrease of 1,848 hours (4.4 hours burden per LTCH per year × 420 total LTCHs) in burden for all LTCHs. Given the registered nurse hourly rate of $69.40 per hour, and medical records or health information technician rate of $39.86 per hour for the submission of VAE data to the NHSN per LTCH per year, we estimate that the total cost of complying with the LTCH QRP will be reduced by $293.54 per LTCH annually, or $123,288.48 for all LTCHs annually.

In addition, in section VIII.C.5.c. of the preamble of this final rule, we are finalizing our proposal to remove the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2021 LTCH QRP. LTCHs will no longer be required to submit data on this measure beginning with October 1, 2018 admissions and discharges. As a result, the estimated burden and cost for LTCHs for complying with requirements of the LTCH QRP will be reduced. Specifically, we believe that there will be a 1.8 minute reduction in clinical staff time to report data per patient stay. We estimate 136,476 discharges from 420 LTCHs annually. This equates to a decrease of 4,094 hours in burden for all LTCHs (0.03 hours per assessment × 136,476 discharges). Given 1.8 minutes of registered nurse time at $69.40 per hour completing an average of 325 sets of LTCH CARE Data Set assessments per LTCH per year, we estimate that the total cost will be reduced by $676.53 per LTCH annually, or $284,143.03 for all LTCHs annually. This decrease in burden will be accounted for in the information collection under OMB control number 0938–1163.

Overall, the cost associated with the finalized changes to the LTCH QRP is estimated at a reduction of $1,148.73 per LTCH annually or $482,468.71 for all LTCHs.

7. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

In section IV.J. of the preambles of the proposed rule (83 FR 20426 through 20437) and this rule, we discuss requirements for the HAC Reduction Program. In the proposed rule, we did not propose to adopt any new measures into the HAC Reduction Program. In this final rule, the Hospital IQR Program is finalizing its proposal to remove the claims-based Patient Safety and Adverse Events Composite (PSI 90) measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule and finalizing with modification, its proposal five NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI), with the removal of these measures beginning with the CY 2020 reporting period/FY 2022 payment determination. These measures had been previously adopted for, and will remain in, the HAC Reduction Program.

We do not believe that retaining the claims-based PSI 90 measure in the HAC Reduction Program will create or reduce any burden for hospitals because it will continue to be collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes.

We note the burden associated with collecting and submitting data for the HAI measures (CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI) via the NHSN system is captured under a separate OMB control number, 0920–0666, and therefore will not impact our burden estimates.

We anticipate the finalized discontinuation of the HAI measure validation process under the Hospital IQR Program will result in a net burden decrease to the Hospital IQR Program, but will result in an off-setting net burden increase to the HAC Reduction Program because hospitals selected for validation will continue to be required to submit validation templates for the HAI measures. Therefore, because of our finalized proposals in sections VIII.A.5.b.(2)(b) and IV.J.4.e. of the preamble of this final rule to remove the HAI chart-abstracted measures from the Hospital IQR Program, data validation for the measures will transfer to the HAC Reduction Program, and this is will result in a net neutral shift of 43,200 hours and approximately $1.6 million from the Hospital IQR Program to the HAC Reduction Program, with no overall net change in burden.

Under the Hospital IQR Program, we have previously estimated a reporting burden of 80 hours (1,200 minutes per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for validation per year to submit the CLABSI and CAUTI templates, and 64 hours (960 minutes

per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for validation per year to submit the MRSA and CDI templates. Therefore, we estimate a total burden shift of 43,200 hours ([80 hours per hospital to submit CLABSI and CAUTI templates + 64 hours per hospital to submit MRSA and CDI templates] × 300 hospitals selected for validation) and approximately $1.6 million (43,200 hours × $36.58 per hour[424]) as a result of our finalized proposals to discontinue HAI validation under the Hospital IQR Program and begin a validation process under the HAC Reduction Program.

8. ICRs Relating to the Hospital Readmissions Reduction Program

In section IV.H. of the preamble of this final rule, we discuss our finalized proposals for the Hospital Readmissions Reduction Program. In this final rule, we did not adopt any new measures into the Hospital Readmissions Reduction Program. However, we are finalizing our proposals to remove six claims-based measures from the Hospital IQR Program, which have been finalized previously for, and will remain in, the Hospital Readmissions Reduction Program. We do not believe that these claims-based measures remaining in the Hospital Readmissions Reduction Program will create any additional burden for hospitals because they will continue to be collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes.

9. ICRs for the Promoting Interoperability Programs

a. Background and Finalized Update to Hourly Wage Rate

In section VIII.D. of the preambles of the proposed rule (83 FR 20515 through 20544) and this final rule, we discuss our proposals and newly finalized policies for a new performance-based scoring methodology and changes to the Stage 3 objectives and measures for eligible hospitals and CAHs that attest to CMS for the Medicare Promoting Interoperability Program. We also discuss our proposal and final policy to change the EHR reporting period to a minimum of any continuous 90-day period in CYs 2019 and 2020 for all new and returning participants attesting to CMS or their State Medicaid agency. In addition, we establish the CQM reporting period and criteria for CY 2019 and the removal of eight CQMs beginning in CY 2020. Lastly, we codify the policies for subsection (d) Puerto Rico hospitals who participate in the Medicare Promoting Interoperability Program for eligible hospitals, including policies previously implemented through program instruction. We did not propose to change the requirement for the 2015 Edition of CEHRT to be used beginning in CY 2019. In this final rule, we discuss and finalize our proposals with a few modifications regarding a new performance-based scoring methodology and changes to the Stage 3 objectives and measures for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program. We are finalizing the new measures Query of PDMP and Support Electronic Referral Loops by Receiving and Incorporating Health Information. We are finalizing the removal of the Coordination of Care Through Patient Engagement objective and its associated measures Secure Messaging, View, Download or Transmit, and Patient Generated Health Data as well as the measures Request/Accept Summary of Care, Clinical Information Reconciliation and Patient-Specific Education. We are renaming measures within the Health Information Exchange objective. These changes include changing the name from Send a Summary of Care, to Support Electronic Referral Loops by Sending Health Information; renaming the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange with the requirement to report on any two measures options; renaming the name the Patient Electronic Access to Health Information objective to Provider to Patient Exchange objective, and renaming the remaining measure, Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information measure.

In prior rules (81 FR 57260), we have estimated that the electronic reporting of CQM data could be accomplished by staff with a mean hourly wage of $16.42 per hour.[425] Because this wage rate is based on Bureau of Labor Statistics (BLS) data dating to 2012, in the proposed rule (83 FR 20562), we proposed to update the wage rate to the most recent data available from the BLS, which is the 2016 wage rate of $19.93.[426] We are calculating the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. This is an estimated adjustment, since both fringe benefits and overhead costs vary significantly from employer-to-employer and the methods of estimating such costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.44 × 2 = $39.86) to estimate total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs. We refer readers to the Hospital IQR Program discussion in section XIV.B.3. the preamble of this final rule, for more information regarding the information collection burden related to reporting of CQMs.

We did not receive any public comments regarding this information collection. For the expected effects relating to the above proposals, we refer readers to section I.N. of Appendix A of this final rule.

b. Burden Estimates

In sections VIII.D.5. and 6. of the preamble of this final rule, we discuss our finalized policies for a new scoring methodology for eligible hospitals and CAHs that attest to CMS for the Promoting Interoperability Program, and the addition of one new opioid measure that is optional in 2019 and 2020. This scoring approach requires eligible hospitals and CAHs to report by attestation on only six measures. We consider this scoring methodology to be based more on performance and not solely on whether an eligible hospital or CAH meets the thresholds for measures. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20562 through 20564), we estimated that the new scoring methodology reduces the necessary response time by .25 hours. This is a reduction to the previous burden estimate provided in the 2015 EHR Incentive Programs final rule (80 FR 62928). In the proposed rule, we updated the burden estimate to take into account the reduced burden associated with the proposed new requirements for eligible hospitals and CAHs for Stage 3 of meaningful use.

We believe the burden will be different for eligible hospitals that attest to a State for purposes of receiving a Medicaid incentive payment because the existing Stage 3 requirements will continue to apply to them. We note that under section 101(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10), the Medicare EHR Incentive Program was sunset for EPs in 2018, and now many of these EPs are subject to the requirements of the Quality Payment Program (QPP). Currently the burden is estimated at $388,408,189 annually. We estimate the

[424] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[425] Occupational Outlook Handbook. Available at: *http://www.bls.gov/oes/2012/may/oes292071.htm.*

[426] Occupational Outlook Handbook. Available at: *https://www.bls.gov/oes/current/oes292071.htm.*

burden for all participants in the Medicare and Medicaid Promoting Interoperability Programs represents a total cost of $61,113,527.80, which is a reduction of $327,294,661 annually. We also note that the currently approved burden in hours are 4,230,155 and as a result of this finalized proposal we believe it will be reduced to 623,562.19 hours. This burden reduction will occur as a result of the reduced numbers of EPs and the new scoring methodology for eligible hospitals and CAHs proposed in the proposed rule. The burden estimate includes subsection (d) Puerto Rico hospitals. Below is the burden table where we take into account these changes and the burden that will ensue as a result of the changes. We note that the information collection request (OMB Control number 0938–1278) has been revised and submitted to OMB.

BURDEN AND COST ESTIMATES ASSOCIATED WITH INFORMATION COLLECTION

Reg section	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.24(d)—Objectives/Measures (Medicaid EPs)	80,000	80,000	7.43	594,400	$100	$59,440,000
§ 495.24(d)—Objectives/Measures Medicaid (eligible hospitals/CAHs)	133	133	7.43	988.19	67.25	66,455.78
§ 495.24(e)—Objectives/Measures Medicare (eligible hospitals/CAHs)	3300	3300	7.18	23,694	67.25	1,593,421.50
§ 495.316—Quarterly Reporting (Medicaid)	56	224	20	4,480	3.047	13,650.56
Totals	83,489	83,489		623,562.19		61,113,527.80

There are 3,300 eligible hospitals and CAHs that attest to CMS (Medicare-only and dual-eligible) under the Medicare Promoting Interoperability Program. Therefore, the total estimated annual cost burden for all eligible hospitals and CAHs in the Medicare Promoting Interoperability Program to attest to meaningful use will be $,1,593,421.5 (3,300 eligible hospitals and CAHs × 7 hours 18 minutes × $67.25).[427]

In this final rule, we are finalizing our proposal that the new scoring methodology and changes to the Stage 3 objectives and measures for eligible hospitals and CAHs that attest to CMS will be optional for States to implement through changes to their State Medicaid HIT Plans approved by CMS for eligible hospitals participating in their Medicaid Promoting Interoperability Program. If States choose not to align, eligible hospitals in those States will continue to attest to the objectives and measures as currently specified under § 495.24(d). Extending this option to States will allow them flexibility to benefit from the improvements to meaningful use scoring outlined in this final rule, if they so choose. If States choose to take this option, we anticipate the same burden reduction for Medicaid eligible hospitals as discussed above, but a significant burden increase for States that choose to overhaul their systems to collect data. If States do not take the option, they will face no burden increase or decrease.

In section VIII.D.7. of the preamble of this final rule, we are finalizing our proposal that the EHR reporting periods in CYs 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency will be a minimum of any continuous 90-day period within each of the CYs 2019 and 2020. This means that EPs that attest to a State for the State's Medicaid Promoting Interoperability Program and eligible hospitals and CAHs attesting to CMS or the State's Medicaid Promoting Interoperability Program will attest to meaningful use of CEHRT for an EHR reporting period of a minimum of any continuous 90-day period from January 1, 2019 through December 31, 2019 and from January 1, 2020 through December 31, 2020, respectively. The applicable incentive payment year and payment adjustment years for the EHR reporting periods in 2019 and 2020, as well as the deadlines for attestation and other related program requirements, will remain the same as established in prior rulemaking. We finalizing our proposals to make corresponding changes to the definition of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4. We do not expect these finalized policies to affect our burden estimates because we have never required a different EHR reporting period.

In section VIII.D.9. of the preamble of this final rule, we are finalizing our proposal that the reporting period for Medicare and Medicaid eligible hospitals and CAHs that report CQMs electronically will be one, self-selected calendar quarter of CY 2019 data. We are also finalizing our proposal that eligible hospitals and CAHs participating in only the EHR Program, or participating in both the Promoting Interoperability Programs and the Hospital IQR Program, report on at least 4 self-selected CQMs. We are also finalizing our proposals to remove eight CQMs beginning in 2020. We believe to report on the 4 self-selected CQMs electronically will cost ($39.86 × 40 min) 1,594.4 per hospital times 3,300 hospitals results in a total burden of $5,261,520 for all eligible hospitals and CAHs.

In section VIII.D.10. of the preamble of this final rule, we are finalizing our proposals to incorporate into our regulations program guidance regarding subsection (d) Puerto Rico hospitals. Because we did not propose any new requirements, we not believe that these proposals will affect burden.

In section VIII.D.12.a. of the preamble of this final rule, we are finalizing our proposals to amend 42 CFR 495.324(b)(2) and 495.324(b)(3) to align with current prior approval policy for MMIS and ADP systems at 45 CFR 95.611(a)(2)(ii), and (b)(2)(iii) and (iv), and to minimize burden on States. Specifically, we are finalizing our proposals that the prior approval dollar threshold in § 495.324(b)(3) be increased to $500,000, and that a prior approval threshold of $500,000 be added to § 495.324(b)(2). In addition, in light of these finalized changes, we are finalizing our proposal to make a conforming amendment to amend the threshold in § 495.324(d) for prior approval of justifications for sole source acquisitions to be the same $500,000 threshold. That threshold is currently

[427] *https://www.bls.gov/oes/current/oes231011.htm.*

aligned with the $100,000 threshold in current § 495.324(b)(3). Amending § 495.324(d) to preserve alignment with § 495.324(b)(3) will reduce burden on States and maintain the consistency of our prior approval requirements. We believe that this finalized proposal will reduce burden on States by raising the prior approval thresholds and generally aligning them with the thresholds for prior approval of MMIS and ADP acquisitions costs.

In section VIII.D.12.b. of the preamble of this final rule, we are finalizing our proposal that the 90 percent FFP for Medicaid Promoting Interoperability Program administration will no longer be available for most State expenditures incurred after September 30, 2022. We are finalizing a later sunset date, September 30, 2023, for the availability of 90 percent enhanced match for State administrative costs related to Medicaid Promoting Interoperability Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities. States will not be able to claim any Medicaid Promoting Interoperability Program administrative match for expenditures incurred after September 30, 2023. We do not believe that these finalized proposals will impose any additional burdens on States, because they only affect the timing of State expenditures.

We did not receive any public comments specific to Medicaid information collection.

10. ICRs for Revisions to the Supporting Documentation Requirements for Medicare Cost Reports

In section IX.B.1. of the preambles of the proposed rule (83 FR 20545) and this final rule, we discuss our proposal and finalized policy to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339 (OMB No. 0938–0301) into the Organ Procurement Organization (OPO) and Histocompatibility Laboratory cost report, Form CMS–216 (OMB No. 0938–0102), which will complete our incorporation of the Form CMS–339 into all Medicare cost reports. We also discuss our finalized policy to update § 413.24(f)(5)(i) to reflect that an acceptable cost report would no longer require the provider to separately submit a Provider Cost Reimbursement Questionnaire, Form CMS–339, by removing the reference to the questionnaire.

There are 58 OPOs and 47 histocompatibility laboratories. This finalized proposal does not require additional data collection from OPOs or histocompatibility laboratories. This policy will benefit OPOs and histocompatibility laboratories because they will no longer be required to complete and submit the Form CMS–339 as a separate form independent of the Medicare cost report in order to have an acceptable cost report submission under § 413.24(f)(5)(i).

Currently, all OPOs and histocompatibility laboratories are required to complete Form CMS–339. The finalized policy to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339, into the OPO and Histocompatibility Laboratory cost report will eliminate the requirement to complete the Form CMS–339. The estimated annual burden associated with Form CMS–339 is 3 hours per respondent. The time required by an OPO or a histocompatibility laboratory to complete the Form CMS–339 is reduced because the form is incorporated into the cost report. The incorporation of the Form CMS–339 into the cost report as a cost report worksheet will decrease burden upon OPOs and histocompatibility laboratories. These entities will no longer be required to review multiple pages of questions not applicable to them. This finalized policy will result in an overall burden reduction to the 58 OPOs and 47 histocompatibility laboratories of a total of 289 hours.

Instead, these entities are required to respond to 5 questions, which we estimate will take 15 minutes per entity. The total estimated burden across all respondents is 26 hours ((105 respondents) × (0.25 hours/response)). By eliminating the requirement to complete the inapplicable parts of the Form CMS–339, each OPO or histocompatibility laboratory will experience a net burden decrease of 2.75 hours.

Based on the most recent Bureau of Labor Statistics (BLS) 2016 Occupational Outlook Handbook, the mean hourly wage for Category 43–3031 (bookkeeping, accounting, and auditing clerk) is $19.34. We added 100 percent of the mean hourly wage to account for fringe benefits and overhead, which calculates to a total hourly wage of $38.68 ($19.34 + $19.34). The overall decrease in costs to the 58 OPOs and 47 histocompatibility laboratories is $11,178.52 ($38.68 × 289 hours).

In section IX.B.6. of the preamble of this final rule, we discuss our final policy (with modifications to the proposal) in § 413.24(f)(5)(i)(E) that, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with the same fiscal year end, a cost report will be rejected for lack of supporting documentation if the home office or chain organization has not submitted, to the provider's contractor, a Home Office Cost Statement that corresponds to the amounts it has allocated to the provider's cost report. Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with a different fiscal year end, a cost report will be rejected for lack of supporting documentation if the home office or chain organization has not submitted, to the provider's contractor, a Home Office Cost Statement that corresponds to some portion of the amounts it has allocated to the provider's cost report. When the provider and its home office have differing fiscal year ends, the provider's home office costs for a portion of the cost reporting period (as reflected on the Home Office Cost Statement) must correspond to a portion of the amount reported in the provider's cost report. When the provider and its home office have the same fiscal year end, the provider's home office's cost for the same time period (as reflected on the Home Office Cost Statement) must correspond to the costs reported in the provider's cost report.

With our final policy, we anticipate that a home office with costs allocated to providers' cost reports within its chain organization will submit a Home Office Cost Statement to the providers' contractors in order for those providers in the chain organization to have an acceptable cost report submission. Based on the most recent available FY 2016 data in CMS' System for Tracking Audit and Reimbursement, there were approximately 94 providers that claimed costs on their cost reports that were allocated from approximately 13 home offices or chain organizations, but did not submit a Home Office Cost Statement with their cost reports to substantiate these allocated costs. Because the existing burden estimate for a Home Office Cost Statement already reflects the requirement that a home office collect, maintain, and submit a list of the providers' contractors within its chain organization on the Home Office Cost Statement, the contractors to whom the Home Office Cost Statement should be sent is already known to the home office, and thus there is no additional burden placed upon home offices as a result of our finalized policy to require the home office or chain organization to submit to the providers'

contractor the Home Office Cost Statement that corresponds to all or any portion of the costs it has allocated to the provider, in order for the providers within its chain organization to have an acceptable cost report submission. To account for the anticipated increase in Home Office Cost Statement submissions, we will adjust the number of respondents in the Home Office Cost Statement (OMB Control number 0938–0202) information collection request that is currently being developed for reinstatement.

11. Summary of All Burden in This Final Rule

Below is a chart reflecting the total burden and associated costs for the provisions included in this final rule.

Information collection requests	Burden hours increase/ decrease (−)*	Cost (+/−)*
Application for GME Resident Slots	N/A	N/A
Changes—Medicare Cost Report	−289	−$10,907
Hospital Inpatient Quality Reporting Program	−1,947,338	−71,233,624
Hospital Value-Based Purchasing Program[1]	N/A	N/A
HAC Reduction Program[2]	43,200	1,580,256
Hospital Readmissions Reduction Program[3]	N/A	N/A
Promoting Interoperability Programs	−3,606,593	−327,294,661
LTCH Quality Reporting Program	−7,202	−482,468
PPS-Exempt Hospital Quality Reporting Program	−27,709	−1,013,595
Total	−5,545,931	−396,428,082

* Numbers rounded.

[1] Because the Hospital VBP Program uses quality measure collected under other programs or via Medicare fee-for-service claims hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with finalizing removal of measures from the Program or retaining claims-based measures in the Hospital VBP Program that will be removed from the Hospital IQR Program.

[2] We note that the net costs reflected in the table for the HAC Reduction Program do not constitute a new information collection requirement on participating hospitals, but a transition of the NHSN HAI measure validation process from one program to another based on our efforts to reduce measure duplication across programs.

[3] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for-service claims hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this final rule, the Centers for Medicare and Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh); secs. 123 and 124 of subtitle A of Title I of Pub. L. 106–113 (113 Stat. 1501A–332); sec. 307 of Subtitle A of Title III of Pub. L. 106–554; sec. 114 of 110–173; sec. 4302 of Pub. L. 111–5; secs. 3106 and 10312 of Pub. L. 111–148; sec. 1206 of Pub. L. 113–67; sec. 112 of Pub. L. 113–93; sec. 231 of Pub. L. 114–113; secs. 15004, 15006, 15007, 15008, 15009, and 15010 of Pub. L. 114–255; and sec. 51005 of Division E of Title X of Pub. L. 115–123.

■ 2. Section 412.3 is amended by revising paragraph (a) to read as follows:

§ 412.3 Admissions.

(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. In addition, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622.

* * * * *

■ 3. Section 412.4 is amended by adding paragraph (c)(4) to read as follows:

§ 412.4 Discharges and transfers.

* * * * *

(c) * * *

(4) For discharges occurring on or after October 1, 2018, to hospice care provided by a hospice program.

* * * * *

■ 4. Section 412.22 is amended by adding paragraph (h)(2)(iii)(A)(*4*) to read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(h) * * *

(2) * * *

(iii) * * *

(A) * * *

(*4*) On or after October 1, 2018, a satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that provides inpatient services in a building also used by another hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is excluded from the prospective payment systems

specified in § 412.1(a)(1), is not required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(*1*) through (*3*) of this section in order to be excluded from the inpatient prospective payment system. A satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) which is located in a building also used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), is required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(*1*) through (*3*) of this section in order to be excluded from the prospective payment systems specified in § 412.1(a)(1).

* * * * *

■ 5. Section 412.23 is amended by revising paragraph (e)(3)(i) and adding paragraph (e)(3)(vii) to read as follows:

§ 412.23 Excluded hospitals: Classifications

* * * * *

(e) * * *

(3) *Calculation of average length of stay.* (i) Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section, the average Medicare inpatient length of stay specified under paragraph (e)(2)(i) of this section is calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting period. Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section, the average inpatient length of stay specified under paragraph (e)(2)(ii) of this section is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period.

* * * * *

(vii) For cost reporting periods beginning on or after October 1, 2019, the Medicare inpatient days and discharges that are associated with patients discharged from a unit of the hospital will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section.

* * * * *

■ 6. Section 412.25 is amended by—

■ a. Revising paragraphs (a)(1)(ii) and (iii), (d), and (e)(2)(iii)(A); and

■ b. Adding paragraph (e)(2)(iv).

The revisions and addition read as follows:

§ 412.25 Excluded hospital units: Common requirements.

(a) * * *

(1) * * *

(ii) Prior to October 1, 2019, is not excluded in its entirety from the prospective payment systems; and

(iii) Unless it is a unit in a critical access hospital, the hospital of which an IRF is a unit must have at least 10 staffed and maintained hospital beds that are paid under the applicable payment system under which the hospital is paid, or at least 1 staffed and maintained hospital bed for every 10 certified inpatient rehabilitation facility beds, whichever number is greater. Otherwise, the IRF will be classified as an IRF hospital, rather than an IRF unit. In the case of an inpatient psychiatric facility unit, the hospital must have enough beds that are paid under the applicable payment system under which the hospital is paid to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.

* * * * *

(d) *Number of excluded units.* Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems specified in § 412.1(a)(1). A hospital excluded from the prospective payment systems as specified in § 412.1(a)(1) may not have an excluded unit (psychiatric or rehabilitation) that is excluded on the same basis as the hospital.

(e) * * *

(2) * * *

(iii) * * *

(A) Except as provided in paragraph (e)(2)(iv) of this section, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

(iv) Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of paragraph (e)(2)(iii)(A) of this section do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1).

* * * * *

■ 7. Section 412.64 is amended by revising paragraphs (d)(1)(vii) and (d)(3) to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(vii) For fiscal years 2017, 2018, and 2019, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.75 percentage point.

* * * * *

(3)(i) Beginning fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

(A) For fiscal year 2015, by 33⅓ percent;

(B) For fiscal year 2016, by 66⅔ percent; and

(C) For fiscal year 2017 and subsequent fiscal years, by 100 percent.

(ii) Beginning fiscal year 2022, in the case of a ''subsection (d) Puerto Rico hospital,'' as defined under section 1886(d)(9)(A) of the Act, that is not a meaningful EHR user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

(A) For fiscal year 2022, by 33⅓ percent;

(B) For fiscal year 2023, by 66⅔ percent; and

(C) For fiscal year 2024 and subsequent fiscal years, by 100 percent.

* * * * *

■ 8. Section 412.90 is amended by revising paragraph (j) to read as follows:

§ 412.90 General rules.

* * * * *

(j) *Medicare-dependent, small rural hospitals.* For cost reporting periods beginning on or after April 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before October 1, 2022, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

* * * * *

§ 412.92 [Amended]

■ 9. Section 412.92 is amended—
■ a. In paragraph (a)(1)(ii) by removing the term ''intermediary'' and adding the term ''MAC'' in its place;
■ b. By adding paragraph (a)(4);
■ c. In paragraph (b)(1)(i) by removing the term ''fiscal intermediary'' and adding the term ''MAC'' in its place;
■ d. In paragraphs (b)(1)(iii)(B) and (b)(1)(iv) by removing the term ''intermediary'' and adding the term ''MAC'' in its place;
■ e. In paragraph (b)(1)(v) by removing the term ''intermediary's'' and adding the term ''MAC's'' in its place, and removing the term ''intermediary'' and adding the term ''MAC'' in its place;
■ f. By revising paragraphs (b)(2)(i) and (ii) introductory text and (b)(2)(ii)(B);
■ g. By adding paragraph (b)(2)(ii)(C);
■ h. By revising paragraph (b)(2)(iv);
■ i. In paragraphs (b)(3)(i), (ii) and (iii) by removing the term ''fiscal intermediary'' and adding the term ''MAC'' in its place;
■ j. In paragraph (b)(3)(iv) by removing the phrase ''fiscal intermediary or'';
■ k. In paragraph (d)(2) introductory text and (e)(1) and (3) by removing the term ''intermediary'' wherever it appears and adding the term ''MAC'' in its place;
■ l. In paragraph (e)(2) introductory text by removing the term ''intermediary's'' and adding the term ''MAC's'' in its place;
■ m. In paragraph (e)(2)(i) by removing the term ''intermediary'' and adding the term ''MAC'' in its place; and
■ n. In paragraphs (e)(3)(i), (ii), and (iii) by removing the term ''intermediary'' and adding the term ''MAC'' in its place.

The revisions and addition read as follows:

§ 412.92 Special treatment: Sole community hospitals.

(a) * * *

(4) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria specified in paragraphs (a)(1)(i) and (ii) of this section are met. For the mileage and rural location criteria in paragraph (a) of this section and the mileage, accessibility, and travel time criteria specified in paragraphs (a)(1) through (3) of this section, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements.

(b) * * *

(2) * * *

(i) For applications received on or before September 30, 2018, sole community hospital status is effective 30 days after the date of CMS' written notification of approval, except as provided in paragraph (b)(2)(v) of this section. For applications received on or after October 1, 2018, sole community hospital status is effective as of the date the MAC receives the complete application, except as provided in paragraph (b)(2)(v) of this section.

(ii) When a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses a CMS denial of sole community hospital status and no further appeal is made, the sole community hospital status is effective as follows:

* * * * *

(B) If the hospital's application for sole community hospital status was received on or after October 1, 1983 and on or before September 30, 2018, the effective date is 30 days after the date of CMS' original written notification of denial.

(C) If the hospital's application for sole community hospital status was received on or after October 1, 2018, the effective date is the date the MAC receives the complete application.

* * * * *

(iv) For applications received on or before September 30, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after 30 days after the date of CMS' approval of the classification. For applications received on or after October 1, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after the date the MAC receives the complete application.

* * * * *

■ 10. Section 412.96 is amended by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(d) *Criteria for hospitals that have remote location(s).* For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria specified in paragraphs (b)(1) and (2) and (c)(1) through (5) of this section are met. For the rural location criteria specified in paragraphs (b)(1) and (c) of this section and the mileage criteria specified in paragraphs (b)(2)(ii) and (c)(4) of this section, the hospital must demonstrate that the main campus and its remote locations each independently satisfy those requirements.

* * * * *

■ 11. Section 412.101 is amended by—
■ a. Revising paragraph (b)(2);
■ b. Revising paragraphs (c)(1) and (2) introductory text;
■ c. Adding paragraph (c)(3); and
■ d. Revising paragraph (d).

The revisions and addition read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

* * * * *

(b) * * *

(2) In order to qualify for this adjustment, a hospital must meet the following criteria, subject to the provisions of paragraph (e) of this section:

(i) For FY 2005 through FY 2010 and FY 2023 and subsequent fiscal years, a hospital must have fewer than 200 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 25 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(ii) For FY 2011 through FY 2018, a hospital must have fewer than 1,600 Medicare discharges, as defined in

paragraph (a) of this section, during the fiscal year, based on the hospital's Medicare discharges from the most recently available MedPAR data as determined by CMS, and be located more than 15 road miles, as defined in paragraph (a) of this section, from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(iii) For FY 2019 through FY 2022, a hospital must have fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 15 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

* * * * *

(c) * * *

(1) For FY 2005 through FY 2010 and FY 2023 and subsequent fiscal years, the adjustment is an additional 25 percent for each Medicare discharge.

(2) For FY 2011 through FY 2018, the adjustment is as follows:

* * * * *

(3) For FY 2019 through FY 2022, the adjustment is as follows:

(i) For low-volume hospitals with 500 or fewer total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, the adjustment is an additional 25 percent for each Medicare discharge.

(ii) For low-volume hospitals with more than 500 and fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, the adjustment for each Medicare discharge is an additional percent calculated using the formula [(95/330) − (number of total discharges/13,200)]. ''Total discharges'' is determined as described in paragraph (b)(2)(iii) of this section.

(d) *Eligibility of new hospitals for the adjustment.* For FYs 2005 through 2010 and FY 2019 and subsequent fiscal years, a new hospital will be eligible for a low-volume adjustment under this section once it has submitted a cost report for a cost reporting period that indicates that it meets discharge requirements during the applicable fiscal year and has provided its Medicare administrative contractor with sufficient evidence that it meets the distance requirement, as specified in paragraph (b)(2) of this section.

* * * * *

■ 12. Section 412.103 is amended by adding paragraph (a)(7) and revising paragraph (b)(6) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) * * *

(7) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, the hospital is required to demonstrate that the main campus and its remote location(s) each independently satisfy the location conditions specified in paragraphs (a)(1) and (2) of this section.

(b) * * *

(6) *Lock-in date for the wage index calculation and budget neutrality.* In order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for the payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of this section no later than 60 days after the public display date at the Office of the Federal Register of the inpatient prospective payment system proposed rule for the next Federal fiscal year.

* * * * *

§ 412.105 [Amended]

■ 13. Section 412.105 is amended in paragraph (f)(1)(vii) by removing the reference ''§§ 413.79(e)(1) through (e)(4)'' and adding in its place the reference ''§ 413.79(e)''.

■ 14. Section 412.106 is amended by adding paragraph (g)(1)(iii)(C)(*5*) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(*5*) For fiscal year 2019, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data), and for hospitals other than Puerto Rico hospitals, IHS or Tribal hospitals, and all-inclusive rate providers, data on uncompensated care costs, defined as charity care costs plus non-Medicare and nonreimbursable Medicare bad debt costs from 2014 and 2015 cost reports from the most recent HCRIS database extract.

* * * * *

§ 412.108 [Amended]

■ 15. Section 412.108 is amended—

■ a. By revising paragraph (a)(1);

■ b. By adding paragraph (a)(3);

■ c. By revising paragraph (b)(4) introductory text;

■ d. In paragraphs (b)(1) and (3), and (b)(4)(i), (ii), and (iii), (b)(5), (6), (7), (8), and (9), and (d)(1), (d)(2)(i), (d)(3) introductory text, and (d)(3)(i), (ii), and (iii) by removing the terms ''fiscal intermediary'' and ''intermediary'' wherever they appear and adding the term ''MAC'' in their place;

■ e. In paragraph (b)(8) and (9) and (d)(2) introductory text by removing the terms ''fiscal intermediary's'' and ''intermediary's'' and adding the term ''MAC's'' in their place; and

■ f. By revising paragraph (c)(2)(iii) introductory text.

The revisions and additions read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

(a) * * *

(1) *General considerations.* For cost reporting periods beginning on or after April 1, 1990, and ending before October 1, 1994, or for discharges occurring on or after October 1, 1997, and before October 1, 2022, a hospital is classified as a Medicare-dependent, small rural hospital if it meets all of the following conditions:

(i) It is located in a rural area (as defined in subpart D of this part) or it is located in a State with no rural area and satisfies any of the criteria under § 412.103(a)(1) or (3) or under § 412.103(a)(2) as of January 1, 2018.

(ii) The hospital has 100 or fewer beds as defined in § 412.105(b) during the cost reporting period.

(iii) The hospital is not also classified as a sole community hospital under § 412.92.

(iv) At least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the hospital's cost reporting period or periods as follows, subject to the provisions of paragraph (a)(1)(v) of this section:

(A) The hospital's cost reporting period ending on or after September 30, 1987 and before September 30, 1988.

(B) If the hospital does not have a cost reporting period that meets the criterion set forth in paragraph (a)(1)(iv)(A) of this section, the hospital's cost reporting period beginning on or after October 1, 1986, and before October 1, 1987.

(C) At least two of the last three most recent audited cost reporting periods for which the Secretary has a settled cost report.

(v) If the cost reporting period determined under paragraph (a)(1)(iv) of this section is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used.

* * * * *

(3) *Criteria for hospitals that have remote location(s).* For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location (s) are required to demonstrate that the criteria in paragraphs (a)(1) and (2) of this section are met. For the location requirement specified in paragraph (a)(1)(i) of this section, the hospital must demonstrate that the main campus and its remote locations each independently satisfy this requirement.

(b) * * *

(4) For applications received on or before September 30, 2018, a determination of MDH status made by the MAC is effective 30 days after the date the MAC provides written notification to the hospital. For applications received on or after October 1, 2018, a determination of MDH status made by the MAC is effective as of the date the MAC receives the complete application. An approved MDH status determination remains in effect unless there is a change in the circumstances under which the status was approved.

* * * * *

(c) * * *

(2) * * *

(iii) For discharges occurring during cost reporting periods (or portions thereof) beginning on or after October 1, 2006, and before October 1, 2022, 75 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the highest of the following:

* * * * *

■ 16. Section 412.152 is amended by adding, in alphabetical order, definitions of ''Applicable period for dual-eligibility'', ''Dual-eligible'', and ''Proportion of dual-eligibles'' to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Applicable period for dual-eligibility is the 3-year data period corresponding to the applicable period as established by the Secretary for the Hospital Readmissions Reduction Program.

* * * * *

Dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Modernization Act (MMA) files for the month the beneficiary was discharged from the hospital.

* * * * *

Proportion of dual-eligibles is the number of dual-eligible patients among all Medicare Fee-for-Service and Medicare Advantage stays during the applicable period.

* * * * *

■ 17. Section 412.164 is amended by revising paragraph (a) to read as follows:

§ 412.164 Measure selection under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will select measures, other than measures of readmissions, for purposes of the Hospital VBP Program. The measures will be selected from the measures specified under section 1886(b)(3)(B)(viii) of the Act (the Hospital Inpatient Quality Reporting Program).

* * * * *

■ 18. Section 412.200 is revised to read as follows:

§ 412.200 General provisions.

Beginning with discharges occurring on or after October 1, 1987, hospitals located in Puerto Rico are subject to the rules governing the prospective payment system for inpatient operating costs. Except as provided in this subpart, the provisions of subparts A, B, C, F, G, and H of this part apply to hospitals located in Puerto Rico. Except for § 412.60, which deals with DRG classification and weighting factors, or as otherwise specified, the provisions of subparts D and E, which describe the methodology used to determine prospective payment rates for inpatient operating costs for hospitals, do not apply to hospitals located in Puerto Rico. Instead, the methodology for determining prospective payment rates for inpatient operating costs for these hospitals is set forth in §§ 412.204 through 412.212.

■ 19. Section 412.230 is amended by revising paragraph (d)(5) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(d) * * *

(5) *Single hospital MSA exception.* The requirements of paragraph (d)(1)(iii) of this section do not apply if a hospital is the single hospital in its MSA with published 3-year average hourly wage data included in the current fiscal year inpatient prospective payment system final rule.

■ 20. Section 412.500 is amended by adding paragraphs (a)(9) and (10) to read as follows:

§ 412.500 Basis and scope of subpart.

(a) * * *

(9) Section 51005(a) of Public Law 115–123 which extended the blended payment rate for the site neutral payment rate cases to apply to discharges occurring in cost reporting periods beginning in FYs 2018 and 2019.

(10) Section 51005(b) of Public Law which reduces the IPPS comparable amount for the site neutral payment rate cases by 4.6 percent for FYs 2018 through 2026.

* * * * *

■ 21. Section 412.522 is amended by—

■ a. Adding paragraph (c)(1)(iii);

■ b. Removing paragraph (c)(2)(v); and

■ c. Revising paragraph (c)(3) introductory text.

The addition and revision read as follows:

§ 412.522 Application of site neutral payment rate.

* * * * *

(c) * * *

(1) * * *

(iii) For discharges occurring in fiscal years 2018 through 2026, the amount in paragraph (c)(1)(i) of this section is reduced by 4.6 percent.

* * * * *

(3) *Transition.* For discharges occurring in cost reporting periods beginning on or after October 1, 2015 and on or before September 30, 2019, payment for discharges under paragraph (c)(1) of this section are made using a blended payment rate, which is determined as—

* * * * *

■ 22. Section 412.523 is amended by adding paragraphs (c)(3)(xv) and (d)(6) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xv) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2018, and ending September 30, 2019.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2018, and ending September 30, 2019, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.35 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(6) *Adjustment for the elimination of the limitation on long-term care hospital admissions from referring hospitals.* The standard Federal payment rate determined in paragraph (c)(3) of this section is adjusted as follows:

(i) For discharges occurring on or after October 1, 2018 and before October 1, 2019, by a one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2019, and the portion of estimated aggregate payments to site neutral cases that are paid based on the LTCH PPS standard Federal rate in FY 2019, are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the elimination of the limitation on long-term care hospital admissions from referring hospitals. This adjustment only applies to the fiscal year involved and will not be taken into account in computing the standard Federal payment rate for a subsequent fiscal year.

(ii) For discharges occurring on or after October 1, 2019 and before October 1, 2020, by a one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2020, and the portion of estimated aggregate payments to site neutral payment rate cases that are paid based on the LTCH PPS standard Federal rate in FY 2020, are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the elimination of the limitation on long-term care hospital admissions from referring hospitals. This adjustment only applies to the fiscal year involved and will not be taken into account in computing the standard Federal payment rate for a subsequent fiscal year.

(iii) For discharges occurring on or after October 1, 2020, by a permanent, one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2021 are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the elimination of the limitation on long-term care hospital admissions from referring hospitals.

* * * * *

§ 412.525 [Amended]

■ 22. Section 412.525 is amended by removing paragraph (d)(6).

§ 412.538 [Removed and reserved]

■ 23. Section 412.538 is removed and reserved.

■ 24. Section 412.560 is amended by—

■ a. Adding paragraph (b)(3); and

■ b. Revising paragraphs (d)(1) and (3).

The addition and revisions read as follows:

§ 412.560 Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

* * * * *

(b) * * *

(3) CMS may remove a quality measure from the LTCH QRP based on one or more of the following factors:

(i) Measure performance among long-term care hospitals is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(ii) Performance or improvement on a measure does not result in better patient outcomes.

(iii) A measure does not align with current clinical guidelines or practice.

(iv) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic.

(v) The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(vi) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(vii) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

* * * * *

(d) * * *

(1) *Written letter of non-compliance decision.* Long-term care hospitals that do not meet the requirement in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system, the United States Postal Service, or via an email from the MAC.

* * * * *

(3) *CMS decision on reconsideration request.* CMS will notify long-term care hospitals, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: The QIES ASAP system, the United States Postal Service, or via an email from the MAC.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 25. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; and sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 26. Section 413.24 is amended by revising paragraph (f)(5)(i) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(5) * * *

(i) All providers—The provider must accurately complete and submit the required cost reporting forms, including all necessary signatures and supporting documents. For providers claiming costs on their cost reports that are allocated from a home office or chain organization, the Home Office Cost statement must be submitted by the home office or chain organization as set forth in paragraph (f)(5)(i)(E) of this section. A cost report is rejected for lack of supporting documentation if it does not include the following, except as provided in paragraph (f)(5)(i)(E) of this section:

(A) *Teaching hospitals*—For teaching hospitals, the Intern and Resident Information System (IRIS) data.

(B) *Bad debt*—Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a detailed bad debt listing that corresponds to the amount of bad debt claimed in the provider's cost report.

(C) *DSH eligible hospitals*—Effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a disproportionate share hospital payment adjustment, a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. If the hospital submits an amended cost report that changes its Medicaid eligible days, the hospital must submit an amended listing or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report.

(D) *Charity care and uninsured discounts*—Effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the DSH eligible hospital's cost report.

(E) *Home office cost allocation.* (*1*) *Same fiscal year end.* Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with the same fiscal year end, a Home Office Cost Statement completed and submitted by the home office or chain organization to its chain provider's servicing contractor that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report.

(*2*) *Differing fiscal year end.* Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with a different fiscal year end, a Home Office Cost Statement completed and submitted by the home office or chain organization to its chain provider's servicing contractor that corresponds to some portion of the amounts allocated from the home office or chain organization to the provider's cost report.

* * * * *

■ 27. Section 413.79 is amended by revising paragraph (e)(1)(iv) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(e) * * *

(1) * * *

(iv)(A) Effective for Medicare GME affiliation agreements entered into on or after October 1, 2005, exceptas provided in paragraph (e)(1)(iv)(B) of this section, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(B) Effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE cap, provided the Medicare GME affiliated group meets one of the following conditions:

(*1*) The Medicare GME affiliated group consists solely of two or more urban hospitals that qualify for adjustments to their FTE caps under paragraph (e)(1) of this section.

(*2*) The Medicare GME affiliated group includes an urban hospital(s) that received FTE cap(s) under paragraph (c)(2)(i) of this section or § 412.105(f)(1)(iv)(A) of this subchapter, or both. This Medicare GME affiliated group must be established effective with a July 1 date (the residency training year) that is at least 5 years after the start of the cost reporting period that coincides with or follows the start of the sixth program year of the first new program for which the hospital's FTE cap was adjusted in accordance with paragraph (e)(1) of this section or § 412.105(f)(1)(v)(C) or (D) of this subchapter, or both.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 28. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 29. Section 424.11 is amended by revising paragraphs (b) and (c) to read as follows:

§ 424.11 General procedures.

* * * * *

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification. If supporting information for the signed statement is contained in other provider records (such as physicians' progress notes), it need not be repeated in the statement itself.

(c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 30. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 31. Section 495.4 is amended—

■ a. In the definition of ''EHR reporting period'' by revising paragraph (1)(iii), adding paragraph (1)(iv), revising paragraphs (2)(ii)(C) and (D) and (2)(iii), and adding paragraph (2)(iv);

■ b. In the definition of ''EHR reporting period for a payment adjustment year'' by revising paragraph (2)(iii) and adding paragraph (2)(iv), revising paragraph (3)(iii), and adding paragraph (3)(iv); and

■ c. By revising the definitions of ''Payment adjustment year'' and ''Payment year''.

The revisions and additions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(1) * * *

(iii) For the CY 2019 payment year under the Medicaid Promoting Interoperability Program:

(A) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2019.

(B) For the EP who has successfully demonstrated he or she is a meaningful

EHR user in any prior year, any continuous 90-day period within CY 2019.

(iv) For the CY 2020 payment year under the Medicaid Promoting Interoperability Program:

(A) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2020.

(B) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2020.

(2) * * *

(ii) * * *

(C) For the FY 2017 payment year as follows:

(*1*) Under the Medicaid EHR Incentive Program:

(*i*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2017.

(*ii*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2017.

(*iii*) For the eligible hospital or CAH demonstrating the Stage 3 objectives and measures at § 495.24, any continuous 90-day period within CY 2017.

(*2*) Under the Medicare EHR Incentive Program, for a Puerto Rico eligible hospital, any continuous 14-day period within CY 2017.

(D) For the FY 2018 payment year as follows:

(*1*) Under the Medicaid Promoting Interoperability Program:

(*i*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2018.

(*ii*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2018.

(*2*) Under the Medicare Promoting Interoperability Program, for a Puerto Rico eligible hospital, any continuous 90-day period within CY 2018.

(iii) For the FY 2019 payment year as follows:

(A) Under the Medicaid Promoting Interoperability Program:

(*1*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2019.

(*2*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2019.

(B) Under the Medicare Promoting Interoperability Program, for a Puerto Rico eligible hospital, any continuous 90-day period within CY 2019.

(iv) For the FY 2020 payment year as follows:

(A) Under the Medicaid Promoting Interoperability Program:

(*1*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2020.

(*2*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2020.

(B) Under the Medicare Promoting Interoperability Program, for a Puerto Rico eligible hospital, any continuous 90-day period within CY 2020.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(iii) The following are applicable for 2019:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2019 and applies for the FY 2020 and 2021 payment adjustment years. For the FY 2020 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2019.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2019 and applies for the FY 2021 payment adjustment year.

(iv) The following are applicable for 2020:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2020 and applies for the FY 2021 and 2022 payment adjustment years. For the FY 2021 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2020.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2020 and applies for the FY 2022 payment adjustment year.

(3) * * *

(iii) The following are applicable for 2019:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2019 and applies for the FY 2019 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2019 and applies for the FY 2019 payment adjustment year.

(iv) The following are applicable for 2020:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2020 and applies for the FY 2020 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2020 and applies for the FY 2020 payment adjustment year.

* * * * *

Payment adjustment year means the following:

(1) For an EP, a calendar year beginning with CY 2015.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2015.

(3) For a Puerto Rico eligible hospital, a Federal fiscal year beginning with FY 2022.

Payment year means the following:

(1) For an EP, a calendar year beginning with CY 2011.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2011.

(3) For a Puerto Rico eligible hospital, a Federal fiscal year beginning with FY 2016.

* * * * *

■ 32. Section 495.24 is amended by revising the introductory text, paragraphs (c) and (d) headings and adding paragraph (e) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

The criteria specified in paragraphs (c) and (d) of this section are optional for 2017 and 2018 for EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year. The criteria specified in paragraph (d) of this section are applicable for all EPs for 2019 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid Promoting

Interoperability Program for 2019 and subsequent years. The criteria specified in paragraph (e) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years.

* * * * *

(c) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS—*

* * * * *

(d) *Stage 3 objectives and measures for all EPs for 2019 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid Promoting Interoperability Program for 2019 and subsequent years—*

* * * * *

(e) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years—* (1) *General rule.* Except as specified in paragraph (e)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in this paragraph (e) and earn a total score of at least 50 points to meet the definition of a meaningful EHR user.

(2) *Exclusion for nonapplicable measures.* (i) An eligible hospital or CAH may exclude a particular measure that includes an option for exclusion contained in this paragraph (e) if the eligible hospital or CAH meets the following requirements:

(A) Meets the criteria in the applicable measure that would permit the exclusion.

(B) Attests to the exclusion.

(ii) *Distribution of points for nonapplicable measures.* For eligible hospitals or CAHs that claim such exclusion, the points assigned to the excluded measure will be distributed to other measures as outlined in this paragraph (e).

(3) *Objectives and associated measures in this paragraph (e) that rely on measures that count unique patients or actions.* (i) If a measure (or associated objective) in this paragraph (e) references paragraph (e)(3) of this section, the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(ii) If the objective and associated measure does not reference this paragraph (e)(3), the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(4) *Protect patient health information*—(i) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(ii) *Measure scoring.* Eligible hospitals and CAHs are required to report on the security risk analysis measure in paragraph (e)(4)(iii) of this section, but no points are available for this measure.

(iii) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(5) *Electronic prescribing*—(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *Measures scoring.* (A) In 2019, eligible hospitals and CAHs must meet the e-Prescribing measure in paragraph (e)(5)(iii)(A) of this section and have the option to report on the query of PDMP measure and verify opioid treatment agreement measure in paragraphs (e)(5)(iii)(B) and (C) of this section. The electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 20 points.

(B) In 2020 and subsequent years, eligible hospitals and CAHs must meet the e-Prescribing measure in paragraph (e)(5)(iii)(A) of this section and the query of PDMP measure in paragraph (e)(5)(iii)(B) of this section. In 2020, eligible hospitals and CAHs have the option to report on the verify opioid treatment agreement measure in paragraph (e)(5)(iii)(C) of this section. In 2020, the electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 15 points.

(iii) *Measures.* (A) *e-Prescribing measure.* Subject to paragraph (e)(3) of this section, at least one hospital discharge medication order for permissible prescriptions (for new and changed prescriptions) is queried for a drug formulary and transmitted electronically using CEHRT. This measure is worth up to 10 points in 2019 and 5 points in subsequent years.

(B) *Query of prescription drug monitoring program (PDMP) measure.* Subject to paragraph (e)(3) of this section, for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law. This measure is worth up to 5 bonus points in CY 2019 and 5 points in subsequent years.

(C) *Verify opioid treatment agreement measure.* Subject to paragraph (e)(3) of this section, for at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT. This measure is worth up to 5 bonus points in CY 2019 and CY 2020.

(iv) *Exclusions in accordance with paragraph (e)(2) of this section and redistribution of points.* An exclusion claimed under paragraph (e)(5)(v)(A) of this section will redistribute 10 points in CY 2019 and 5 points in CY 2020 equally among the measures associated with the health information exchange objective under paragraph (e)(6) of this section. Beginning in CY 2020, an exclusion claimed under paragraph (e)(5)(v)(B), (C), or (D) of this section will redistribute 5 points from the measure specified in paragraph (e)(5)(iii)(B) of this section to the e-Prescribing measure under paragraph (e)(5)(iii)(A) of this section.

(v) *Exclusions in accordance with paragraph (e)(2) of this section.* (A) Beginning with the EHR reporting period in CY 2019, any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period may be excluded from the measure specified in paragraph (e)(5)(iii)(A) of this section.

(B) Beginning with the EHR reporting period in CY 2020, an eligible hospital or CAH that qualifies for the exclusion in paragraph (e)(5)(v)(A) of this section is also excluded from the measure specified in paragraph (e)(5)(iii)(B) of this section.

(C) Beginning with the EHR reporting period in CY 2020, any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances

and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period may be excluded from the measure specified in paragraph (e)(5)(iii)(B) of this section.

(D) Beginning with the EHR reporting period in CY 2020, any eligible hospital and CAH that is unable to report on the measure specified in paragraph (e)(5)(iii)(B) of this section in accordance with applicable law may be excluded from that measure.

(6) *Health information exchange*—(i) *Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(ii) *Measures.* Eligible hospitals and CAHs must meet both of the following measures (each worth up to 20 points), and could receive up to 40 points for this objective:

(A) *Support electronic referral loops by sending health information measure:* Subject to paragraph (e)(3) of this section, for at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(*1*) Creates a summary of care record using CEHRT; and

(*2*) Electronically exchanges the summary of care record.

(B) *Support electronic referral loops by receiving and incorporating health information measure:* Subject to paragraph (e)(3) of this section, for at least one electronic summary of care record received for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, mediation allergy, and current problem list.

(iii) *Exclusions in accordance with paragraph (e)(2) of this section.* Any eligible hospital or CAH that is unable to implement the support electronic referral loops by receiving and incorporating health information measure under paragraph (e)(6)(ii)(B) of this section for an EHR reporting period in 2019 may be excluded from that measure. Claiming the exclusion will redistribute 20 points to the support electronic referral loops by sending health information measure under paragraph (e)(6)(ii)(A) of this section.

(7) *Provider to patient exchange.*—(i) *Objective.* The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information.

(ii) *Provide patients electronic access to their health information measure.* Eligible hospitals and CAHs must meet the following measure, and could receive up to 40 points for this objective beginning in CY 2019. For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23)—

(A) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(B) The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT. This measure is worth up to 40 points beginning in CY 2019.

(8) *Public health and clinical data exchange.*—(i) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measures.* In order to meet the objective under paragraph (e)(8)(i) of this section, an eligible hospital or CAH must meet any two measures specified in paragraphs (e)(8)(ii)(A) through (F) of this section. Eligible hospitals and CAHs could receive a total of 10 points for this objective.

(A) *Syndromic surveillance reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(B) *Immunization registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(C) *Electronic case reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(D) *Public health registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(E) *Clinical data registry reporting measure.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(F) *Electronic reportable laboratory result reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(iii) *Exclusions in accordance with paragraph (e)(2) of this section.* If an exclusion is claimed under paragraphs (e)(8)(iii)(A) through (F) of this section for each of the two measures selected for reporting, the 10 points for the objective specified in paragraph (e)(8)(i) of this section will be redistributed to the provide patients electronic access to their health information measure under paragraph (e)(7)(ii) of this section.

(A) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (e)(8)(ii)(A) of this section if the eligible hospital or CAH—

(*1*) Does not have an emergency or urgent care department.

(*2*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

(B) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from to the immunization registry reporting measure specified in paragraph (e)(8)(ii)(B) of this section if the eligible hospital or CAH—

(*1*) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(C) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic case reporting measure specified in paragraph (e)(8)(ii)(C) of this section if the eligible hospital or CAH—

(*1*) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(D) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (e)(8)(ii)(D) of this section if the eligible hospital or CAH—

(*1*) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(E) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (e)(8)(ii)(E) of this section if the eligible hospital or CAH—

(*1*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(F) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (e)(8)(ii)(F) of this section if the eligible hospital or CAH—

(*1*) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

■ 33. Section 495.40 is amended by adding paragraph (b)(2)(vii) to read as follows:

§ 495.40 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(vii) *Exception for dual-eligible eligible hospitals and CAHs beginning in CY 2019.* (A) Beginning with the EHR reporting period in CY 2019, dual-eligible eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use, and are also eligible to earn a Medicaid incentive payment for meaningful use) must satisfy the requirements under paragraph (b)(2) of this section by attestation and reporting information to CMS, not to their respective state Medicaid agency.

(B) Dual-eligible eligible hospitals and CAHs that demonstrate meaningful use to their state Medicaid agency may only qualify for an incentive payment under Medicaid and will not qualify for an incentive payment under Medicare and/or avoid the Medicare payment reduction.

* * * * *

■ 34. Section 495.100 is amended by revising the definition of ''Eligible hospital'' and adding a definition of ''Puerto Rico eligible hospital'' in alphabetical order to read as follows:

§ 495.100 Definitions.

* * * * *

Eligible hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter, excluding those hospitals specified in § 412.23 of this chapter, excluding those hospital units specified in § 412.25 of this chapter, and including Puerto Rico eligible hospitals unless otherwise indicated.

* * * * *

Puerto Rico eligible hospital means a subsection (d) Puerto Rico hospital as defined in section 1886(d)(9)(A) of the Social Security Act.

* * * * *

■ 35. Section 495.104 is amended by adding paragraphs (b)(6) through (10) and (c)(5)(vi) through (x) to read as follows:

§ 495.104 Incentive payments to eligible hospitals.

* * * * *

(b) * * *

(6) Puerto Rico eligible hospitals whose first payment year is FY 2016 may receive such payments for FYs 2016 through 2019.

(7) Puerto Rico eligible hospitals whose first payment year is FY 2017 may receive such payments for FYs 2017 through 2020.

(8) Puerto Rico eligible hospitals whose first payment year is FY 2018 may receive such payments for FYs 2018 through 2021.

(9) Puerto Rico eligible hospitals whose first payment year is FY 2019 may receive such payments for FYs 2019 through 2021.

(10) Puerto Rico eligible hospitals whose first payment year is FY 2020 may receive such payments for FYs 2020 through 2021.

(c) * * *

(5) * * *

(vi) For Puerto Rico eligible hospitals whose first payment year is FY 2016—

(A) 1 for FY 2016;

(B) ¾ for FY 2017;

(C) ½ for FY 2018; and

(D) ¼ for FY 2019.

(vii) For Puerto Rico eligible hospitals whose first payment year is FY 2017—

(A) 1 for FY 2017;

(B) ¾ for FY 2018;

(C) ½ for FY 2019; and

(D) ¼ for FY 2020;

(viii) For Puerto Rico eligible hospitals whose first payment year is FY 2018—

(A) 1 for FY 2018;

(B) ¾ for FY 2018;

(C) ½ for FY 2019; and

(D) ¼ for FY 2020.

(ix) For Puerto Rico eligible hospitals whose first payment year is FY 2019—

(A) ¾ for FY 2019;

(B) ½ for FY 2020; and

(C) ¼ for FY 2021.

(x) For Puerto Rico eligible hospitals whose first payment year is FY 2020—

(A) ½ for FY 2020; and

(B) ¼ for FY 2021.

* * * * *

■ 36. Section 495.200 is amended by revising the definitions of ''MA payment adjustment year'' and ''Payment year'' to read as follows:

§ 495.200 Definitions.

* * * * *

MA payment adjustment year means—

(1) Except as provided in paragraph (2) of this definition, for qualifying MA organizations that receive an MA EHR incentive payment for at least 1 payment year, calendar years beginning with CY 2015.

(2) For qualifying MA organizations that receive an MA EHR incentive payment for a qualifying MA-affiliated eligible hospital in Puerto Rico for at least 1 payment year, and that have not previously received an MA EHR incentive payment for a qualifying MA-affiliated eligible hospital not in Puerto Rico, calendar years beginning with CY 2022.

(3) For MA-affiliated eligible hospitals, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the Federal fiscal year ending in the MA payment adjustment year.

(4) For MA EPs, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the calendar year concurrent with the payment adjustment year.

* * * * *

Payment year means—

(1) For a qualifying MA EP, a calendar year beginning with CY 2011 and ending with CY 2016; and

(2) For an eligible hospital, a Federal fiscal year beginning with FY 2011 and ending with FY 2016; and

(3) For an eligible hospital in Puerto Rico, a Federal fiscal year beginning with FY 2016 and ending with FY 2021.

* * * * *

■ 37. Section 495.211 is amended by adding paragraph (e)(4) to read as follows:

§ 495.211 Payment adjustments effective for 2015 and subsequent MA payment years with respect to MA EPs and MA-affiliated eligible hospitals.

* * * * *

(e) * * *

(4) For MA payment adjustment years prior to 2022, subsection (d) Puerto Rico hospitals are neither potentially qualifying MA-affiliated eligible hospitals nor qualifying MA-affiliated eligible hospitals for purposes of applying the payment adjustments under paragraph (e) of this section.

■ 38. Section 495.316 is amended by revising paragraph (g)(2) to read as follows:

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(g) * * *

(2) Subject to paragraph (h)(2) of this section, provider-level attestation data for each eligible hospital that attests to demonstrating meaningful use for each payment year beginning with 2013 and ending after 2018.

* * * * *

■ 39. Section 495.322 is revised to read as follows:

§ 495.322 FFP for reasonable administrative expenses.

(a) Subject to prior approval conditions at § 495.324, FFP is available at 90 percent in State expenditures for administrative activities in support of implementing incentive payments to Medicaid eligible providers.

(b) FFP available under paragraph (a) of this section is available only for expenditures incurred on or before September 30, 2022, except for expenditures related to audit and appeal activities required under this subpart, which must be incurred on or before September 30, 2023.

■ 40. Section 495.324 is amended by revising paragraphs (b)(2) and (3) and (d) to read as follows:

§ 495.324 Prior approval conditions.

* * * * *

(b) * * *

(2) For the acquisition solicitation documents and any contract that a State may utilize to complete activities under this subpart, unless specifically exempted by the Department of Health and Human Services, prior to release of the acquisition solicitation documents or prior to execution of the contract, when the contract is anticipated to or will exceed $500,000.

(3) For contract amendments, unless specifically exempted by the Department of Health and Human Services, prior to execution of the contract amendment, involving contract cost increases exceeding $500,000 or contract time extensions of more than 60 days.

* * * * *

(d) A State must obtain prior written approval from HHS of its justification for a sole source acquisition, when it plans to acquire noncompetitively from a nongovernmental source HIT equipment or services, with proposed FFP under this subpart if the total State and Federal acquisition cost is more than $500,000.

Dated: July 27, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: July 30, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2018, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2018

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2019 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2019. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2018.

In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that will be applicable to Medicare LTCHs for FY 2019.

In general, except for SCHs and MDHs, for FY 2019, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also

known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.G. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), for FY 2019, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion below does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, as we proposed, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2019. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2019. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2019. In section V. of this Addendum, we discuss policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2019. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2019

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we used for determining the prospective payment rates for FY 2019.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2019, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.B. of the preamble of this final rule for a complete discussion on the FY 2019 inpatient hospital update. Below is a table with these four options:

FY 2019	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.725	−0.725
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.175	0.0	−2.175
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.35	−0.825	0.625	−1.55

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2019.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS

final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.

- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2018 budget neutrality factor and applying a revised factor.
- A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years, as amended by section 15003 of Public Law 114–255 which amended section 410A of Public Law 108–173 to provide for a 10-year extension of the demonstration program (in place of the 5-year extension required by the Affordable Care Act) beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173, are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2018 outlier offset and apply an offset for FY 2019, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2019, consistent with current law, as we proposed, we applied the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, as we proposed, we applied a uniform, national budget neutrality adjustment to the FY 2019 wage index for the rural floor. We note that, in section III.H.2.b. of the preamble to this final rule, as we proposed, we are not extending the imputed floor policy (neither the original methodology nor the alternative methodology) for FY 2019. Therefore, for FY 2019, in this final rule, we are not including the imputed floor (calculated under the original methodology and alternative methodology) in calculating the uniform, national rural floor budget neutrality adjustment, which is reflected in the FY 2019 wage index.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2019, as we proposed, we are continuing to use the national labor-related and nonlabor-related shares (which are based on the 2014-based hospital market basket) that were used in FY 2018. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2019, as discussed in section III. of the preamble of this final rule, as we proposed, we are continuing to use a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, as we proposed, we applied the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, as we proposed, we calculated the FY 2019 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this final rule, as we proposed, we used the 2014-based IPPS operating and capital market baskets for FY 2019. As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, as we proposed, we reduced the FY 2019 applicable percentage increase (which for this final rule is based on IGI's second quarter 2018 forecast of the 2014-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2019) of 0.8 percentage point, which for this final rule is also calculated based on IGI's second quarter 2018 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, as we proposed, we further updated the standardized amount for FY 2019 by the estimated market basket percentage increase less 0.75 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of the Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services required as inputs to provide hospital inpatient services.

Based on IGI's 2018 second quarter forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the forecast of the hospital market basket increase for FY 2019 for this final rule is 2.9 percent. As discussed earlier, for FY 2019, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this final rule for a complete discussion on the FY 2019 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that will be applied to update the national standardized amount. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2019 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2019 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the FY 2019 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: Include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf); exclude CAHs at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.

• As in the past, as we proposed, we adjusted the FY 2019 standardized amount to remove the effects of the FY 2018 geographic reclassifications and outlier payments before applying the FY 2019 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2019 payment policies.

• We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

• For FY 2019, the Bundled Payments for Care Improvement (BPCI) Initiative will have ended and a new model, the BPCI Advanced model will have begun. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI Initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). For FY 2019, consistent with how we have treated hospitals that participated in the BPCI Initiative, as we proposed, we are including all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2019 and subsequent years, as we proposed, we are continuing to apply a proxy hospital readmissions payment adjustment and a proxy hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we applied a proxy readmissions payment adjustment factor and a proxy hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the proxy FY 2019 readmissions payment adjustment factors, for both the proposed rule and this final rule, as discussed in section IV.H. of the preamble of this final rule, as we proposed, we used the proportion of dually-eligible Medicare beneficiaries, excess readmission ratios, and aggregate payments for excess readmissions from the prior fiscal year's applicable period because, at the time of the development of the final rule, hospitals have not yet had the opportunity to review and correct the data (program calculations based on the FY 2019 applicable period of July 1, 2014 to June 30, 2017) before the data are made public under our policy regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400) and section IV.H. of the preamble of this final rule.)

In addition, for FY 2019, for the purpose of modeling aggregate payments when determining all budget neutrality factors, as we proposed, we used proxy hospital VBP payment adjustment factors for FY 2019 that are based on data from a historical period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2019 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment

period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and an additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2019 (as we did for the last 5 fiscal years), as we proposed, we included estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.F. of the preamble to this final rule and below, as we proposed, we are continuing to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we included estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV.F. of the preamble of this final rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, as we proposed, we continued to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

• As we proposed, we include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2019. Similar to FY 2018, we are including this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2019.

• In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2.b. of the preamble of this final rule.

Comment: Based on their review of the rate information CMS made available with the proposed rule, a few commenters noted that there appeared to be an error in the determination of the hospital-specific payment rates for SCHs and MDHs that resulted in hospital-specific payment rates that are too low. These commenters urged CMS to carefully reexamine its calculations and correct the apparent error in the determination of hospital-specific payment rates.

Response: We appreciate these commenters' analysis and their bringing this to our attention. Upon review, we found that we inadvertently omitted the applicable FY 2013 factors needed to update the hospital-specific payment rates in the PSF from FY 2012 dollars. We have corrected this inadvertent omission in the determination of the hospital-specific payment rates used for this final rule.

a. Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this final rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, as we proposed, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For FY 2019, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2017 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2018 labor-related share percentages, the FY 2018 relative weights, and the FY 2018 pre-reclassified wage data, and applied the FY 2019 hospital readmissions payment adjustments and estimated FY 2019 hospital VBP payment adjustments; and

• Aggregate payments using the FY 2018 labor-related share percentages, the FY 2019 relative weights, and the FY 2018 pre-reclassified wage data, and applied the FY 2019 hospital readmissions payment adjustments and estimated FY 2019 hospital VBP payment adjustments applied above. (We note that these FY 2019 relative weights reflect our temporary measure for FY 2019, as discussed in section II.G. of the preamble of this final rule, to set the FY 2019 relative weight at the FY 2018 final relative weight for MS–DRGs where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2019 relative weight would have declined by 20 percent or more from the FY 2018 relative weight.)

Based on this comparison, we computed a budget neutrality adjustment factor equal to 0.997192 and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we also proposed, we applied the MS–DRG reclassification and recalibration budget neutrality factor of 0.997192 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2018.

b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage

index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2019, as we proposed, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2017 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2019 relative weights and the FY 2018 pre-reclassified wage indexes, applied the FY 2018 labor-related share of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the FY 2019 hospital readmissions payment adjustment and the estimated FY 2019 hospital VBP payment adjustment; and
- Aggregate payments using the FY 2019 relative weights and the FY 2019 pre-reclassified wage indexes, applied the labor-related share for FY 2019 of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same FY 2019 hospital readmissions payment adjustments and estimated FY 2019 hospital VBP payment adjustments applied above.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2018 to FY 2019. By applying this methodology, we determined a budget neutrality adjustment factor of 1.000748 for changes to the wage index.

c. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2019, we used FY 2017 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2019 labor-related share percentages, the FY 2019 relative weights, and the FY 2019 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the FY 2019 hospital readmissions payment adjustments and the estimated FY 2019 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2019 labor-related share percentages, the FY 2019 relative weights, and the FY 2019 wage data after such reclassifications, and applied the same FY 2019 hospital readmissions payment adjustments and the estimated FY 2019 hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2019, and applies the policies explained in section III. of the preamble of this final rule. Based on these simulations, we calculated a budget neutrality adjustment factor of 0.985932 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The FY 2019 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2018 budget neutrality adjustment factor. We note that the FY 2019 budget neutrality adjustment reflects FY 2019 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule.

d. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

As noted above and as discussed in section III.G.2. of the preamble of this final rule, the imputed floor is set to expire effective October 1, 2018, and as we proposed, we are not extending the imputed floor policy.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2019, as we proposed, we are calculating a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2019 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we used the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2019 rural Puerto Rico wage index is calculated based on the average of the FY 2019 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2017 discharge data to simulate payments and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the national rural floor; and
- National simulated payments with the national rural floor.

Based on this comparison, we determined a national rural floor budget neutrality adjustment factor of 0.993142. The national adjustment was applied to the national wage indexes to produce a national rural floor budget neutral wage index.

e. Rural Community Hospital Demonstration Program Adjustment

In section IV.L. of the preamble of this final rule, we discuss the Rural Community Hospital Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed below). We make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer the reader to section IV.L. of the preamble of this final rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2019, the total amount that we are applying to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $58,129,609. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2019, we computed a factor of 0.999467 for the Rural Community Hospital Demonstration budget neutrality adjustment that will be applied to the IPPS standard Federal payment rate. We refer readers to section IV.L. of the preamble of this final rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amount.

We note that, as discussed in section IV.L. of the preamble of this final rule, as we proposed, we used updated data to the extent

appropriate to determine the budget neutrality offset amount for FY 2019. We refer readers to section IV.L. of the preamble of this final rule on complete details regarding the availability of additional data prior to the FY 2019 IPPS/LTCH PPS final rule.

f. Adjustment for FY 2019 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2019, as we proposed, we are implementing the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

g. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2019 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm*.

(1) FY 2019 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the FY 2019 outlier threshold, we simulated payments by applying FY 2019 payment rates and policies using cases from the FY 2017 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described below) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the FY 2019 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2017 to FY 2019. As discussed in the FY 2015 IPPS/LTCH PPS final rule, we believe a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57282), we are using the following methodology to calculate the charge inflation factor for FY 2019:

- To produce the most stable measure of charge inflation, we applied the following inclusion and exclusion criteria of hospitals claims in our measure of charge inflation: Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49779 through 49780), we stated that commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. In response to those comments, we stated that we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. In response to those comments, similar to FY 2016, FY 2017, and FY 2018, for FY 2019, we grouped claims data by quarter in the table below in order that the public would be able to replicate the claims summary for the claims with discharge dates through September 30, 2017, that are available under the current limited data set (LDS) structure. In order to provide even more information in response to the commenters' request, similar to FY 2016, FY 2017, and FY 2018, for FY 2019, we made available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the links on the left titled ''FY 2019 IPPS Proposed Rule Home Page'' and then click the link ''FY 2019 Proposed Rule Data Files'') more detailed summary tables by provider with the monthly charges that were used to compute the charge inflation factor. In the proposed rule, we stated that we continue to work with our systems teams and privacy office to explore expanding the information available in the current LDS, perhaps through the provision of a supplemental data file for future rulemaking.

Quarter	Covered charges (January 1, 2016, through December 31, 2016)	Cases (January 1, 2016, through December 31, 2016)	Covered charges (January 1, 2017, through December 31, 2017)	Cases (January 1, 2017, through December 31, 2017)
1	$140,753,065,878	2,506,525	$149,358,509,178	2,551,065
2	135,409,469,345	2,414,710	140,445,911,726	2,397,110
3	132,239,610,957	2,356,131	135,004,161,478	2,293,958
4	138,440,787,173	2,412,708	108,175,925,297	1,821,225
Total	546,842,933,353	9,690,074	532,984,507,679	9,063,358

Under this methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2019, we compared the average covered charge per case of $56,433 ($546,842,933,353/9,690,074) from the second quarter of FY 2016 through the first quarter of FY 2017 (January 1, 2016, through December 31, 2016) to the average covered charge per case of $58,806.52 ($532,984,507,679/9,063,358) from the second quarter of FY 2017 through the first quarter of FY 2018 (January 1, 2017, through December 31, 2017). This rate-of-change was 4.2 percent (1.04205) or 8.6 percent (1.085868) over 2 years. (We note that in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581) we inadvertently stated the rate-of-change over 2 years as 9.5 percent instead of 8.6 percent. However, the factor in the parenthetical, 1.085868, was shown correctly.) The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

Comment: Several commenters were concerned with what they stated was a lack of transparency with respect to the charge inflation component of the fixed-loss threshold calculation. The commenters concluded that, in the absence of access to the data or more specific data and information about how CMS arrived at the totals used in the charge inflation calculation, their ability to comment is limited. Several commenters requested that CMS add the claims data used to compute the charge inflation factor to the list of limited data set (LDS) files that can be ordered through the usual LDS data request process.

Another commenter stated that it was unable to match the figures in the table from the proposed rule with publicly available data sources and that CMS did not disclose the source of the data. The commenter further stated that CMS has not made the necessary data available, or any guidance that describes whether and how CMS edited such data to arrive at the total of quarterly charges and charges per case used to measure charge inflation. Consequently, the commenter stated that the table provided in the proposed rule was not useful in assessing the accuracy of the charge inflation figure that CMS used in the proposed rule to calculate the outlier threshold. The commenter noted that CMS provided a detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. The commenters appreciated the additional data, but still believed that CMS had not provided enough specific information and data to allow the underlying numbers used in CMS' calculation of the charge inflation factor to be replicated and/or tested for accuracy.

Response: We responded to a similar comment in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50375), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49779 through 49780), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57283), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524) and refer readers to those final rules for our complete response. We have not yet been able to restructure the files (such as ensuring that personal identification information is compliant with privacy regulations) for release with the publication of the proposed rule and this final rule. As we stated in last year's final rule and prior rulemaking, while the charge data may not be immediately available after the issuance of this final rule, we believe the data and supporting files we have provided do provide the commenters with additional information that can be verified once the charge data are available. We have produced the actual figures we used and disclosed our formula. We intend to post the actual charge data as soon as possible so that the public can verify the raw data with the figures we used in the calculation. As stated earlier and in the proposed rule, the charge data used to calculate the charge inflation factor are sourced from our MedPAR database. In addition, as stated in the FY 2018 final rule and prior rulemaking, for this final rule we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. Similar to FY 2018, the commenters did not recommend using charge data from a different period to compute the charge inflation factor. If we computed the charge inflation factor using the latest data available to the public at the time of issuance of this final rule, we would need to compare charge data from FY 2016 (October 2015 through September 2016) to FY 2017 (October 2016 through September 2017), data which would be at least 10 months old compared to the charge data we use for the final rule under our current approach, which are 4 months old.

With respect to those comments requesting that CMS add the claims data used to compute the charge inflation factor to the list of LDS files that can be ordered through the usual LDS data request process, we note that the commenters' views were similar to comments received and we responded to in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524 through 38525) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49779 through 49780), and we refer readers to those rules for additional details our response. As we stated in response to a similar comment in last year's final rule (82 FR 38525), there are limitations on how expeditiously we can add the charge data to the LDS, and we do not anticipate being able to provide the charge data we currently use to calculate the charge inflation factor within the commenters' requested timeframe. We continue to be confronted with the dilemma of either using older data that commenters can access earlier, or using the most up-to-date data which will be more accurate, but will not be available to the public until after publication of the proposed and final rules. We again invite commenters to inform us if they believe their need to have complete access to the data we use in our methodology outweighs the greater accuracy provided by the use of more up-to-date data. We continue to prefer using the latest data available at the time of the proposed and final rules to compute the charge inflation factor because we believe it leads to greater accuracy in the calculation of the fixed-loss cost outlier threshold. However, for the FY 2020 IPPS/LTCH PPS proposed rule, we are continuing to consider using data that commenters can access earlier.

For these reasons, we disagree that CMS has not provided adequate information to allow for meaningful comment, and continue to believe that our current methodology is the most appropriate way to measure charge inflation to result in the most accurate calculation of the outlier threshold based on the best available data.

As we have done in the past, in the FY 2019 IPPS/LTCH PPS proposed rule (8 FR 20581), we proposed to establish the proposed FY 2019 outlier threshold using hospital CCRs from the December 2017 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of that proposed rule. We proposed to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described below to hospitals assigned the statewide average CCR. For FY 2019, we also proposed to continue to apply an

adjustment factor to the CCRs to account for cost and charge inflation (as explained below). In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581), we also proposed that, if more recent data become available, we would use that data to calculate the final FY 2019 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done since FY 2014, we proposed to adjust the CCRs from the December 2017 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2016 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2017 update of the PSF. We note that, in the proposed rule, we used total transfer-adjusted cases from FY 2017 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, for the proposed rule, we calculated a proposed December 2016 operating national average case-weighted CCR of 0.266065 and a proposed December 2017 operating national average case-weighted CCR of 0.262830. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2016 operating national average case-weighted CCR from the December 2017 operating national average case-weighted CCR and then dividing the result by the December 2016 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.987842.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, we calculated a December 2016 capital national average case-weighted CCR of 0.023104 and a December 2017 capital national average case-weighted CCR of 0.022076. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2016 capital national average case-weighted CCR from the December 2017 capital national average case-weighted CCR and then dividing the result by the December 2016 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.955517.

As discussed in section III.B.3. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.G.3. of the preamble of this final rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments were applied after rural floor budget neutrality adjustments were applied for all labor market areas, in order to ensure that no hospital in a frontier State would receive a wage index less than 1.0000 due to the rural floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the outlier threshold for FY 2019, it was necessary to adjust the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2019. If we did not take the above into account, our estimate of total FY 2019 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2019 outlier payments, we proposed not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that we have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that period. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we proposed not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

Comment: Commenters expressed concern with CMS' decision not to consider outlier reconciliation in developing the outlier threshold and stated that CMS did not provide any statistics or analysis concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process.

In addition to the cited resources received in previous iterations of this comment, one commenter referenced and provided an OIG report from September of 2017 (available on the website at: *https://oig.hhs.gov/oas/reports/region7/71402800.pdf*) focused on the reconciliation of outlier payments titled ''Vulnerabilities Remain in Medicare Hospital Outlier Payments.'' The commenter stated that CMS now has 15 full fiscal years of experience with reconciliation, from which to project the impact of its reconciliation in the upcoming fiscal year. The commenter noted that the amount of outlier payments subject to reconciliation does not appear to be de minimis. The commenter cited a 2012 OIG Report (available on the website at: *https://oig.hhs.gov/oas/reports/region7/71002764.pdf*) which identified approximately $664 million in unreconciled outlier payments. Therefore, the commenter concluded that the impact of reconciliation that should not be ignored when setting the threshold. The commenter asserted that CMS' policy of refusing to account for the impact of reconciliation in setting the FY 2019 outlier fixed-loss cost threshold is neither reasonable nor consistent with the outlier statute.

Response: The commenters' views were similar to comments received and we responded to in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979 to 509080) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50376 through 50377), and we refer readers to those rules for our responses. In the FY 2014 IPPS/LTCH PPS final rule, we stated that outlier reconciliation is a function of the cost report and Medicare contractors record the outlier reconciliation amount on each provider's cost report. Therefore, as the MACs continue to perform these outlier reconciliations, they record these amounts on the cost report, which are then publicly available through the HCRIS database. Therefore, the outlier reconciliation data and information that the commenter requested should be publicly available through the cost report.

Outlier cases are, by definition, out of the ordinary, and the occurrence of an individual outlier case is not easily predicted. It is also difficult to predict their occurrence for each hospital in the country. This alone makes incorporating reconciliation into the modeling of the outlier threshold challenging and even more so when combined with the challenges of predicting not only outliers for use at hospital level, but which of those hospitals in the future will be reconciled. We note that the commenter did not specifically address how any projection of the impact of reconciliation would account for these issues, but we welcome recommendations or suggestions from the commenter or other members of the public based on the cost report data on how to account for reconciliation in the calculation of the outlier threshold. We intend to revisit this issue in next year's proposed rule as we continue to consider the feasibility of including outlier reconciliation in the modeling of the outlier threshold.

Lastly, we note that the $664 million estimated figure from the OIG report was an aggregate estimate over an older 10-year period from 2002 to 2012 and was not a single year estimate. We note this to avoid any suggestion that if we were able to feasibly incorporate an estimate of outlier reconciliations in the modelling of the outlier threshold in future years, such an estimate would be of this magnitude.

Comment: One commenter cited CMS' response in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49781 and 49782) which stated in regard to the OIG's November 13, 2013 report (available on the website at: *https://oig.hhs.gov/oei/reports/oei-06-10-00520.pdf*) that ''we note that the OIG report used CCRs from 2008–2011. The CCRs are updated in the PSF at the time the MAC tentatively settles the hospital cost report, which is approximately 6 to 7 months after the cost report has been submitted. * * * Because hospitals typically increase their charges, over time CCRs will decrease but, due to the lag these lower CCRs will not be reflected in the PSF until the following tentative settlement. Thus, it is possible that the PSF will reflect CCRs that are similar for hospitals with high and low outlier payments. In addition, providers determine what they will charge for items, services, and procedures provided to patients, and these charges are the amount that the providers bill for an item, service, or procedure. Moreover, different hospitals can have similar lengths of stay but different CCRs. * * * In addition, as the commenter noted, there are mechanisms to avoid outlier overpayments or underpayments as CMS and the MACs have the authority to specify an alternative CCR. Also, in addition to the examples cited by the commenter, as we note in every proposed and final rule, hospitals can also request alternative CCRs. Therefore, if hospitals make these requests, these CCRs would be reflected in the PSF which would be used to compute the fixed-loss threshold.''

The commenter stated that this response infers that the findings from the 2013 OIG report (that high-outlier hospitals charge Medicare substantially more for the same MS–DRGs, even though their patients had similar lengths of stay as those in all other hospitals) are no longer an area of concern because the report was based on CCRs from 2008 through 2011. The commenter stated that it conducted an analysis of the MedPAR data which concludes that the findings from the 2013 OIG Report have continued without interruption to present. The commenter also stated that CMS' response that providers may determine their charges overlooks section 2202.4.2 of the Provider Reimbursement Manual, Part I, Chapter 22, that provides that charges should reflect ''the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients,'' and they ''should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.'' The commenter asserted that CMS' failure to reconcile ''high-outlier'' payments effectively condones charging decisions based on maximizing outlier payments.

The commenter also cited CMS' statement from the FY 2015 IPPS/LTCH PPS final rule (79 FR 50377 and 50378) which stated ''that the CCRs will reflect these low costs and high charges that the commenter referred to, and when applied to the charges on the claim will result in less outlier payments for such cases because the costs of the case will be lower when compared to the total MS–DRG payments excluding outlier payments.'' The commenter disagreed with this statement and cited the OIG's 2013 report. The commenter stated that the 2103 report revealed that ''high-outlier hospitals charged Medicare substantially more for the same MS–DRGs, yet had similar average lengths of stay and CCRs,'' which the commenter asserted is directly opposite CMS' statement.

The commenter also asserted that it is neither consistent with the outlier statute nor reasonable for CMS, in modeling outlier payments for the upcoming fiscal year, to include outlier payments that were based on excessively high charges for particular MS–DRGs and not based on truly unusually high costs.

The commenter also asserted that CMS is fully authorized to reconcile the ''high-outlier'' payments and that according to its position in *Clarian Health* v. *Price,* No. 16–5307 (D.C. Cir.), all outlier payments are subject to reconciliation, regardless of whether they satisfy the reconciliation criteria. The commenter asserted that the discretion to subject all outlier payments to reconciliation is necessary to respond to hospitals, like those identified in the 2013 OIG Report, that seek to ''inappropriately maximize outlier payments'' by ''operating just below the threshold to avoid detection.''

Response: It is challenging to evaluate the assertion regarding a possible current correlation between high outlier hospitals and hospital charges because the commenter provided no information regarding its analysis. Also, even if there is some degree of correlation between the two, it does not necessarily mean categorically that these hospitals are inappropriately charging for purposes of Medicare outlier payments. In the absence of audits and analysis of these hospitals, the commenter is incorrect in concluding from any degree of correlation that every high outlier hospital must have charges not relative to their costs.

We also note we simply indicated that providers determine what they will charge for items, services, and procedures provided to patients, and these charges are the amount that the providers bill for an item, service, or procedure. We never stated that providers should disregard the PRM when setting those charges. Any assertion or suggestion that CMS condones hospitals inappropriately charging to maximize outlier payments is incorrect. In the June 9, 2003 final rule, we implemented the use of tentatively settled CCRs and the reconciliation policy directly in response to inappropriate charging. In addition, the PRM cited above states that charges should reflect ''the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients,'' and they ''should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.'' We expect hospitals to follow these guidelines and the manual when setting their charges.

With respect our statement from the FY 2015 IPPS/LTCH PPS final rule regarding CCRs, it is correct: CCRs will reflect low costs and high charges and, when applied to the charges on the claim, will result in less outlier payments because the costs of the case will be lower when compared to the total MS–DRG payments, excluding outlier payments. There are many factors that influence outlier payments. Consider a simplified example of two hospitals. One higher outlier hospital with average charges of $100,000 and average costs of $33,000 and a resulting CCR of 0.33, and another lower outlier hospital with average charges of $60,000 and average costs of $20,000 which also will result in a CCR of 0.33. As noted above, in the absence of audits and analysis of these hospitals, the commenter is incorrect in concluding from the fact that one hospital has higher charges and costs but the same CCR that the higher outlier hospital must have charges not relative to their costs. The higher outlier hospital may treat more resource intensive patients, which would factor into the aggregate outlier payments the hospital receives. Length of stay is not an exclusive measure of resource intensity.

For similar reasons, the commenter is incorrect that the inclusion of hospitals with higher charges in our estimation of the outlier threshold means that we include ''excessively high charges for particular MS–DRGs and not based on truly unusually high costs.''

We agree with the commenter that CMS has broad authority to reconcile outlier payments. However, we disagree that it is necessary to reconcile all outlier payments in order to address any individual circumstances where we believe reconciliation may be appropriate. As discussed in the June 9, 2003 Outlier Final Rule (68 FR 34503), we acknowledged the commenters' concerns about the administrative costs associated with reprocessing and reconciling all inpatient claims and the desirability of limiting which hospitals' outlier payments will be reconciled. Therefore, we agreed that any reconciliation of outlier payments should be done on a limited basis. As described in sections IV.H. and IV.I., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments will continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment

methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2019, we proposed allocating an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2019, we proposed to include estimated FY 2019 uncompensated care payments in the computation of the outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We proposed a threshold of $27,545 and calculated total operating Federal payments of $92,908,351,672 and total outlier payments of $4,738,377,622. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target. As a result, we proposed an outlier fixed-loss cost threshold for FY 2019 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $27,545.

Comment: One commenter stated that, in the proposed rule, CMS indicated that it divided total outlier payments ($4,738,377,622) by total operating Federal payments plus total outlier payments ($92,908,351,672 + $4,738,377,622) to calculate the Agency's 5.1 percent target. However, the commenter stated, $4,738,377,622/($92,908,351,672 + $4,738,377,622) does not yield 5.1 percent. Instead, the commenter strared, it yields approximately 4.85 percent. The commenter added that, in fact, 5.1 percent is the quotient of $4,738,377,622/$92,908,351,672. Thus, based on that description, the commenter stated that it appears that CMS has mistakenly based the proposed outlier threshold on outlier payments totaling only 4.85 percent and, consequently, set the proposed outlier threshold too high.

Response: The commenter is correct. We inadvertently referred to total operating payments of $92,908,351,672 in the proposed rule, when that figure reflected the sum of total operating Federal payments and total outlier payments. The corrected total operating Federal payments for the proposed rule is $88,169,974,050. Dividing the proposed total outlier payments of $4,738,377,622 by the corrected proposed total operating Federal payments of $88,169,974,050 plus proposed total outlier payments of $4,738,377,622 yields the 5.1 percent target. Therefore we believe that the proposed outlier threshold and the subsequent outlier payments were appropriately calculated. We thank the commenter for noting this error.

Comment: One commenter believed that it is important that CMS accurately calculate prior year actual payment comparisons to the 5.1 percent target. The commenter asserted that it is not possible for CMS to appropriately modify the methodology to achieve an accurate result if CMS is not aware of, or misinformed about, inaccuracies resulting from the prior year's methodology. The commenter cited the FY 2017 IPPS/LTCH PPS proposed rule as an example where CMS indicated that actual outlier payments for FY 2015 were approximately 4.68 percent of overall payments. The commenter stated that it was concerned that CMS believed the Agency would reach the 5.1 percent target for FY 2015 only to learn that the original estimate was overestimated and still raise the threshold for the subsequent year.

One commenter noted that the final outlier threshold established by CMS is always significantly lower than the threshold set forth in the proposed rule. The commenter believed the decline is most likely due to the use of updated CCRs or other data in calculating the final threshold. The commenter questioned whether CMS used more updated data for the FY 2017 and FY 2018 proposed rules as compared to prior years to calculate the proposed threshold. The commenter stated that, if this was the case, the use of more updated data may account for the decreased variance seen between the proposed and final thresholds in FYs 2017 and 2018 as compared to prior years. The commenter stated that this emphasizes that CMS must use the most recent data available when the Agency calculates the outlier threshold.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer readers to that rule for our response. Regarding the data used for the FY 2017 proposed rule and final rule, we used the same update of the MedPAR data as in prior fiscal years. Specifically, we use the December update of the MedPAR for the proposed rule and the March update of the MedPAR for the final rule. Also, in addition to the CCRs that can change from the proposed rule to the final rule, other factors such as the market basket typically change. For example, in the proposed rule, the market basket was 2.8 percent, and for this final rule, the market basket is 2.9 percent. Focusing only on the market basket, a higher market basket will increase the amount of Federal payments (a higher standardized amount) and lower the amount of total outlier payments requiring a lower outlier threshold to meet the 5.1 percent target. Therefore, the result of a lower or higher outlier threshold in the final rule when comparing to the proposed rule can be as a result of different variables.

Comment: Commenters expressed concerned with the increase of the outlier threshold from $26,601 in FY 2018 to $27,545 in FY 2019. They stated that the continued rise in the outlier threshold results in hospitals experiencing higher losses in order to receive payment relief, in particular.

One commenter requested CMS to examine the reasons for the continued rise in the outlier threshold and to identify whether interventions can be taken to ensure outlier payments remain equitable for hospitals. Another commenter suggested a reduction to the outlier threshold amount. Another commenter noted that the proposed FY 2019 outlier threshold of $27,545 is a 3.5 percent increase over the FY 2018 outlier threshold. This commenter stated that while CMS has not made any methodological changes to its determination of the outlier threshold, its rise is resulting in hospitals having to experience higher losses in order to receive any payment relief.

One commenter noted that CMS' estimate of FY 2017 outlier payments in the proposed rule was 5.53 percent, which is above the 5.1 percent target but falls within the statutory 5.0 to 6.0 percent outlier payment range. The commenter favored a simplified methodology and believed that, by applying a 2-year charge inflation factor and a 1-year CCR factor, CMS is inadvertently compounding its charge increase with lower costs and overstating the outlier threshold. The commenter suggested that CMS apply the following formula to compute the FY 2019 outlier threshold: FFY 2019 charge inflator Error = (9.5% − 8.5868% = 0.9132%)/9.5% = 9.61% Overstatement *Suggested FY 2019 Outlier Threshold* = $27,545 (proposed 2019) * (100% − 9.61% = 90.39%) = $24,897. The commenter concluded that the FY 2019 fixed-loss cost threshold should not exceed $24,897.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50379) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49783) and refer readers to those final rules for our complete responses. We also note that the final outlier threshold for FY 2019 (finalized below at $25,769) is lower than the final threshold for FY 2018 ($26,537).

Comment: One commenter asked that CMS consider whether it is appropriate to include extreme cases when calculating the

threshold. The commenter explained that high charge cases have a significant impact on the threshold. The commenter observed that the amount of cases with over $1.5 million in charges has increased significantly from FY 2011 (926 cases) to FY 2017 (2,291 cases). The commenter believed that the impact of these cases will cause the threshold to rise and recommended that CMS consider the removal of high charge cases from the calculation of the threshold.

Response: As we explained when responding to a similar comment in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38526), the methodology used to calculate the outlier threshold includes all claims in order to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We believe excluding these cases would artificially lower the threshold. We believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we disagree with the commenter.

Comment: Some commenters believe that an error exists in the calculation of the proposed FY 2019 outlier threshold related to the use of an incorrect national average CCR. These commenters did not provide any additional details on the possible nature of the error, but urged CMS to reevaluate the outlier calculation process.

Response: We appreciate commenters pointing this potential error. However, we were unable to identify such error. We have reviewed our outlier calculations for this final rule to ensure the national average CCR was calculated using the most recent available data at the time of the development of the final rule.

After consideration of the public comments we received, we are not making any changes to our methodology in this final rule for FY 2019. Therefore, we are using the same methodology we proposed to calculate the final outlier threshold. We note that, as stated above, we will consider for FY 2020 using data that commenters can access earlier to validate the charge inflation factor.

Similar to the table provided in the proposed rule, for this final rule, we are providing the following table that displays covered charges and cases by quarter in the periods used to calculate the charge inflation factor based on the latest claims data from the MedPAR file.

Quarter	Covered charges (April 1, 2016, through March 31, 2017)	Cases (April 1, 2016, through March 31, 2017)	Covered charges (April 1, 2017, through March 31, 2018)	Cases (April 1, 2017, through March 31, 2018)
April–June	$133,106,496,424	2,356,775	$137,726,975,443	2,319,109
July–September	139,415,422,805	2,413,871	142,676,638,337	2,363,685
October–December	151,053,166,855	2,559,371	121,360,081,623	1,983,155
January–March	136,264,070,864	2,415,120	142,121,633,027	2,407,887
Total	559,839,156,948	9,745,137	543,885,328,430	9,073,836

Under our current methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2019, we compared the average covered charge per case of $57,448 ($559,839,156,948/9,745,137) from the third quarter of FY 2016 through the second quarter of FY 2017 (April 1, 2016, through March 31, 2017) to the average covered charge per case of $59,939.96 ($543,885,328,430/9,073,836) from the third quarter of FY 2017 through the second quarter of FY 2018 (April 1, 2017, through March 31, 2018). This rate-of-change was 4.3 percent (1.04338) or 8.9 percent (1.08864) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

Similar to the proposed rule, for this final rule, we have made available a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor on the CMS website at: *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left titled ''FY 2019 IPPS Final Rule Home Page'' and then click the link ''FY 2019 Final Rule Data Files'').

As we have done in the past, we are establishing the FY 2019 outlier threshold using hospital CCRs from the March 2018 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of the final rule. We applied the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described below to hospitals assigned the statewide average CCR. For FY 2019, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below).

For this final rule, as we have done since FY 2014, we are adjusting the CCRs from the March 2018 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2017 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2018 update of the PSF. We note that we used total transfer-adjusted cases from FY 2017 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the methodology above, for this final rule, we calculated a March 2017 operating national average case-weighted CCR of 0.265819 and a March 2018 operating national average case-weighted CCR of 0.260874. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2017 operating national average case-weighted CCR from the March 2018 operating national average case-weighted CCR and then dividing the result by the March 2017 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.981397.

We used the same methodology above to adjust the capital CCRs. Specifically, for this final rule, we calculated a March 2017 capital national average case-weighted CCR of 0.022671 and a March 2018 capital national average case-weighted CCR of 0.021554. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2017 capital national average case-weighted CCR from the March 2018 capital national average case-weighted CCR and then dividing the result by the March 2017 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.950739.

As discussed above, similar to the proposed rule, for FY 2019, we applied the following policies (as discussed in more details above):

- In accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States.
- As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2019 outlier payments, we

did not make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement.

- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We used a threshold of $25,769 and calculated total operating Federal payments of $88,484,589,041 and total outlier payments of $4,755,375,555. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target (($88,484,589,041/$93,239,964,596) × 100 = 5.1 percent). As a result, we are finalizing an outlier fixed-loss cost threshold for FY 2019 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $25,769.

(2) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2019 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.06 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, as we proposed, we reduced the FY 2019 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors applied to the standardized amount based on the FY 2019 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948999	0.949431

We applied the outlier adjustment factors to the FY 2019 payment rates after removing the effects of the FY 2018 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.159 or capital CCRs greater than 0.151, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the internet on the CMS website) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the above range. These statewide average ratios will be effective for discharges occurring on or after October 1, 2018 and will replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B will be used during FY 2019 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS website: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) Alternative Considered for a Potential Change to the CCRs Used for Outliers, New Technology Add-on Payments, and Payments to IPPS-Excluded Cancer Hospitals for Chimeric Antigen Receptor (CAR) T-Cell Therapy

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20583), we stated we believe that, in the context of the pending new technology add-on payment applications for KYMRIAH® and YESCARTA®, there may also be merit in the suggestion from the public to allow hospitals to utilize a CCR specific to procedures involving the ICD–10–PCS procedures codes describing CAR T-cell therapy drugs for FY 2019 as part of the determination of the cost of a case for purposes of calculating outlier payments for individual FY 2019 cases, new technology add-on payments, if approved, for individual FY 2019 cases, and payments to IPPS-excluded cancer hospitals beginning in FY 2019.

We invited public comments on this alternative approach for FY 2019. We also invited public comments on how this payment alternative would affect access to care, as well as how it affects incentives to encourage lower drug prices, which is a high priority for this Administration. In addition, we stated that we were considering alternative approaches and authorities to encourage value-based care and lower drug prices. We solicited comments on how the payment methodology alternatives may intersect and affect future participation in any such alternative approaches. A summary of those comments and our responses can be found in section II.F.2.d. of the preamble of this final rule.

As also discussed in section II.F.2.d. of the preamble of this final rule, building on President Trump's *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,* the CMS Center for Medicare and Medicaid Innovation (Innovation Center) solicited public comment in the CY 2019 OPPS/ASC proposed rule on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out of pocket spending. Given the relative newness of CAR T-cell therapy, the potential model, and our request for feedback on this model approach, we believe it would be premature to adopt changes to our existing payment mechanisms for FY 2019, including allowing hospitals to utilize a CCR specific to procedures involving the ICD–10–PCS procedures codes describing CAR T-cell therapy drugs for FY 2019 as part of the determination of the cost of a case for purposes of calculating outlier payments for individual FY 2019 cases, new technology add-on payments for individual FY 2019 cases, and payments to IPPS-excluded cancer hospitals beginning in FY 2019.

(4) FY 2017 Outlier Payments

Our current estimate, using available FY 2017 claims data, is that actual outlier payments for FY 2017 were approximately 5.57 percent of actual total MS–DRG payments. Therefore, the data indicate that,

for FY 2017, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2017. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2017 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2018 will not be available until after September 30, 2018, we are unable to provide an estimate of actual outlier payments for FY 2018 based on FY 2018 claims data in this final rule. We will provide an estimate of actual FY 2018 outlier payments in the FY 2020 IPPS/LTCH PPS proposed rule.

Comment: One commenter noted that, in the proposed rule, CMS stated that actual outlier payments for FY 2017 were approximately 5.53 percent of total MS–DRG payments. The commenter performed its own analysis and concluded that outlier payments for FY 2017 are approximately 5.30 percent of total MS–DRG payments. The commenter was concerned that CMS' estimate was overstated.

Response: We thank the commenter for the comments. We reviewed our data to ensure the estimate provided is accurate. Therefore, we believe we have provided a reliable estimate of the outlier percentage for FY 2017. The commenter did not provide details regarding the discrepancy. We welcome additional suggestions from the public, including the commenter, to improve the accuracy of our estimate of actual outlier payments.

5. FY 2019 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2019. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 68.3 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2019.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2019 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similar to above, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2018 national standardized amount to the FY 2019 national standardized amount. The second through fifth columns display the changes from the FY 2018 standardized amounts for each applicable FY 2019 standardized amount. The first row of the table shows the updated (through FY 2018) average standardized amount after restoring the FY 2018 offsets for outlier payments and the geographic reclassification budget neutrality. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2018 adjustment factors are not removed from this table.

CHANGES FROM FY 2018 STANDARDIZED AMOUNTS TO THE FY 2019 STANDARDIZED AMOUNTS

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
FY 2018 Base Rate after removing: 1. FY 2018 Geographic Reclassification Budget Neutrality (0.987985) 2. FY 2018 Operating Outlier Offset (0.948998)	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36. Nonlabor (30.4%): $1,884.07. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92. Nonlabor (38%): $2,258.50.	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36. Nonlabor (30.4%): $1,884.07. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92. Nonlabor (38%): $2,258.50.	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36. Nonlabor (30.4%): $1,884.07. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92. Nonlabor (38%): $2,258.50.	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36. Nonlabor (30.4%): $1,884.07. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92. Nonlabor (38%): $2,258.50.
FY 2019 Update Factor	1.0135	0.99175	1.00625	0.9845.
FY 2019 MS-DRG Recalibration Budget Neutrality Factor.	0.997192	0.997192	0.997192	0.997192.
FY 2019 Wage Index Budget Neutrality Factor.	1.000748	1.000748	1.000748	1.000748.
FY 2019 Reclassification Budget Neutrality Factor.	0.985932	0.985932	0.985932	0.985932.
FY 2019 Operating Outlier Factor	0.948999	0.948999	0.948999	0.948999.
FY 2019 Rural Demonstration Budget Neutrality Factor.	0.999467	0.999467	0.999467	0.999467.
Adjustment for FY 2019 Required under Section 414 of Public Law 114–10 (MACRA).	1.005	1.005	1.005	1.005.
National Standardized Amount for FY 2019 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7).	Labor: $3,858.62 Nonlabor: $1,790.90	Labor: $3,775.81 Nonlabor: $1,752.47	Labor: $3,831.02 Nonlabor: $1,778.09	Labor: $3,748.21. Nonlabor: $1,739.66.

CHANGES FROM FY 2018 STANDARDIZED AMOUNTS TO THE FY 2019 STANDARDIZED AMOUNTS—Continued

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
National Standardized Amount for FY 2019 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $3,502.70 ..... Nonlabor: $2,146.82	Labor: $3,427.53 ..... Nonlabor: $2,100.75	Labor: $3,477.65 ..... Nonlabor: $2,131.46	Labor: $3,402.48. Nonlabor: $2,085.39.

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the labor-related and nonlabor-related shares that we used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2019. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2019, as discussed in section IV.B.3. of the preamble of this final rule, we are applying a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2019 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2018, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530 through 38531), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, for FY 2019, as we proposed, we are continuing to use the same COLA factors in FY 2019 that were used in FY 2018 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the COLA factors for FY 2019.

FY 2019 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur at the same time as the update to the labor-related share of the IPPS market basket (no later than FY 2022).

C. Calculation of the Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2019

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2019 equals the Federal rate (which includes uncompensated care payments).

Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section V.G. of the preamble of this final rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2019 equals the higher of the applicable

Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2019 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

1. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula below is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described above) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight for each claim based on the ICD–10–CM procedure and diagnosis codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described above.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))
—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)
—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)
—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount
—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)
—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)
—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor
—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the total claim payment amount. As noted in the formula above, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted above, as discussed in section IV.G. of the preamble of this FY 2019 IPPS/LTCH PPS final rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018, enacted February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2019

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2019	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.725	−0.725
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.175	0	−2.175
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.35	−0.825	0.625	−1.55

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this final rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital-specific rate for an SCH or an MDH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor of 0.997192, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH will receive for its discharges beginning on or after October 1, 2018. We note that, in this final rule, for FY 2019, we are not making a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2019

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the capital Federal rate for FY 2019, which will be effective for discharges occurring on or after October 1, 2018.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2019

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2019. In particular, we explain why the FY 2019 capital Federal rate will increase approximately 1.27 percent, compared to the FY 2018 capital Federal rate. As discussed in the impact analysis in Appendix A to this final rule, we estimate that capital payments per discharge will increase approximately 2.1 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2019 under that framework is 1.4 percent based on a projected 1.4 percent increase in the 2014-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2019 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are applying in the update framework for FY 2019.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2019, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will equal 0.5 percent for FY 2019. The net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the net adjustment for case-mix change in FY 2019 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2017 DRG reclassification and recalibration as part of our update for FY 2019. We assume, for purposes of this adjustment, that the estimate of FY 2017 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, as we proposed, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2019.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input

price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of 0.0 percentage point was calculated for the FY 2017 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2017 CIPI (1.2 percent) used in calculating the FY 2017 update factor was 0.0 percentage point higher than actual realized price increases (1.2 percent). As this does not exceed the 0.25 percentage point threshold, as we proposed, we are not making an adjustment for forecast error in the update for FY 2019.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, as we proposed, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2019 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2019, we are using an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2012 and extending through FY 2016. Based on these data, we estimated that case-mix constant intensity declined during FYs 2012 through 2016. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity will decline during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2019. Therefore, as we proposed, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2019.

Above we described the basis of the components we used to develop the 1.4 percent capital update factor under the capital update framework for FY 2019, as shown in the following table.

CMS FY 2019 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.4
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.4
Effect of FY 2017 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.4

*The capital input price index represents the 2014-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2018 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2019. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2018, Chapter 3, available on the website at: *http://www.medpac.gov*.)

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2018, we estimated that outlier payments for capital would equal 5.17 percent of inpatient capital-related payments based on the capital Federal rate in FY 2018. Based on the thresholds, as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 5.06 percent for inpatient capital-related payments based on the capital Federal rate in FY 2019. Therefore, we are applying an outlier adjustment factor of 0.9494 in determining the capital Federal rate for FY 2019. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2019 will be lower than the percentage for FY 2018.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2019 outlier adjustment of 0.9494 is a 0.12 percent change from the FY 2018 outlier adjustment of 0.9483. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2019 is 1.0012 (0.9494/0.9483) so that the outlier adjustment will increase the FY 2019 capital Federal rate by 0.12 percent compared to the FY 2018 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. The budget neutrality factor for DRG reclassifications and recalibration nationally is applied in determining the capital IPPS Federal rate, and is applicable for all hospitals, including those hospitals located in Puerto Rico.

To determine the factors for FY 2019, we compared estimated aggregate capital Federal rate payments based on the FY 2018 MS–DRG classifications and relative weights and the FY 2018 GAF to estimated aggregate capital Federal rate payments based on the FY 2018 MS–DRG classifications and relative weights and the FY 2019 GAFs. To achieve budget neutrality for the changes in the GAFs, based on calculations using updated data, we are applying an incremental budget neutrality adjustment factor of 0.9986 for FY 2019 to the previous cumulative FY 2018 adjustment factor.

We then compared estimated aggregate capital Federal rate payments based on the FY 2018 MS–DRG relative weights and the FY 2019 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the FY 2019 MS–DRG classifications and relative weights and the FY 2019 GAFs. The incremental adjustment factor for DRG classifications and changes in relative weights is 0.9989. The incremental adjustment factors for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2019 is 0.9975. We note that all the values are calculated with unrounded numbers.

The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG

relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor for changes in the GAF (including geographic reclassification) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

The incremental adjustment factor of 0.9975 (the product of the incremental national GAF budget neutrality adjustment factor of 0.9986 and the incremental DRG budget neutrality adjustment factor of 0.9989) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2019 geographic reclassification decisions made by the MGCRB compared to FY 2018 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2019

For FY 2018, we established a capital Federal rate of $453.95 (82 FR 46144 through 46145). We are establishing an update of 1.4 percent in determining the FY 2019 capital Federal rate for all hospitals. As a result of this update and the budget neutrality factors discussed earlier, we are establishing a national capital Federal rate of $459.72 for FY 2019. The national capital Federal rate for FY 2019 was calculated as follows:

- The FY 2019 update factor is 1.014; that is, the update is 1.4 percent.
- The FY 2019 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9975.
- The FY 2019 outlier adjustment factor is 0.9494.

We are providing the following chart that shows how each of the factors and adjustments for FY 2019 affects the computation of the FY 2019 national capital Federal rate in comparison to the FY 2018 national capital Federal rate as presented in the FY 2018 IPPS/LTCH PPS Correction Notice (82 FR 46144 through 46145). The FY 2019 update factor has the effect of increasing the capital Federal rate by 1.4 percent compared to the FY 2018 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.25 percent. The FY 2019 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.12 percent compared to the FY 2018 capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by approximately 1.27 percent, compared to the FY 2018 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2018 CAPITAL FEDERAL RATE AND FY 2019 CAPITAL FEDERAL RATE

	FY 2018	FY 2019	Change	Percent change
Update Factor [1]	1.0130	1.0140	1.014	1.40
GAF/DRG Adjustment Factor [1]	0.9987	0.9975	0.9975	−0.25
Outlier Adjustment Factor [2]	0.9483	0.9494	1.0012	0.12
Capital Federal Rate	$453.95	$459.72	1.0127	1.27 [3]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2018 to FY 2019 resulting from the application of the 0.9975 GAF/DRG budget neutrality adjustment factor for FY 2019 is a net change of 0.9975 (or –0.25 percent).

[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2019 outlier adjustment factor is 0.9494/0.9483 or 1.0012 (or 0.12 percent).

[3] Percent change may not sum due to rounding.

In this final rule, we also are providing the following chart that shows how the final FY 2019 capital Federal rate differs from the proposed FY 2019 capital Federal rate as presented in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20587 through 20589).

COMPARISON OF FACTORS AND ADJUSTMENTS: PROPOSED FY 2019 CAPITAL FEDERAL RATE AND FINAL FY 2019 CAPITAL FEDERAL RATE

	Proposed FY 2019	Final FY 2019	Change	Percent change *
Update Factor	1.0120	1.0140	1.0020	0.20
GAF/DRG Adjustment Factor	0.9997	0.9975	−0.0022	−0.22
Outlier Adjustment Factor	0.9494	0.9494	0.0000	0.00
Capital Federal Rate	$459.78	$459.72	0.9999	−0.01

* Percent change may not sum due to rounding.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2019

For purposes of calculating payments for each discharge during FY 2019, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier thresholds for FY 2019 are in section II.A. of this Addendum. For FY 2019, a case will qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.g.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the fixed-loss amount of $25,769.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior

capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this FY 2019 IPPS/LTCH PPS final rule, we are using the rebased and revised IPPS operating and capital market baskets that reflect a 2014 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of the FY 2018 IPPS/LTCH PPS final rule (82 FR 38170).

2. Forecast of the CIPI for FY 2019

Based on IHS Global Inc.'s second quarter 2018 forecast, for this final rule, we are forecasting the 2014-based CIPI to increase 1.4 percent in FY 2019. This reflects a projected 1.6 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.9 percent increase in other capital expense prices in FY 2019, partially offset by a projected 1.2 percent decline in vintage-weighted interest expense prices in FY 2019. The weighted average of these three factors produces the forecasted 1.4 percent increase for the 2014-based CIPI in FY 2019.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2019

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

The FY 2019 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, RNHCIs, and extended neoplastic disease care hospitals is the estimated percentage increase in the IPPS operating market basket for FY 2019, in accordance with applicable regulations at § 413.40. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20449), based on IGI's 2017 fourth quarter forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2019 was 2.8 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2019. For this final rule, based on IGI's 2018 second quarter forecast (which is the most recent available data), we estimated that the 2014-based IPPS operating market basket update for FY 2019 is 2.9 percent (that is, the estimate of the market basket rate-of-increase). Therefore, for children's hospitals, the 11 cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), extended neoplastic disease care hospitals, and RNHCIs, the FY 2019 rate-of-increase percentage that will be applied to the FY 2018 target amounts, in order to determine the FY 2019 target amounts is 2.9 percent.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this final rule and section V. of the Addendum to this final rule for the updated changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2019. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Changes to the Payment Rates for the LTCH PPS for FY 2019

A. LTCH PPS Standard Federal Payment Rate for FY 2019

1. Overview

In section VII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2019.

Under § 412.523(c)(3) of the regulations, for LTCH PPS FYs 2012 through 2017, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3)(A)(i) (citing sections 1886(b)(3)(B)(xi)(II), 1886(m)(3)(A)(ii), and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (c)(3)(xiii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312).)

Sections 1886(m)(3)(A) and 1886(m)(3)(C) of the Act specify that, for rate year 2010 and each subsequent rate year, except FY 2018, any annual update to the standard Federal payment rate shall be reduced:

- For rate year 2010 through 2019, by the ''other adjustment'' specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.D.2. of the preamble of this final rule.

This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.D.2.a. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the FY 2019 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice, for FY 2019, as we proposed, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2019, we also are making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2019 LTCH PPS standard Federal payment rate, as we proposed, we are applying a budget neutrality adjustment factor for the changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4) and a temporary budget neutrality adjustment factor to LTCH PPS standard Federal payment rate cases only for the cost of the elimination of the 25-percent threshold policy for FY 2019 (discussed in VII.E. of the preamble of this final rule).

In this FY 2019 IPPS/LTCH PPS final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.35 percent. Accordingly, under § 412.523(c)(3)(xv), we are applying a factor of 1.0135 to the FY 2018 LTCH PPS standard Federal payment rate of $41,415.11 to determine the FY 2019 LTCH PPS standard Federal payment rate. Also, under § 412.523(c)(3)(xv), applied in conjunction with the provisions of § 412.523(c)(4), we are establishing an annual update to the LTCH PPS standard Federal payment rate of -0.65 percent (that is, an update factor of 0.9935) for FY 2019 for LTCHs that fail to submit the required quality reporting data for FY 2019 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also are applying an area wage level budget neutrality factor to the FY 2019 LTCH PPS standard Federal payment rate of 0.999713 based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard

Federal rate payments. Finally, we are applying a temporary budget neutrality adjustment factor of 0.990884 to LTCH PPS standard Federal payment rate cases only for the cost of the elimination of the 25-percent threshold policy for FY 2019 (discussed in VII.E. of the preamble of this final rule). Accordingly, we are establishing an LTCH PPS standard Federal payment rate of $41,579.65 (calculated as $41,415.11 × 1.0135 × 0.999713 × 0.990884) for FY 2019 (calculations performed on rounded numbers). For LTCHs that fail to submit quality reporting data for FY 2019, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $40,759.12 (calculated as $41,415.11 × 0.9935 × 0.999713 × 0.990884) (calculations performed on rounded numbers) for FY 2019.

We did not receive any public comments on the proposed development of the FY 2019 LTCH PPS standard Federal payment rate. Therefore, we are finalizing our proposals as described above, without modification.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2019

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

2. Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area. (Information on OMB's MSA delineations based on the 2010 standards can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf.*)

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. We adopted these labor market area delineations because they are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that these OMB delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. We adopted the updates contained in OMB Bulletin No. 15–01, as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913 through 56914). On August 15, 2017, OMB issued OMB Bulletin No. 17–01 that updated and superseded Bulletin No. 15–01. As discussed in the proposed rule and in section III.A.2. of the preamble of this final rule, OMB Bulletin No. 17–01 and its attachments provide detailed information on the update to statistical areas since the July 15, 2015 release of Bulletin No. 15–01 and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014, and July 1, 2015. A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

OMB Bulletin No. 17–01 made the following change that is relevant to the LTCH PPS CBSA-based labor market area (geographic classification) delineations:

- Twin Falls, ID, with principal city Twin Falls, ID and consisting of counties Jerome County, ID and Twin Falls County, ID, which was a Micropolitan (geographically rural) area, now qualifies as an urban area under new CBSA 46300 entitled Twin Falls, ID.

This change affects all providers located in CBSA 46300, but our database shows no LTCHs located in CBSA 46300.

We believe that this revision to the CBSA-based labor market area delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, as we proposed, we are adopting this revision under the LTCH PPS, effective October 1, 2018. Accordingly, the FY 2019 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website) reflect the revision to the CBSA-based labor market area delineations described above. We note that, as discussed in section III.A.2. of the preamble of this final rule, the revision to the CBSA-based delineations also is being used under the IPPS.

We did not receive any public comments in response to our proposal.

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH-specific market basket. In addition, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH-specific market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) As noted previously, we rebased and revised the 2009-based LTCH-specific market basket to reflect a 2013 base year. In conjunction with that policy, as discussed in section VII.D. of the preamble of this FY 2019 IPPS/LTCH PPS final rule, as we proposed, we are establishing that the LTCH PPS labor-related share for FY 2019 is the sum of the FY 2019 relative importance of each labor-related cost category in the 2013-based LTCH market basket using the most recent available data.

In the proposed rule, we proposed to establish that the labor-related share for FY 2019 includes the sum of the labor-related

portion of operating costs from the 2013-based LTCH market basket (that is, the sum of the FY 2019 relative importance share of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the Capital-Related cost weight from the 2013-based LTCH PPS market basket. Based on IGI's fourth quarter 2017 forecast of the 2013-based LTCH market basket, we proposed to establish a labor-related share under the LTCH PPS for FY 2019 of 66.2 percent. (We noted that a proposed labor-related share of 66.2 percent was the same as the labor-related share for FY 2018, and although the relative importance of some components of the market basket have changed, the proposed labor-related share remained at 66.2 percent when aggregating these components and rounding to one decimal.) This proposed labor-related share was determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares. Consistent with our historical practice, we also proposed that if more recent data became available, we would use that data, if appropriate, to determine the final FY 2019 labor-related share in the final rule.

We did not receive any public comments in response to our proposals. Therefore, we are finalizing our proposals, without modification.

In this final rule, we are establishing that the labor-related share for FY 2019 includes the sum of the labor-related portion of operating costs from the 2013-based LTCH market basket (that is, the sum of the FY 2019 relative importance share of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the Capital-Related cost weight from the 2013-based LTCH PPS market basket. Based on IGI's second quarter 2018 forecast of the 2013-based LTCH market basket, consistent with our proposal, we are establishing a labor-related share under the LTCH PPS for FY 2019 of 66.0 percent. This labor-related share is determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares.

The labor-related share for FY 2019 is the sum of the FY 2019 relative importance of each labor-related cost category, and reflects the different rates of price change for these cost categories between the base year (2013) and FY 2019. The sum of the relative importance for FY 2019 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) is 61.8 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (the same percentage applied to the 2009-based LTCH-specific market basket). Because the relative importance for capital-related costs under our policies is 9.1 percent of the 2013-based LTCH market basket in FY 2019, as we proposed, we are taking 46 percent of 9.1 percent to determine the labor-related share of capital-related costs for FY 2019 (0.46×9.1). The result is 4.2 percent, which we added to 61.8 percent for the operating cost amount to determine the total labor-related share for FY 2019. Therefore, as we proposed, we are establishing that the labor-related share under the LTCH PPS for FY 2019 is 66.0 percent.

4. Wage Index for FY 2019 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38538 through 38539), we calculated the FY 2018 LTCH PPS area wage index values using the same data used for the FY 2018 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2014), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2018 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, as discussed in the FY 2019 IPPS/LTCH PPS proposed rule, to determine the applicable area wage index values for the FY 2019 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we proposed to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2015, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act because these data were the most recent complete data available. We also note that these are the same data we are using to compute the FY 2019 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule. We proposed to compute the FY 2019 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, labor market area delineations, including the updates, as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We also proposed to continue continuing to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2019, we proposed to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data will be determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data will be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

We did not receive any public comments in response to our proposals. Therefore, we are finalizing our proposals, without modification.

Based on the FY 2015 IPPS wage data that we used to determine the FY 2019 LTCH PPS standard Federal payment rate area wage index values, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the FY 2019 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2015 IPPS wage data that we used to determine the FY 2019 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2019. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future. The FY 2019 LTCH PPS standard Federal payment rate wage index values that will be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2018, through September 30, 2019, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website.

5. Budget Neutrality Adjustment for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

In the FY 2019 IPS/LTCH PPS proposed rule, we set forth the proposed methodologies we would use to determine an area wage level adjustment budget factor that would be applied to the LTCH PPS standard Federal payment rate for FY 2019. We did not receive any public comments in response to our proposals. Therefore, we are finalizing our proposals, without modification.

In this final rule, for FY 2019 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), we are applying an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we determined an area wage level adjustment budget neutrality factor that will be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2019 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2018 wage index values and the FY 2018 labor-related share of 66.2 percent (as established in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38314 and 38315)).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2019 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this final rule and available via the internet on the CMS website) and the FY 2019 labor-related share of 66.0 percent (based on the latest available data as previously discussed in this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2018 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2019 area wage level adjustments (calculated in Step 2) to determine the area wage level adjustment budget neutrality factor for FY 2019 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the FY 2019 area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2019 LTCH PPS standard Federal payment rate after the application of the FY 2019 annual update (discussed previously in section V.A. of this Addendum).

We note that, with the exception of cases subject to the transitional blend payment rate provisions and certain temporary exemptions for certain spinal cord specialty hospitals and certain severe wound cases, under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate had been in effect at the time of discharge to calculate the FY 2019 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above.

For this final rule, using the steps in the methodology previously described, we determined a FY 2019 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 0.999713. Accordingly, in section V.A. of the Addendum to this final rule, to determine the FY 2019 LTCH PPS standard Federal payment rate, we are applying an area wage level adjustment budget neutrality factor of 0.999713, in accordance with § 412.523(d)(4). The FY 2019 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this final rule reflects this adjustment factor.

C. LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology described above every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2018 (82 FR 38539 through 38540).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in the FY 2019 IPPS/LTCH PPS proposed rule, for FY 2019, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we proposed to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2016 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2018 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2018 COLA factors, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540).)

We did not receive any public comments on our proposal. Therefore, we are adopting our proposal, without modification. Consistent with our historical practice, we are establishing that the COLA factors shown in the following table will be used to adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2019

Area	FY 2018 and FY 2019
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 2-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted above, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, as we proposed, we used the most recent data available to determine the LTCH total CCR ceiling for FY 2019 in this final rule. Specifically, in this final rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2018 update of the Provider Specific File (PSF), which is the most recent data available, we are establishing an LTCH total CCR ceiling of 1.27 under the LTCH PPS for FY 2019 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described above, without modification.

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(C)(*2*), the current SSO policy at § 412.529(f)(4)(iii)(B), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it

is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2018 update of the PSF, as we proposed, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2018, through September 30, 2019, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the internet on the CMS website). Consistent with our historical practice, as we also proposed, we used more recent data to determine the LTCH PPS statewide average total CCRs for FY 2019 in this final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in that area as of March 2018. Therefore, consistent with our existing methodology, as we proposed, we used the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one IPPS provider whose CCR is an atypical 1.215. Because this is much higher than the statewide urban average and furthermore implies costs exceeded charges, as with Connecticut, as we proposed, we used the national average total CCR for rural hospitals for hospitals located in rural Massachusetts. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, as we proposed, we are continuing to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described above, without modification.

d. Reconciliation of HCO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Changes to High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Establishment of the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2019

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20595), we proposed to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2019 using the best available data that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in that proposed rule).

Specifically, based on the most recent complete LTCH data available at that time (that is, LTCH claims data from the December 2017 update of the FY 2017 MedPAR file and CCRs from the December 2017 update of the PSF), we determined a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2019 of $30,639 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2019 payments for such cases. Under this proposal, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,639).

Comment: Several commenters expressed concerns with the proposed fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate, noting that the proposed fixed-loss amount, 11.9 percent greater than the fixed-loss amount in FY 2018, is the third consecutive year with a greater than 10-percent increase. Moreover, some commenters noted that the provider data used for the proposed rule included one new provider with a CCR of 1.029 which accounted for 2.65 percent of all outlier payments, despite accounting for only 0.116 percent of all LTCH PPS standard Federal

payment rate cases. Commenters attributed approximately $1,100 of the proposed increase to the fixed-loss amount to this one provider.

Response: In the FY 2019 IPPS/LTCH PPPS proposed rule (83 FR 20595), we noted that the proposed fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate in FY 2019 of $30,639 is higher than the FY 2018 fixed-loss amount of $27,381 for LTCH PPS standard Federal payment rate cases. However, based on the most recent available data at the time of the development of the proposed rule, we found that the current FY 2018 HCO threshold of $27,381 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 7.988 percent of the estimated total LTCH PPS payments in FY 2018, which exceeds the 7.975 percent target by 0.01 percentage points.

As described in the FY 2019 IPPS/LTCH PPS proposed rule (82 FR 20595), we used CCRs from the December 2017 update of the PSF as they were the best available data at that time, which included the provider with a CCR of 1.029 as point out by some commenters. We note that while a CCR over 1.0 is generally considered high, and is significantly higher than prior CCRs for that provider, a CCR of 1.029 is within the current CCR ceiling of 1.280 established in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38541). In addition, that provider's CCR was in the PSF with an effective date of July 1, 2016 and, therefore, was the CCR used to determine that provider's LTCH PPS payments (such as outliers and site neutral payment rate payments) until it was updated with an effective date of January 1, 2018, which, as anticipated by some commenters, has resulted in lowering the fixed-loss amount for FY 2019 as compared to the proposed FY 2019 fixed-loss amount of $30,639 (as described in more detail below). For these reasons, we did not believe it was inappropriate to use that provider's CCR for the calculations in the proposed rule.

Consistent with our historical practice of using the best data available, as we proposed, for this final rule we are using the best available data, including CCRs from the March 2018 update of the PSF as described below. We note that the CCR for the provider noted by the commenters has decreased from 1.029 to 0.323, which we used for the calculations in this final rule.

Comment: A few commenters requested that CMS provide more information regarding the fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate, specifically requesting the charge inflation factor for LTCH PPS standard Federal payment rate cases and an explanation on its calculation.

Response: We regret the inadvertent omission of the 2-year inflation factor from FY 2017 to FY 2019 in the FY 2019 IPPS/LTCH PPS proposed rule. Consistent with our historical approach, in the proposed rule we applied a factor based on IGI's most recent estimate of the 2013-based LTCH market basket increase from FY 2017 to FY 2019, which, at that time, was 5.3 percent. For this FY 2019 IPPS/LTCH PPS final rule, based on the Office of Actuary's most recent second quarter 2018 forecast of the 2013-based of the LTCH market basket increase from FY 2017 to FY 2019, we are using an inflation factor of 5.7 percent.

Comment: One commenter stated that, with the increasing the fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate over the past 5 years, the ''additional 'days of losses' covered by the HCO amount is now approaching 10 days'', and requested that CMS evaluate if the 8-percent outlier target is satisfactory under the LTCH PPS.

Response: We agree that an increase in the HCO amount can lead to an increase in the ''days of losses.'' However, a change to the HCO payment target for LTCH PPS standard Federal payment rate cases can only be accomplished through statute. Specifically, section 1886(m)(7) of the Act, requires that the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

Consistent with our historical practice of using the best data available, as we proposed, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2019 in this final rule, we used the most recent available LTCH claims data and CCR data. In this FY 2019 IPPS/LTCH PPS final rule, we are continuing to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2019 using the best available data that will maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in this final rule). Specifically, based on the most recent complete LTCH data available at this time (that is, LTCH claims data from the March 2018 update of the FY 2017 MedPAR file and CCRs from the March 2018 update of the PSF), we determined a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2019 of $27,124 that will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2019 payments for such cases. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are establishing a fixed-loss amount of $27,124 for LTCH PPS standard Federal payment rate cases for FY 2019. Under this policy, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,124).

We note that the fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate in FY 2019 of $27,124 is significantly lower than proposed FY 2019 fixed-loss amount of $30,639, and slightly lower than the FY 2018 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,381. This decrease is primarily attributable to the updated CCRs used for this final rule, including the provider discussed above whose CCR decreased from 1.029 to 0.323.

Based on the most recent available data at the time of this final rule, we found that the current FY 2018 HCO threshold of $27,381 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 7.4 percent of the estimated total LTCH PPS payments in FY 2018, which is below the 7.975 percent target by approximately 0.6 percentage points. We also note the change in our estimate of FY 2018 HCO payments between the proposed and final rule decreased from 8.0 percent to 7.4 percent, and this change is largely attributable to updates to CCRs, from the December 2017 update of the PSF to the March 2018 update of the PSF and includes the provider discussed above whose CCR decreased from 1.029 to 0.323.

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under § 412.525(a), site neutral payment rate cases receive an additional HCO payment for costs that exceed the HCO threshold that is equal to 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold (80 FR 49618 through 49629). In the following discussion, we note that the statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the LTCH PPS standard Federal payment rate amount for the discharge (§ 412.522(c)(3)). As such, for FY 2019 discharges paid under the transitional payment method, the discussion below pertains only to the site neutral payment rate portion of the blended payment rate under § 412.522(c)(3)(i).

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FY 2019, we continue to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2017 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2018, at that time our actuaries projected that the proportion of

cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2018 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2018. In particular, in FY 2018, we established the fixed-loss amount for site neutral payment rate cases as the FY 2018 IPPS fixed-loss amount of $26,537 (82 FR 46145).

As noted earlier, because not all claims in the data used for this final rule were subject to the site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2018 when developing a fixed-loss amount for site neutral payment rate cases for FY 2019. Because our actuaries continue to project that site neutral payment rate cases in FY 2019 will continue to mirror an IPPS case paid under the same MS–DRG, we continue to believe that it would be inappropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS. More specifically, as with FYs 2016 through 2018, our actuaries project that the costs and resource use for FY 2019 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. (Based on the most recent FY 2017 LTCH claims data, approximately 64 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 36 percent of LTCH cases would have been paid the site neutral payment rate for discharges occurring in FY 2017.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2019 is the IPPS fixed-loss amount for FY 2019. Therefore, consistent with past practice, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20595 and 20596), for FY 2019, we proposed that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we proposed a fixed-loss amount for site neutral payment rate cases of $27,545, which is the same proposed FY 2019 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to the proposed rule. We continue to believe that this policy would reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, for FY 2019, we proposed to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $27,545).

We did not receive any public comments on our proposals to use the FY 2019 IPPS fixed-loss amount and 5.1 percent HCO target for LTCH discharges paid at the site neutral payment rate in FY 2019. In this final rule, we are finalizing these proposals without modification.

Therefore, for FY 2019, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $25,769, which is the same FY 2019 IPPS fixed-loss amount discussed in section II.A.4.g.(1). of the Addendum to this final rule. We continue to believe that this policy will reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, under this policy, for FY 2019, we will calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed loss amount for site neutral payment rate cases of $25,769).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2019 would not result in any increase in estimated aggregate FY 2019 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments (or the portion of the blended payment rate payment for FY 2018 discharges occurring in LTCH cost reporting periods beginning before October 1, 2017) by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2019. In order to achieve this, for FY 2019, in general, as we proposed, we are continuing to use the policy adopted for FY 2018.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate our fixed-loss threshold of $25,769 results in HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2019 would not result in any increase in estimated aggregate FY 2019 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2019. In order to achieve this, for FY 2019, we proposed to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as $1.0 - 5.1/100 = 0.949$) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We noted that, consistent with the policy adopted for FY 2018, this proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

Comment: As was the case in the FY 2016 through FY 2018 rulemaking cycles, commenters again objected to the proposed site neutral payment rate HCO budget neutrality adjustment, claiming that it results in savings to the Medicare program instead of being budget neutral. The commenters' primary objection was again based on their belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (that is, a 5.1 percent adjustment on the operating IPPS

standardized amount), an ''additional'' budget neutrality factor is not necessary and is, in fact, duplicative.

Response: We continue to disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is inappropriate, unnecessary, or duplicative. As we discussed in response to similar comments (82 FR 38545 through 38546, 81 FR 57308 through 57309, and 80 FR 49621 through 49622), we have the authority to adopt the site neutral payment rate HCO policy in a budget neutral manner. More importantly, we continue to believe this budget neutrality adjustment is appropriate for reasons outlined in our response to the nearly identical comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57308 through 57309) and our response to similar comments in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49621 through 49622).

After consideration of the public comments we received, we are finalizing our proposal to apply a budget neutrality adjustment for HCO payments made to site neutral payment rate cases. Therefore, to ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2019 will not result any increase in estimated aggregate FY 2019 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate portion of the blended rate payment by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2019. In order to achieve this, for FY 2019, in this final rule, as proposed, we are applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate (without any applicable HCO payment).

E. Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that is based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2019, as discussed in greater detail in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20596) as well as in section IV.F.3. of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 67.51 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2018. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act will be adjusted to 50.63 percent (the product of 75 percent and 67.51 percent) and the resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2019, we projected that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 75.63 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 50.63 percent = 75.63 percent).

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20596), for FY 2019, we proposed to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 75.63 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we proposed that if more recent data became available, if appropriate, we would use that data to determine this factor in this final rule.

We did not receive any public comments in response to our proposal. In addition, there are no more recent data available to use that would affect the calculations determined in the proposed rule. Therefore, we are finalizing our proposal that, for FY 2019, the calculation of the ''IPPS comparable amount'' under § 412.529 includes an applicable operating Medicare DSH payment amount that is equal to 75.63 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. (We note that we also proposed that the ''IPPS equivalent amount'' under § 412.538 would include an applicable operating Medicare DSH payment amount that is equal to 75.63 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. However, as discussed in section VII.E. of the preamble of this final rule, we are finalizing our proposal to remove the provisions of § 412.538, and reserving this section.)

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2019

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the FY 2019 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this final rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the FY 2019 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, as we proposed, we are establishing an LTCH PPS standard Federal payment rate for FY 2019 of $41,579.65, as discussed in section V.A. of the Addendum to this final rule. We illustrate the

methodology to adjust the LTCH PPS standard Federal payment rate for FY 2019 in the following example:

Example:

During FY 2019, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in Chicago, Illinois (CBSA 16974). The FY 2019 LTCH PPS wage index value for CBSA 16974 is 1.0511 (obtained from Table 12A listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2019 of 0.9583 (obtained from Table 11 listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). The LTCH submitted quality reporting data for FY 2019 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2019, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2019 LTCH PPS standard Federal payment rate ($41,579.65) by the labor-related share (66.0 percent) and the wage index value (1.0511). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (34.0 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9583) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2019 ($41,189.62). The table below illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$41,579.65
Labor-Related Share	× 0.660
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $27,442.57
Wage Index (CBSA 16974)	× 1.0511
Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate	= $28,844.89
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($41,579.65 × 0.340)	+ $14,137.08
Adjusted LTCH PPS Standard Federal Payment Amount	= $42,981.97
MS–LTC–DRG 189 Relative Weight	× 0.9583
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $41,189.62

VI. Tables Referenced in This Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this final rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register**, as part of the annual proposed and final rules. However, similar to FYs 2012 through 2018, for the FY 2019 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register**, as part of the annual proposed and final rules.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49807), we streamlined and consolidated the wage index tables for FY 2016 and subsequent fiscal years.

As discussed in section III. J. of the preamble to this FY 2019 IPPS/LTCH PPS final rule, we are adding a new Table 4, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019,'' associated with this final rule. This table consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2019 identified by FIPS county code, the FY 2019 out-migration adjustment, and the number of years the adjustment will be in effect. We believe this new table will make the information more transparent and provide the public with easier access to this information. We intend to make the information available annually, via Table 4 in the IPPS/LTCH PPS proposed and final rules, and are including it among the tables associated with this FY 2019 IPPS/LTCH PPS final rule that are available via the internet on the CMS website.

As discussed in sections II.F.13., II.F.15.b. and d., II.F.16., and II.F.18. of the preamble of this final rule, we have developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2019: Table 6A.—New Diagnosis Codes; Table 6B.—New Procedure Codes; Table 6C.—Invalid Diagnosis Codes; Table 6D.—Invalid Procedure Codes; Table 6E.—Revised Diagnosis Code Titles; Table 6F.—Revised Procedure Code Titles; Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusion List; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusion List; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusion List; Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusion List; Table 6I.—Complete MCC List; Table 6I.1.—Additions to the MCC List; Table 6I.2.—Deletions to the MCC List; Table 6J.—Complete CC List; Table 6J.1.—Additions to the CC List; Table 6J.2.—Deletions to the CC List; Table 6K.—Complete List of CC Exclusions; and Table 6P.—ICD–10–CM and ICD–10–PCS Codes for MS–DRG Changes. Table 6P contains multiple tables, 6P.1c. through 6P.1f., that include the ICD–10–CM and ICD–10–PCS code lists relating to specific MS–DRG changes.

In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. However, as discussed in section IV.K. of the preamble of this final rule, we are not providing the hospital-level data as a table associated with this final rule. The hospital-level data for the FY 2019 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

As discussed in section II.H.1. of the preamble of this final rule, Table 10 that we have released in prior fiscal years contained the thresholds that we use to evaluate applications for new medical service and technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. In an effort to clarify for the public that the listed thresholds will be used for new technology add-on payment applications for the next fiscal year (in this case, for FY 2020) rather than the fiscal year that is otherwise the subject of the rulemaking (in this case, for FY 2019), we are providing the thresholds previously included in Table 10 as one of the publicly available data files posted via the internet on the CMS website for the rulemaking for the upcoming fiscal year at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, which is the same URL where the impact data files associated with the rulemaking for the applicable fiscal year are posted. We refer readers to section II.H.1. of the preamble of this final rule regarding our inclusion of the thresholds previously included in Table 10 as one of our public data files.

As discussed in section VII.B of the preamble of this final rule, in previous fiscal years, Table 13A.—Composition of Low-Volume Quintiles for MS–LTC–DRGs (which was listed in section VI. of the Addendum to the proposed and final rules and available via the internet on the CMS website) listed the composition of the low-volume quintiles for MS–LTC–DRGs for the respective year, and Table 13B.—No Volume MS–LTC–DRG Crosswalk (also listed in section VI. of the Addendum to the proposed and final rules and available via the internet on the CMS website) listed the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs). The information contained in Tables 13A and 13B is used in the development of Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges, which

contains the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases) for the respective fiscal year (and also is listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). Because the information contained in Tables 13A and 13B does not contain payment rates or factors for the applicable payment year, we are generally providing the data previously published in Tables 13A and 13B for each annual proposed rule and final rule as one of our supplemental data files via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* (that is, the same URL address where the impact data files associated with the rule are posted). To streamline the information made available to the public that is used in the annual development of Table 11, we believe that this change in the presentation of the information contained in Tables 13A and 13B will make it easier for the public to navigate and find the relevant data and information used for the development of payment rates or factors for the applicable payment year, while continuing to furnish the same information contained in the tables provided in previous fiscal years.

As discussed in section IV.H. of the preamble of this final rule, the final FY 2019 readmissions payment adjustment factors, which are typically included in Table 15 of the final rule, are not available at this time because hospitals have not yet had the opportunity to review and correct the data (program calculations based on the FY 2019 applicable period of July 1, 2014 to June 30, 2017) before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2019, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2019 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2018. We expect Table 15 will be posted on the CMS website in the fall of 2018.

In addition, Table 18 associated with this final rule contains the Factor 3 for purposes of determining the FY 2019 uncompensated care payment for all hospitals and identifies whether or not a hospital is projected to receive Medicare DSH payments and, therefore, eligible to receive the additional payment for uncompensated care for FY 2019. A hospital's Factor 3 determines the proportion of the aggregate amount available for uncompensated care payments that a Medicare DSH eligible hospital will receive under section 3133 of the Affordable Care Act.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this final rule are generally available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2019 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.''

Table 2.—Case-Mix Index and Wage Index Table by CCN—FY 2019
Table 3.—Wage Index Table by CBSA—FY 2019
Table 4.—List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019
Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2019
Table 6A.—New Diagnosis Codes—FY 2019
Table 6B.—New Procedure Codes—FY 2019
Table 6C.—Invalid Diagnosis Codes—FY 2019
Table 6D.—Invalid Procedure Codes—FY 2019
Table 6E.—Revised Diagnosis Code Titles—FY 2019
Table 6F.—Revised Procedure Code Titles—FY 2019
Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2019
Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2019
Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2019
Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2019
Table 6I.—Complete MCC List—FY 2019
Table 6I.1.—Additions to the MCC List—FY 2019
Table 6I.2.—Deletions to the MCC List—FY 2019
Table 6J.—Complete CC List—FY 2019
Table 6J.1.—Additions to the CC List—FY 2019
Table 6J.2.—Deletions to the CC List—FY 2019
Table 6K.—Complete List of CC Exclusions—FY 2019
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for MS–DRG Changes—FY 2019
Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2017 MedPAR Update—March 2018 GROUPER V35.0 MS–DRGs
Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2017 MedPAR Update—March 2018 GROUPER V36.0 MS–DRGs
Table 8A.—FY 2019 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—FY 2019 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 15.—FY 2019 Readmissions Adjustment Factors (We note that, as discussed earlier, Table 15 will be posted on the CMS website in the fall of 2018.)
Table 16A.—Updated Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2019
Table 18.—FY 2019 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2019 final rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1694–F:

Table 8C.—FY 2019 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2018 through September 30, 2019
Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2018 through September 30, 2019
Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2018 through September 30, 2019

TABLE 1A—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR

[(68.3 percent labor share/31.7 percent nonlabor share if wage index is greater than 1)—FY 2019]

Hospital submitted quality data and is a meaningful EHR user (update = 1.5 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.825 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.625 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR User (update = −1.55 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,858.62	$1,790.90	$3,775.81	$1,752.47	$3,831.02	$1,778.09	$3,748.21	$1,739.66

TABLE 1B—NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR

[(62 percent labor share/38 percent nonlabor share if wage index is less than or equal to 1)—FY 2019]

Hospital submitted quality data and is a meaningful EHR user (update = 1.35 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.825 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.625 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.55 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,502.70	$2,146.82	$3,427.53	$2,100.75	$3,477.65	$2,131.46	$3,402.48	$2,085.39

TABLE 1C—ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR

[(National: 62 percent labor share/38 percent nonlabor share because wage index is less than or equal to 1)—FY 2019]

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$3,502.70	$2,146.82

[1] For FY 2019, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—CAPITAL STANDARD FEDERAL PAYMENT RATE

[FY 2019]

	Rate
National	$459.72

TABLE 1E—LTCH PPS STANDARD FEDERAL PAYMENT RATE

[FY 2019]

	Full update (1.35 percent)	Reduced update * (−0.65 percent)
Standard Federal Rate	$41,579.65	$40,759.12

* For LTCHs that fail to submit quality reporting data for FY 2019 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also as we note below, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule, such as the updates to the IPPS and LTCH PPS rates, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the changes for FY 2019 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $4.8 billion increase in FY 2019 payments, primarily

driven by a combined $4.4 billion increase in FY 2019 operating payments and uncompensated care payments, and a combined $0.4 billion increase in FY 2019 capital payments, new technology add-on payments, and low-volume hospital payments. These changes are relative to payments made in FY 2018. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by $39 million in FY 2019 relative to FY 2018.

Our operating impact estimate includes the 0.5 percent adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this final rule. In addition, our operating payment impact estimate includes the 1.35 percent hospital update to the standardized amount (which includes the estimated 2.9 percent market basket update less 0.8 percentage point for the multifactor productivity adjustment and less 0.75 percentage point required under the Affordable Care Act). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule will affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this final rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2019, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case-mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific policies in the discussion of those policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 29 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of July 2018, there were 3,256 IPPS acute care hospitals included in our analysis. This represents approximately 54 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,398 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, extended neoplastic disease care hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2019 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2018, there were 98 children's hospitals, 11 cancer hospitals, 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 18 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 280 rehabilitation hospitals and 846 rehabilitation units, and approximately 417 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 538 psychiatric hospitals and 1,084 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, extended neoplastic disease care hospitals, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2019 percentage increase in the 2014-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's 2018 second quarter forecast of the 2014-based IPPS market basket increase, we are estimating the FY 2019 update to be 2.9 percent (that is, the estimate of the market basket rate-of-increase). We used the most recent data available for this final rule to calculate the IPPS operating market basket update for FY 2019. However, the Affordable Care Act requires an adjustment for multifactor productivity (0.8 percentage point for FY 2019) and a 0.75 percentage point reduction to the market basket update, resulting in a 1.35 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this final rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, extended neoplastic disease care hospitals, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2014-based IPPS operating market basket for FY 2019, estimated at 2.9 percent, without the reductions described previously under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2019 for operating costs of acute care hospitals. The FY 2019 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2019 operating payments will increase by 2.4 percent, compared to FY 2018. In addition to the applicable percentage increase, this amount reflects the 0.5 percent permanent adjustment to the standardized amount required under section 414 of the MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available claims data to enable us to estimate the impacts on payments per case of certain changes in this final rule. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented in this section are taken from the FY 2017 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2017 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, and the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2019 are discussed in section I.I. of this Appendix.

We discuss the following changes:

- The effects of the application of the adjustment required under section 414 of the MACRA and the applicable percentage increase (including the market basket update, the multifactor productivity adjustment, and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2015, compared to the FY 2014 wage data, to calculate the FY 2019 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2019.
- The effects of the rural floor with the application of the national budget neutrality factor to the wage index, and the expiration of the imputed floor.
- The effects of the frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2019. This provision is not budget neutral.
- The total estimated change in payments based on the FY 2019 policies relative to payments based on FY 2018 policies that include the applicable percentage increase of 1.35 percent (or 2.9 percent market basket update with a reduction of 0.8 percentage point for the multifactor productivity adjustment, and a 0.75 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the FY 2019 changes, our analysis begins with a FY 2018 baseline simulation model using: The FY 2018 applicable percentage increase of 1.35 percent, the 0.4588 percent adjustment to the Federal standardized amount, and the adjustment factor of (1/1.006) to both the national standardized amount and the hospital-specific rate; the FY 2018 MS–DRG GROUPER (Version 35); the FY 2018 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2018 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2019, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act will receive an applicable percentage increase of 0.625 percent. At the time this impact was prepared, 49 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2019 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2019 using a reduced update for these hospitals.

For FY 2019, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, for FY 2019, hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of −0.825 percent. At the time this impact analysis was prepared, 137 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2019 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the payment changes for FY 2019 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of –1.55 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 40 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2019 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2019 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the percent change in payments per case from FY 2018 to FY 2019. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2019 using an applicable percentage increase of 1.35 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.9 percent with a 0.8 percentage point reduction for the multifactor productivity adjustment and a 0.75 percentage point reduction, as required, under the Affordable Care Act. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users will receive an update of 0.625 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users will receive an update of −0.825 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users will receive an update of −1.55 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 1.35 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2018 to FY 2019 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2018 that are no longer reclassified in FY 2019. Conversely, payments may increase for hospitals not reclassified in FY 2018 that are reclassified in FY 2019.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2019. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,256 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,483 hospitals located in urban areas included in our analysis. Among these, there are 1,302 hospitals located in large urban areas (populations over 1 million), and 1,181 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 773 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2019 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,264, 1,317, 947, and 992, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,157 nonteaching hospitals in our analysis, 849 teaching hospitals with fewer than 100 residents, and 250 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, MDHs and RRCs). There were 327 RRCs, 312 SCHs, 140 MDHs, 134 hospitals that are both SCHs and RRCs, and 16 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total inpatient days. These data were taken from the FY 2016 or FY 2015 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2019. The second grouping shows the MGCRB rural reclassifications.

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2019

	Number of hospitals [1]	Hospital rate update and adjustment under MACRA (1) [2]	FY 2019 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2019 wage data with application of wage budget neutrality (3) [4]	FY 2019 MGCRB reclassifications (4) [5]	Rural floor with application of national rural floor budget neutrality (5) [6]	Application of the frontier wage index and out-migration adjustment (6) [7]	All FY 2019 changes (7) [8]
All Hospitals	3,256	1.8	0	0	0	0	0.1	2.4
By Geographic Location:								
Urban hospitals	2,483	1.8	0	0	−0.1	0	0.1	2.5
Large urban areas	1,302	1.8	0.1	0	−0.7	0	0	2.4
Other urban areas	1,181	1.8	0	0	0.5	0.1	0.2	2.5
Rural hospitals	773	1.5	−0.3	−0.1	1.2	−0.2	0.1	1.2
Bed Size (Urban):								
0–99 beds	644	1.7	−0.5	0.1	−0.7	0.1	0.2	1.7
100–199 beds	763	1.8	0	0	−0.1	0.1	0.2	2.2
200–299 beds	433	1.8	0	0	0.1	0	0.1	2.3
300–499 beds	424	1.8	0.1	0	−0.1	0	0.1	2.5
500 or more beds	219	1.8	0.1	0	−0.2	0	0	2.9
Bed Size (Rural):								
0–49 beds	306	1.4	−0.5	0	0.3	−0.2	0.2	0.9
50–99 beds	274	1.3	−0.4	0	0.7	−0.1	0.2	1.1
100–149 beds	108	1.6	−0.5	−0.1	0.9	−0.2	0	1.2
150–199 beds	45	1.7	−0.1	−0.2	2	−0.2	0.3	1.4
200 or more beds	40	1.7	0.1	−0.2	2.4	−0.2	0	1.6
Urban by Region:								
New England	113	1.8	0.1	−0.5	2.6	2.5	0.1	4.7
Middle Atlantic	310	1.8	0.2	0	0.3	−0.4	0.1	2.3
South Atlantic	401	1.8	0	−0.1	−0.5	−0.3	0	2.1
East North Central	386	1.8	0.1	−0.2	−0.4	−0.4	0.1	2.1
East South Central	147	1.8	0	0	−0.4	−0.3	0	2.1

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2019—Continued

	Number of hospitals [1]	Hospital rate update and adjustment under MACRA (1) [2]	FY 2019 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2019 wage data with application of wage budget neutrality (3) [4]	FY 2019 MGCRB reclassifications (4) [5]	Rural floor with application of national rural floor budget neutrality (5) [6]	Application of the frontier wage index and out-migration adjustment (6) [7]	All FY 2019 changes (7) [8]
West North Central	158	1.8	−0.1	0	−0.8	−0.3	0.6	2.1
West South Central	379	1.8	0	0.2	−0.7	−0.3	0	2.3
Mountain	164	1.7	−0.1	−0.7	−0.2	1.1	0.3	2.1
Pacific	374	1.8	−0.1	0.8	0.1	0.2	0.1	3.2
Puerto Rico	51	1.8	0	−1.2	−1.2	0.1	0.1	0.8
Rural by Region:								
New England	20	1.5	0.1	−0.5	1.5	−0.3	0	0.9
Middle Atlantic	53	1.5	−0.2	−0.1	0.7	−0.2	0.1	1.4
South Atlantic	122	1.6	−0.2	−0.2	1.7	−0.2	0.1	1.2
East North Central	114	1.5	−0.3	0.1	0.9	−0.1	0	1.1
East South Central	150	1.7	−0.1	−0.2	2.5	−0.3	0.1	1.8
West North Central	94	1.3	−0.5	0	0.1	0	0.2	0.9
West South Central	145	1.5	−0.3	0.2	1.3	−0.3	0.2	1.5
Mountain	52	1.3	−1.1	−0.4	0	−0.1	0.8	0.8
Pacific	23	1.4	−0.4	−0.2	0.8	−0.1	0	1
By Payment Classification:								
Urban hospitals	2,264	1.8	0	0	−0.6	0	0.1	2.3
Large urban areas	1,317	1.8	0.1	0	−0.7	0	0	2.4
Other urban areas	947	1.8	0	0	−0.3	0.2	0.2	2.1
Rural areas	992	1.7	−0.1	0	1.9	−0.1	0.1	2.7
Teaching Status:								
Nonteaching	2,157	1.7	−0.1	0	0.1	0.1	0.1	2.1
Fewer than 100 residents	849	1.8	0	0	−0.2	−0.1	0.2	2.2
100 or more residents	250	1.8	0.2	0	0.1	−0.1	0	3.1
Urban DSH:								
Non-DSH	520	1.8	−0.3	−0.2	−0.2	−0.1	0.2	2.1
100 or more beds	1,462	1.8	0.1	0	−0.6	0.1	0.1	2.3
Less than 100 beds	367	1.7	−0.2	0.3	−0.6	0.1	0.1	1.9
Rural DSH:								
SCH	256	1.2	−0.6	−0.1	0	−0.1	0	0.7
RRC	382	1.7	0	0.1	2.3	−0.2	0.1	3.1
100 or more beds	33	1.8	0	−0.6	1	0.2	0.1	2.9
Less than 100 beds	236	1.6	−0.3	0	0.8	−0.2	0.3	1.5
Urban teaching and DSH:								
Both teaching and DSH	805	1.8	0.1	0	−0.6	−0.1	0.1	2.4
Teaching and no DSH	89	1.9	−0.1	−0.1	−0.5	−0.1	0	2.3
No teaching and DSH	1,024	1.8	0	0.1	−0.4	0.3	0.1	2.2
No teaching and no DSH	346	1.8	−0.3	−0.2	−0.6	−0.1	0.2	1.8
Special Hospital Types:								
RRC	327	1.8	0	0.2	2.5	−0.2	0.2	3.4
SCH	312	1.1	−0.5	0.1	−0.1	−0.1	0	0.8
MDH	140	1.5	−0.5	−0.1	0.8	0	0	1.2
SCH and RRC	134	1.4	−0.2	−0.2	0.3	0	0.1	1.2
MDH and RRC	16	1.5	−0.4	0	0.8	−0.1	0	1.1
Type of Ownership:								
Voluntary	1,899	1.8	0	0	0	0	0.1	2.4
Proprietary	856	1.8	0	−0.1	−0.1	0	0.1	2.1
Government	501	1.7	0.1	0.2	−0.1	−0.1	0	2.5
Medicare Utilization as a Percent of Inpatient Days:								
0–25	602	1.8	0.1	−0.1	−0.5	0	0	2.3
25–50	2,139	1.8	0	0	0	0	0.1	2.5
50–65	421	1.7	−0.2	−0.1	0.6	0.2	0.1	1.7
Over 65	73	1.1	0.5	−0.1	−0.4	−0.3	0.1	2.5
FY 2019 Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	856	1.8	0	0.1	2.4	−0.2	0	2.8
Non-Reclassified Hospitals	2,400	1.8	0	0	−1	0.1	0.1	2.2
Urban Hospitals Reclassified	585	1.8	0	0.1	2.4	−0.2	0	3
Urban Non-Reclassified Hospitals	1,838	1.8	0	0	−1.1	0.1	0.1	2.3
Rural Hospitals Reclassified Full Year	271	1.5	−0.2	−0.1	2.1	−0.2	0.1	1.5

TABLE I—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2019—Continued

	Number of hospitals [1]	Hospital rate update and adjustment under MACRA (1) [2]	FY 2019 weights and DRG changes with application of recalibration budget neutrality (2) [3]	FY 2019 wage data with application of wage budget neutrality (3) [4]	FY 2019 MGCRB reclassifications (4) [5]	Rural floor with application of national rural floor budget neutrality (5) [6]	Application of the frontier wage index and out-migration adjustment (6) [7]	All FY 2019 changes (7) [8]
Rural Non-Reclassified Hospitals Full Year	455	1.4	−0.5	−0.1	−0.4	−0.1	0.3	0.8
All Section 401 Reclassified Hospitals	266	1.7	0	0.1	2.3	−0.1	0.1	3.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	1.7	−0.2	−0.1	2.8	−0.3	0	1.5

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2017, and hospital cost report data are from reporting periods beginning in FY 2016 and FY 2015.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 1.35 percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 2.9 percent market basket update reduced by 0.8 percentage point for the multifactor productivity adjustment and the 0.75 percentage point reduction under the Affordable Care Act), and the 0.5 percent adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 36 GROUPER, the changes to the relative weights and the recalibration of the MS–DRG weights based on FY 2017 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.997192 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2015 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000748.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2019 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2019. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.985932.

[6] This column displays the effects of the rural floor and expiration of the imputed floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.993142.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2018 to FY 2019.

a. Effects of the Hospital Update and Other Adjustments (Column 1)

As discussed in section IV.B. of the preamble of this final rule, this column includes the hospital update, including the 2.9 percent market basket update, the reduction of 0.8 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction, in accordance with the Affordable Care Act. In addition, as discussed in section II.D. of the preamble of this final rule, this column includes the FY 2019 +0.5 percent adjustment required under section 414 of the MACRA. As a result, we are making a 1.85 percent update to the national standardized amount. This column also includes the update to the hospital-specific rates which includes the 2.9 percent market basket update, the reduction of 0.8 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act. As a result, we are making a 1.35 percent update to the hospital-specific rates.

Overall, hospitals will experience a 1.8 percent increase in payments primarily due to the combined effects of the hospital update to the national standardized amount and the hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate will experience a 1.35 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital specific rate will experience a lower than average increase in payments.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this final rule, the FY 2019 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2019, the MS–DRGs are calculated using the FY 2017 MedPAR data grouped to the Version 36 (FY 2019) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.997192 to the standardized amount. Hospital categories that generally treat more medical cases than surgical cases will experience a decrease in their payments under the relative weights. For example, rural hospitals will experience a 0.3 percent decrease in payments in part because rural hospitals tend to treat fewer surgical cases than medical cases. Conversely, teaching hospitals with more than 100 residents will experience an increase in payments of 0.2 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of updated wage data using FY 2015 cost report data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2019 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01 and 17–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index, to section III.A.2. of the preamble of the FY 2017 IPPS/

LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index, and to section III.A.2. of this final rule for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2019 wage index.)

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2019 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2014 and before October 1, 2015. The estimated impact of the updated wage data using the FY 2015 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2018 wage index, based on FY 2014 wage data, the labor-related share of 68.3 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2019 pre-reclassification wage index based on FY 2015 wage data with the labor-related share of 68.3 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the Version 36 MS–DRG GROUPER constant. The FY 2019 occupational mix adjustment is based on the CY 2016 occupational mix survey.

In addition, the column shows the impact of the application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2019, we calculated the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 68.3 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The FY 2019 wage budget neutrality factor is 1.000748, and the overall payment change is 0 percent.

Column 3 shows the impacts of updating the wage data using FY 2015 cost reports. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, will lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage will increase 1.02 percent compared to FY 2018. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the 1.02 percent increase in the national average hourly wage. Of the 3,252 hospitals with wage data for both FYs 2018 and 2019, 1,475 or 45.4 percent will experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2019 relative to FY 2018. Among urban hospitals, 10 will experience a decrease of 10 percent or more, and 3 urban hospitals will experience an increase of 10 percent or more. One hundred five urban hospitals will experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, 3 will experience an increase of 10 percent or more, and 2 will experience a decrease of 10 percent or more. Nine rural hospitals will experience an increase or decrease of at least 5 percent or more but less than 10 percent. However, 726 rural hospitals will experience increases or decreases of less than 5 percent, while 2,360 urban hospitals will experience increases or decreases of less than 5 percent. No urban hospitals and 34 rural hospitals will experience no change to their wage index. These figures reflect changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. (We refer readers to sections III.G. through III.L. of the preamble of this final rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this final rule, which are available via the internet on the CMS website) is used to adjust the labor-related share of a hospital's standardized amount, either 68.3 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than will occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the area wage index values for urban and rural hospitals.

FY 2019 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	3	3
Increase greater than or equal to 5 percent and less than 10 percent	62	3
Increase or decrease less than 5 percent	2,360	726
Decrease greater than or equal to 5 percent and less than 10 percent	43	6
Decrease 10 percent or more	10	2
Unchanged	0	34

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2019.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble to this final rule.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are applying an adjustment of 0.985932 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification will increase payments to rural hospitals by an average of 1.2 percent. By region, with the exception of rural providers in the Mountain region which will experience no change, all the rural hospital categories will experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this final rule and available via

the internet on the CMS website reflects the reclassifications for FY 2019.

e. Effects of the Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2018 IPPS/LTCH PPS final rules, and this FY 2019 IPPS/LTCH PPS final rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We will apply a uniform budget neutrality adjustment to the wage index. As discussed in section III.G. of the preamble of this final rule, we are not extending the imputed floor policy. Therefore, Column 5 shows the effects of the rural floor only.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a FY 2019 rural floor budget neutrality factor to be applied to the wage index of 0.993142, which will reduce wage indexes by 0.69 percent.

Column 5 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the post-reclassification FY 2019 wage index of providers before the rural floor adjustment and the post-reclassification FY 2019 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floors. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) will experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 263 hospitals will receive the rural floor in FY 2019. All IPPS hospitals in our model will have their wage index reduced by the rural floor budget neutrality adjustment of 0.993142. We project that, in aggregate, rural hospitals will experience a 0.2 percent decrease in payments as a result of the application of the rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas will experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region will experience a 2.5 percent increase in payments primarily due to the application of the rural floor in Massachusetts. Twenty nine urban providers in Massachusetts are expected to receive the rural floor wage index value, including the rural floor budget neutrality adjustment, increasing payments overall to hospitals in Massachusetts by an estimated $121 million. We estimate that Massachusetts hospitals will receive approximately a 3.3 percent increase in IPPS payments due to the application of the rural floor in FY 2019. We note that the significant increase in overall payments to hospitals in Massachusetts compared to past years is due primarily to the increase in the Massachusetts rural floor as a result of the recent reclassification of Brigham and Women's Hospital in the city of Boston as a rural hospital under § 412.103. We also note that this table does not reflect all of the additional Medicare payments resulting from the reclassification of Brigham and Women's Hospital in Boston as a rural hospital under § 412.103. Some of this payment impact is reflected in column 4 (Reclassifications) in Table I– Impact Analysis of Changes to the IPPS for Operating Costs for FY 2019.

Urban Puerto Rico hospitals are expected to experience a 0.1 percent increase in payments as a result of the application of the rural floor.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the rural floor with budget neutrality at the State level. Column 1 of the following table displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that will receive the rural floor wage index for FY 2019. Column 3 displays the percentage of total payments each State will receive or contribute to fund the rural floor with national budget neutrality. The column compares the post-reclassification FY 2019 wage index of providers before the rural floor adjustment and the post-reclassification FY 2019 wage index of providers with the rural floor adjustment. Column 4 displays the estimated payment amount that each State will gain or lose due to the application of the rural floor with national budget neutrality.

FY 2019 IPPS Estimated Payments Due to Rural Floor With National Budget Neutrality

State	Number of hospitals (1)	Number of hospitals that will receive the rural floor (2)	Percent change in payments due to application of rural floor with budget neutrality (3)	Difference (in $ millions) (4)
Alabama	84	3	−0.3	$−5
Alaska	6	3	0.1	0
Arizona	56	45	3.0	58
Arkansas	45	0	−0.3	−4
California	297	60	0.3	38
Colorado	46	9	0.6	7
Connecticut	30	10	2.0	32
Delaware	6	0	−0.4	−2
Washington, D.C.	7	0	−0.4	−2
Florida	168	7	−0.3	−23
Georgia	101	0	−0.3	−9
Hawaii	12	0	−0.3	−1
Idaho	14	0	−0.3	−1
Illinois	125	2	−0.4	−16
Indiana	85	0	−0.3	−8
Iowa	34	0	−0.3	−3
Kansas	51	0	−0.3	−3
Kentucky	64	0	−0.3	−6
Louisiana	90	0	−0.3	−5
Maine	17	0	−0.3	−2
Massachusetts	56	29	3.3	121
Michigan	94	0	−0.4	−15
Minnesota	49	0	−0.3	−6

FY 2019 IPPS ESTIMATED PAYMENTS DUE TO RURAL FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Number of hospitals that will receive the rural floor (2)	Percent change in payments due to application of rural floor with budget neutrality (3)	Difference (in $ millions) (4)
Mississippi	59	0	−0.3	−4
Missouri	72	0	−0.3	−7
Montana	13	1	−0.2	−1
Nebraska	23	0	−0.3	−2
Nevada	22	3	0.3	3
New Hampshire	13	8	2.3	14
New Jersey	64	0	−0.5	−18
New Mexico	24	2	−0.2	−1
New York	149	16	−0.3	−24
North Carolina	84	0	−0.3	−10
North Dakota	6	3	0.4	1
Ohio	130	7	−0.3	−12
Oklahoma	79	2	−0.3	−5
Oregon	34	1	−0.3	−3
Pennsylvania	150	3	−0.4	−19
Puerto Rico	51	11	0.1	0
Rhode Island	11	0	−0.4	−2
South Carolina	54	6	−0.1	−2
South Dakota	17	0	−0.2	−1
Tennessee	90	6	−0.3	−8
Texas	310	13	−0.3	−20
Utah	31	0	−0.3	−2
Vermont	6	0	−0.2	0
Virginia	74	1	−0.3	−7
Washington	48	3	−0.4	−8
West Virginia	29	2	−0.2	−2
Wisconsin	66	5	−0.3	−5
Wyoming	10	2	0	0

f. Effects of the Application of the Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and will increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 49 hospitals located in those States will receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $62 million. Rural and urban hospitals located in the West North Central region will experience an increase in payments by 0.2 and 0.6 percent, respectively, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment will receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 220 providers that will receive the out-migration wage adjustment in FY 2019. Rural hospitals generally will qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they will each experience a 0.1 and 0.2 percent increase in payments, respectively. (We note that there has been an increase in the number of RRCs as a result of the decision by the Court of Appeals for the Third Circuit in *Geisinger Community Medical Center vs. Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015) and subsequent regulatory changes (81 FR 23428).) This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase will be approximately $42 million.

g. Effects of All FY 2019 Changes (Column 7)

Column 7 shows our estimate of the changes in payments per discharge from FY 2018 and FY 2019, resulting from all changes reflected in this final rule for FY 2019. It includes combined effects of the year-to-year change of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 2.4 percent for FY 2019 relative to FY 2018 and for this row is primarily driven by the changes reflected in Column 1. Column 7 includes the annual hospital update of 1.35 percent to the national standardized amount. This annual hospital update includes the 2.9 percent market basket update, the 0.8 percentage point reduction for the multifactor productivity adjustment, and the 0.75 percentage point reduction under section 3401 of the Affordable Care Act. As discussed in section II.D. of the preamble of this final rule, this column also includes the +0.5 percent adjustment required under section 414 of the MACRA. Hospitals paid

under the hospital-specific rate will receive a 1.35 percent hospital update. As described in Column 1, the annual hospital update with the +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the annual hospital update for hospitals paid under the hospital-specific rates, will result in a 2.4 percent increase in payments in FY 2019 relative to FY 2018. There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which contribute to our estimate of the changes in payments per discharge from FY 2018 and FY 2019 in Column 7.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.4 percent for FY 2019. Hospitals in urban areas will experience a 2.5 percent increase in payments per discharge in FY 2019 compared to FY 2018. Hospital payments per discharge in rural areas are estimated to increase by 1.2 percent in FY 2019.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2019 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2018 with the estimated average payments per discharge for FY 2019, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2019 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Estimated average FY 2018 payment per discharge	Estimated average FY 2019 payment per discharge	FY 2019 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,256	12,172	12,463	2.4
By Geographic Location:				
Urban hospitals	2,483	12,508	12,819	2.5
Large urban areas	1,302	12,986	13,304	2.4
Other urban areas	1,181	12,049	12,354	2.5
Rural hospitals	773	9,194	9,308	1.2
Bed Size (Urban):				
0–99 beds	644	9,945	10,114	1.7
100–199 beds	763	10,399	10,622	2.2
200–299 beds	433	11,384	11,649	2.3
300–499 beds	424	12,606	12,916	2.5
500 or more beds	219	15,449	15,894	2.9
Bed Size (Rural):				
0–49 beds	306	7,836	7,908	0.9
50–99 beds	274	8,746	8,844	1.1
100–149 beds	108	9,150	9,257	1.2
150–199 beds	45	9,667	9,806	1.4
200 or more beds	40	10,734	10,900	1.6
Urban by Region:				
New England	113	13,491	14,132	4.7
Middle Atlantic	310	14,099	14,429	2.3
South Atlantic	401	11,145	11,373	2.1
East North Central	386	11,830	12,073	2.1
East South Central	147	10,517	10,742	2.1
West North Central	158	12,266	12,525	2.1
West South Central	379	11,310	11,575	2.3
Mountain	164	12,938	13,212	2.1
Pacific	374	15,773	16,284	3.2
Puerto Rico	51	9,117	9,186	0.8
Rural by Region:				
New England	20	12,613	12,729	0.9
Middle Atlantic	53	9,137	9,265	1.4
South Atlantic	122	8,497	8,599	1.2
East North Central	114	9,444	9,552	1.1
East South Central	150	8,142	8,286	1.8
West North Central	94	10,019	10,112	0.9
West South Central	145	7,844	7,959	1.5
Mountain	52	11,128	11,215	0.8
Pacific	23	12,734	12,858	1
By Payment Classification:				
Urban hospitals	2,264	12,276	12,558	2.3
Large urban areas	1,317	12,974	13,291	2.4
Other urban areas	947	11,325	11,559	2.1
Rural areas	992	11,833	12,154	2.7
Teaching Status:				
Nonteaching	2,157	10,059	10,266	2.1
Fewer than 100 residents	849	11,616	11,867	2.2
100 or more residents	250	17,680	18,221	3.1
Urban DSH:				

TABLE II—IMPACT ANALYSIS OF CHANGES FOR FY 2019 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals	Estimated average FY 2018 payment per discharge	Estimated average FY 2019 payment per discharge	FY 2019 changes
	(1)	(2)	(3)	(4)
Non-DSH	520	10,533	10,749	2.1
100 or more beds	1,462	12,643	12,939	2.3
Less than 100 beds	367	9,220	9,398	1.9
Rural DSH:				
SCH	256	10,239	10,313	0.7
RRC	382	12,516	12,899	3.1
100 or more beds	33	13,322	13,713	2.9
Less than 100 beds	236	7,300	7,411	1.5
Urban teaching and DSH:				
Both teaching and DSH	805	13,783	14,113	2.4
Teaching and no DSH	89	11,402	11,665	2.3
No teaching and DSH	1,024	10,322	10,548	2.2
No teaching and no DSH	346	9,951	10,126	1.8
Special Hospital Types:				
RRC	327	12,440	12,860	3.4
SCH	312	11,125	11,218	0.8
MDH	140	7,958	8,057	1.2
SCH and RRC	134	11,502	11,640	1.2
MDH and RRC	16	10,039	10,150	1.1
Type of Ownership:				
Voluntary	1,899	12,323	12,623	2.4
Proprietary	856	10,658	10,880	2.1
Government	501	13,378	13,709	2.5
Medicare Utilization as a Percent of Inpatient Days:				
0–25	602	14,927	15,267	2.3
25–50	2,139	11,996	12,294	2.5
50–65	421	9,817	9,986	1.7
Over 65	73	7,271	7,451	2.5
FY 2019 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	856	12,174	12,516	2.8
Non-Reclassified Hospitals	2,400	12,171	12,439	2.2
Urban Hospitals Reclassified	585	12,761	13,149	3
Urban Nonreclassified Hospitals	1,838	12,374	12,656	2.3
Rural Hospitals Reclassified Full Year	271	9,566	9,711	1.5
Rural Nonreclassified Hospitals Full Year	455	8,753	8,824	0.8
All Section 401 Reclassified Hospitals:	266	13,625	14,088	3.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	8,609	8,736	1.5

H. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. As noted in section I.G. of this Regulatory Impact Analysis, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policy Relating to New Medical Service and Technology Add-On Payments

In section II.H. of the preamble to this final rule, we discuss 11 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2019. We note that three applicants withdrew their applications prior to the issuance of this final rule, and one applicant did not receive FDA approval for its technology by the July 1 deadline. We also discuss the status of the new technologies that were approved to receive new technology add-on payments in FY 2018. As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral.

As discussed in section II.H.5. of the preamble of this final rule, we are approving the following nine applications for new technology add-on payments for FY 2019: KYMRIAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel); VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection); VABOMERE™ (meropenem-vaborbactam); remedē® System; ZEMDRI™ (Plazomicin); GIAPREZA™; Sentinel® Cerebral Protection System; The AQUABEAM System (Aquablation); and AndexXa™ (Andexanet alfa). In addition, as we proposed, in this final rule, we are continuing to make new technology add-on payments for Defitelio® (Defibrotide), Ustekinumab (Stelara®) and Bezlotoxumab (Zinplava™) in FY 2019 because these technologies are still considered new. (As discussed in section II.H.5. of the preamble of this final rule, as we proposed, we are discontinuing new technology add-on payments for Idarucizumab, GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), Edwards/Perceval Sutureless Valves, and Vistogard™ (Uridine Triacetate) for FY

2019 because these technologies will have been on the U.S. market for 3 years.)

We note that new technology add-on payments for each case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in new technology add-on payments for FY 2019 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment.

The following are estimates for FY 2019 for the three technologies for which we are continuing to make new technology add-on payments in FY 2019:

- Based on the applicant's estimate from FY 2017 and the updated cost information provided by the applicant (discussed in section II.H.4.a. of the preamble of this final rule), we currently estimate that new technology add-on payments for Defitelio® will increase overall FY 2019 payments by $5,474,000 (maximum add-on payment of $80,500 * 68 patients).
- Based on the applicant's estimate from FY 2018, we currently estimate that new technology add-on payments for Ustekinumab (Stelara®) will increase overall FY 2019 payments by $400,800 (maximum add-on payment of $2,400 * 167 patients).
- Based on the applicant's estimate for FY 2018, we currently estimate that new technology add-on payments for Bezlotoxumab (Zinplava™) will increase overall FY 2019 payments by $2,857,600 (maximum add-on payment of $1,900 * 1,504 patients).

The following are estimates for FY 2019 for the nine technologies that we are approving for new technology add-on payments beginning with FY 2019.

- Based on both applicants' estimates of the average cost for an administered dose for FY 2019, we currently estimate that new technology add-on payments for KYMRIAH® and YESCARTA® will increase overall FY 2019 payments by $71,989,000 (maximum add-on payment of $186,500 * 373 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for VYXEOS™ will increase overall FY 2019 payments by $34,968,000 (maximum add-on payment of $36,425 * 960 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for VABOMERE™ will increase overall FY 2019 payments by $14,680,512 (maximum add-on payment of $5,544 * 2,648 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for remedē® System will increase overall FY 2019 payments by $1,380,000 (maximum add-on payment of $17,250 * 80 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for ZEMDRI™ will increase overall FY 2019 payments by $6,806,250 (maximum add-on payment of $2,722.50 * 2,500 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for GIAPREZA™ will increase overall FY 2019 payments by $8,595,000 (maximum add-on payment of $1,500 * 5,730 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for Sentinel® Cerebral Protection System will increase overall FY 2019 payments by $9,100,000 (maximum add-on payment of $1,400 * 6,500 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for the AquaBeam System (Aquablation) will increase overall FY 2019 payments by $521,250 (maximum add-on payment of $1,250 * 417 patients).
- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for AndexXa™ will increase overall FY 2019 payments by $75,965,625 (maximum add-on payment of $14,062.50 * 5,402 patients).

2. Effects of Changes to MS–DRGs Subject to the Postacute Care Transfer Policy and the MS–DRG Special Payment Policy

In section IV.A. of the preamble of this final rule, we discuss our changes to the list of MS–DRGs subject to the postacute care transfer policy and the MS–DRG special payment policy. As reflected in Table 5 listed in section VI. of the Addendum to this final rule (which is available via the internet on the CMS website), using criteria set forth in regulations at 42 CFR 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which new or revised MS–DRGs will qualify for the postacute care transfer and MS–DRG special payment policies. As a result of our policies to revise the MS–DRG classifications for FY 2019, which are discussed in section II.F. of the preamble of this final rule, we are including additions to the list of MS–DRGs subject to the MS–DRG special payment policy. Column 2 of Table I in this Appendix A shows the effects of the changes to the MS–DRGs and the relative payment weights and the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate DRG classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods for determining the changes due to the MS–DRGs and relative payment weights account for and include changes as a result of the changes to the MS–DRGs subject to the MS–DRG postacute care transfer and MS–DRG special payment policies. We refer readers to section I.G. of this Appendix A for a detailed discussion of payment impacts due to the MS–DRG reclassification policies for FY 2019.

In section IV.A.2.b. of the preamble of this final rule, we discuss our conforming changes to the regulations at § 412.4(c) to reflect the amendments to section 1886(d)(5)(J) of the Act made by section 53109 of the Bipartisan Budget Act of 2018. Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J) of the Act to include discharges to hospice services provided by a hospice program as a ''qualified discharge'' under the postacute care transfer policy, effective for discharges occurring on or after October 1, 2018. To implement this change, we are establishing that discharges using Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) will be subject to the postacute care transfer policy, effective for discharges occurring on or after October 1, 2018. Our actuaries estimate that this change in the postacute care transfer policy will generate an annual savings of approximately $240 million in Medicare payments in FY 2019, and up to $540 million annually by FY 2028.

3. Effects of Changes to Low-Volume Hospital Payment Adjustment Policy

In section IV.D. of the preamble of this final rule, we discuss the changes to the low-volume hospital payment policy for FY 2019 to implement the provisions of section 50204 of the Bipartisan Budget Act of 2018. Specifically, for FY 2019, qualifying hospitals must have less than 3,800 combined Medicare and non-Medicare discharges (instead of 1,600 Medicare discharges) and must be located more than 15 road miles from another subsection (d) hospital. Section 50204 of the Bipartisan Budget Act of 2018 also modified the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. To implement these requirements, we are establishing that the low-volume hospital payment adjustment will be determined as follows:

- For low-volume hospitals with 500 or fewer total discharges during the fiscal year, an additional 25 percent for each Medicare discharge.
- For low-volume hospitals with total discharges during the fiscal year of more than 500 and fewer than 3,800, an additional percent calculated using the formula [(95/330) − (number of total discharges/13,200)] for each Medicare discharge.

Based upon the best available data at this time, we estimate the changes to the low-volume hospital payment adjustment policy that we are implementing in accordance with section 50204 of the Bipartisan Budget Act of 2018 will increase Medicare payments by $75 million in FY 2019 as compared to FY 2018. More specifically, in FY 2019, we estimate that 628 providers will receive approximately $426 million compared to our estimate of 612 providers receiving approximately $350 million in FY 2018. These payment estimates were determined by identifying providers that, based on the best available data, are expected to qualify under the criteria that will apply in FY 2019 (that is, are located at least 15 miles from the nearest subsection (d) hospital and have less than 3,800 total discharges), and were determined from the same data used in developing the quantitative analyses of changes in payments per case discussed previously in section I.G. of this Appendix A.

4. Effects of the Changes to Medicare DSH and Uncompensated Care Payments for FY 2019

As discussed in section IV.F. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and additional statutory adjustments (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this final rule, we are establishing the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2019 is $8,272,872,447.22. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 67.51 percent. For FY 2018, the amount available to be distributed for uncompensated care was $6,766,695,163.56, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 58.01 percent. To calculate Factor 3 for FY 2019, we used an average of data computed using Medicaid days from hospitals' 2013 cost reports from the HCRIS database as updated through June 30, 2018, uncompensated care costs from hospitals' 2014 and 2015 cost reports from the same extract of HCRIS, and SSI days from the FY 2016 SSI ratios. For each eligible hospital, with the exception of Puerto Rico hospitals, all-inclusive rate providers, and Indian Health Service and Tribal hospitals, we calculated a Factor 3 using information from cost reports for FYs 2013, 2014, and 2015. To calculate Factor 3 for Puerto Rico hospitals, all-inclusive rate providers, and Indian Health Service and Tribal hospitals, we used data regarding low-income insured days for FY 2013. For a complete discussion of the methodology for calculating Factor 3, we refer readers to section IV.F.4. of the preamble of this final rule.

To estimate the impact of the combined effect of changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments (UCP), we compared total UCP estimated in the FY 2018 IPPS/LTCH PPS final rule to total UCP estimated in this FY 2019 IPPS/LTCH PPS final rule. For FY 2018, for each hospital, we calculated 75 percent of the estimated amount that would have been paid as Medicare DSH payments in the absence of section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 58.01 percent and multiplied by a Factor 3 calculated as described in the FY 2018 IPPS/LTCH PPS final rule. For FY 2019, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 67.51 percent and multiplied by a Factor 3 calculated using the methodology described previously.

Our analysis included 2,448 hospitals that are projected to be eligible for DSH in FY 2019. It did not include hospitals that terminated their participation from the Medicare program as of January 1, 2018, Maryland hospitals, new hospitals, MDHs, and SCHs that are expected to be paid based on their hospital-specific rates. The 29 hospitals participating in the Rural Community Hospital Demonstration Program were excluded in this final rule, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, low-income insured days and uncompensated care costs from merged or acquired hospitals were combined into the surviving hospital's CMS certification number (CCN), and the nonsurviving CCN was excluded from the analysis. The estimated impact of the changes in Factors 1, 2, and 3 on uncompensated care payments across all hospitals projected to be eligible for DSH payments in FY 2019, by hospital characteristic, is presented in the following table.

MODELED UNCOMPENSATED CARE PAYMENTS FOR ESTIMATED FY 2019 DSHS BY HOSPITAL TYPE: MODEL UCP $ (IN MILLIONS) * FROM FY 2018 TO FY 2019

	Number of estimated DSHs	FY 2018 final rule CN estimated UCP $ (in millions)	FY 2019 final rule estimated UCP $ (in millions)	Dollar difference: FY 2019–FY 2018 (in millions)	Percent change **
	(1)	(2)	(3)	(4)	(5)
Total	2,448	$6,767	$8,273	$1,506	22.26
By Geographic Location:					
Urban Hospitals	1,952	6,422	7,802	1,380	21.48
Large Urban Areas	1,045	3,847	4,705	858	22.30
Other Urban Areas	907	2,575	3,097	522	20.26
Rural Hospitals	495	345	471	126	36.66
Bed Size (Urban):					
0 to 99 Beds	342	177	257	80	44.83
100 to 249 Beds	859	1,519	1,902	383	25.23
250+ Beds	751	4,726	5,643	917	19.40
Bed Size (Rural):					
0 to 99 Beds	366	164	229	65	39.52
100 to 249 Beds	116	146	199	53	36.35
250+ Beds	13	34	43	8	24.35
Urban by Region:					
New England	91	259	279	20	7.75
Middle Atlantic	244	1,004	1,059	55	5.51
South Atlantic	320	1,343	1,769	426	31.72
East North Central	323	864	1,010	146	16.85
East South Central	133	389	477	88	22.73
West North Central	104	312	386	73	23.49
West South Central	254	981	1,424	442	45.06
Mountain	125	313	397	83	26.61
Pacific	318	874	899	25	2.89

MODELED UNCOMPENSATED CARE PAYMENTS FOR ESTIMATED FY 2019 DSHs BY HOSPITAL TYPE: MODEL UCP $ (IN MILLIONS) * FROM FY 2018 TO FY 2019—Continued

	Number of estimated DSHs	FY 2018 final rule CN estimated UCP $ (in millions)	FY 2019 final rule estimated UCP $ (in millions)	Dollar difference: FY 2019–FY 2018 (in millions)	Percent change **
	(1)	(2)	(3)	(4)	(5)
Puerto Rico	40	82	102	20	24.46
Rural by Region:					
New England	9	14	17	3	19.26
Middle Atlantic	27	19	22	2	12.45
South Atlantic	88	79	116	37	47.57
East North Central	69	40	56	16	41.15
East South Central	135	93	106	13	13.80
West North Central	29	16	22	6	40.31
West South Central	106	66	102	36	53.66
Mountain	27	14	26	12	84.19
Pacific	5	4	5	1	24.86
By Payment Classification:					
Urban Hospitals	1,865	5,917	7,257	1,340	22.66
Large Urban Areas	1,057	3,855	4,716	861	22.34
Other Urban Areas	808	2,062	2,541	479	23.24
Rural Hospitals	582	850	1,016	166	19.49
Teaching Status:					
Nonteaching	1,509	2,020	2,598	578	28.62
Fewer than 100 residents	694	2,246	2,744	497	22.14
100 or more residents	244	2,501	2,932	431	17.23
Type of Ownership:					
Voluntary	1,448	4,137	4,894	757	18.30
Proprietary	561	1,015	1,259	244	24.06
Government	439	1,615	2,119	505	31.26
Medicare Utilization Percent: ***					
0 to 25	472	2,255	2,720	465	20.60
25 to 50	1,674	4,290	5,266	976	22.76
50 to 65	263	215	277	62	28.59
Greater than 65	36	7	11	4	56.59

Source: Dobson | DaVanzo analysis of 2013–2015 Hospital Cost Reports.

* Dollar UCP calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $6,767 million in FY 2018 and $8,273 million in FY 2019.

** Percentage change is determined as the difference between Medicare UCP payments modeled for this FY 2019 IPPS/LTCH PPS final rule (column 3) and Medicare UCP payments modeled for the FY 2018 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare UCP payments modeled for the FY 2018 final rule correction notice (column 2) times 100 percent.

*** Hospitals with Missing or Unknown Medicare Utilization are not shown in table.

Changes in projected FY 2019 uncompensated care payments from payments in FY 2018 are driven by increases in Factor 1 and Factor 2, as well as by an increase in the number of hospitals eligible to receive DSH in FY 2019 relative to FY 2018. Factor 1 has increased from $11.665 billion to $12.254 billion, and the percent change in the percent of individuals who are uninsured (Factor 2) has increased from 58.01 percent to 67.51 percent. Based on the increases in these two factors, the impact analysis found that, across all projected DSH eligible hospitals, FY 2019 uncompensated care payments are estimated at approximately $8.273 billion, or an increase of approximately 22.26 percent from FY 2018 uncompensated care payments (approximately $6.767 billion). While these changes will result in a net increase in the amount available to be distributed in uncompensated care payments, the projected payment increases vary by hospital type. This redistribution of uncompensated care payments is caused by changes in Factor 3.

As seen in the above table, percent increases smaller than 22.26 percent indicate that hospitals within the specified category are projected to experience a smaller increase in uncompensated care payments, on average, compared to the universe of projected FY 2019 DSH hospitals. Conversely, percent increases that are greater than 22.26 percent indicate a hospital type is projected to have a larger increase than the overall average. The variation in the distribution of payments by hospital characteristic is largely dependent on a given hospital's number of Medicaid days and SSI days, as well as its uncompensated care costs as reported in the Worksheet S–10, used in the Factor 3 computation.

Many rural hospitals are projected to experience larger increases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive a 36.66 percent increase in uncompensated care payments, while urban hospitals are projected to receive a 21.48 percent increase in uncompensated care payments.

By bed size, smaller hospitals are projected to receive larger increases in uncompensated care payments than larger hospitals, in both rural and urban settings. Rural hospitals with 0–99 beds are projected to receive a 39.52 percent payment increase, rural hospitals with 100–249 beds are projected to see a 36.35 percent increase, and larger rural hospitals with 250+ beds are projected to experience a 24.35 percent payment increase. These increases for rural hospitals are all greater than the overall hospital average. This trend is consistent with urban hospitals, in which the smallest urban hospitals (0–99 beds) are projected to receive an increase in uncompensated care payments of 44.83 percent, and urban hospitals with 100–250 beds are projected to receive an increase of 25.23 percent, both of which are greater than the overall average. Larger urban hospitals with 250+ beds are projected to receive a 19.40 percent increase in uncompensated care payments, which is smaller than the overall average.

By region, rural hospitals are expected to receive a wide range of payment increases. Rural hospitals in the Mountain region are expected to receive a larger than average increase in uncompensated care payments, as are rural hospitals in the West South Central,

South Atlantic, East North Central, West North Central, and Pacific regions. Rural hospitals in the New England, East South Central, and Middle Atlantic regions are projected to receive smaller than average payment increases. Regionally, urban hospitals are projected to receive a narrower range of payment changes. Smaller than average increases in uncompensated care payments are projected in the Pacific, Middle Atlantic, New England, and East North Central regions. Urban hospitals in the West South Central, South Atlantic, and Mountain regions are projected to receive a larger than average increase in uncompensated payments, as are hospitals in Puerto Rico. The projected increases in the East South Central and West North Central regions are generally consistent with the overall average increase of 22.26 percent.

Nonteaching hospitals are projected to receive a larger than average payment increase of 28.62 percent. Teaching hospitals with fewer than 100 residents are projected to receive a payment increase of 22.14 percent, which is consistent with the overall average, while those teaching hospitals with 100+ residents have a projected payment increase of 17.23 percent, lower than the overall average. Government and proprietary hospitals are projected to receive larger than average increases (31.26 percent and 24.06 percent, respectively), while voluntary hospitals are expected to receive increases lower than the overall average at 18.30 percent. Hospitals with 0 to 25 percent Medicare utilization are projected to receive increases in uncompensated care payments slightly below the overall average, while hospitals with higher levels of Medicare utilization are projected to receive larger increases.

5. Effects of Reductions Under the Hospital Readmissions Reduction Program for FY 2019

In section IV.H. of the preamble of the this final rule, we discuss our finalized policies for the FY 2019 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. The table and analysis below illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. As outlined in section IV.H. of the preamble of this final rule, hospitals are stratified into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2014 and June 30, 2017 (that is, the FY 2019 Hospital Readmissions Reduction Program's performance period). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. To analyze the results by hospital characteristic, we used the FY 2019 IPPS/LTCH Proposed Rule Impact File.

These analyses include 3,062 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2014 and June 30, 2017. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 82.26 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 88.60 percent of eligible hospitals with fewer than 100 residents and 93.95 percent of eligible hospitals with 100 or more residents are expected to be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristics. The table shows the share of penalties as a percentage of all base operating Diagnosis Related-Group (DRG) payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2016 and September 30, 2017 (FY 2017). For example, the penalty as a share of payments for urban hospitals is 0.70 percent. This means that total penalties for all urban hospitals are 0.70 percent of total payments for urban hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals within the characteristic when comparing the financial impact of the program on different groups of hospitals.

ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENTS FOR FY 2019 HOSPITAL READMISSIONS REDUCTION PROGRAM

[By hospital characteristic]

Hospital characteristic	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized [c] (%)	Penalty as a share of payments [d] (%)
All Hospitals	3,062	2,599	84.88	0.67
Geographic Location: [e] (n=3,062):				
Urban hospitals	2,297	1,983	86.33	0.70
1–99 beds	534	377	70.60	0.94
100–199 beds	714	649	90.90	0.83
200–299 beds	417	378	90.65	0.81
300–399 beds	275	253	92.00	0.72
400–499 beds	144	130	90.28	0.56
500 or more beds	213	196	92.02	0.58
Rural hospitals	765	616	80.52	0.72
1–49 beds	285	197	69.12	0.66
50–99 beds	282	242	85.82	0.65
100–149 beds	115	104	90.43	0.75
150–199 beds	44	35	79.55	0.67
200 or more beds	39	38	97.44	0.85
Teaching Status: [f] (n=3,062):				
Non-teaching	2,007	1,651	82.26	0.82
Fewer than 100 Residents	807	715	88.60	0.71
100 or more Residents	248	233	93.95	0.52
Ownership Type (n=3,043):				
Government	476	399	83.82	0.54
Proprietary	748	619	82.75	1.05
Voluntary	1,819	1,573	86.48	0.66
Safety-net Status [g] (n=3,062):				
Safety net hospitals	614	531	86.48	0.60
Non-safety net Hospitals	2,448	2,068	84.48	0.73

ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENTS FOR FY 2019 HOSPITAL READMISSIONS REDUCTION PROGRAM—Continued

[By hospital characteristic]

Hospital characteristic	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized [c] (%)	Penalty as a share of payments [d] (%)
Disproportionate Share Hospital (DSH) Patient Percentage [h] (n=3,062):				
0–24	1,221	997	81.65	0.80
25–49	1,485	1,293	87.07	0.66
50–64	189	171	90.48	0.66
65 and over	167	138	82.63	0.63
Medicare Cost Report (MCR) Percent [i] (n=3,048):				
0–24	432	364	84.26	0.49
25–49	2,087	1,802	86.34	0.71
50–64	467	381	81.58	0.98
65 and over	62	42	67.74	0.94
Region (n=3,062):				
New England	129	114	88.37	0.89
Middle Atlantic	352	320	90.91	0.89
South Atlantic	509	461	90.57	0.79
East North Central	482	421	87.34	0.62
East South Central	289	253	87.54	0.90
West North Central	246	193	78.46	0.44
West South Central	474	384	81.01	0.68
Mountain	217	163	75.12	0.57
Pacific	364	290	79.67	0.48

Source: The table results are based on the estimated FY 2019 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. FY 2019 payment adjustment factors are based on discharges between July 1, 2014 and June 30, 2017. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2018 public reporting open hospital list since these hospitals are not eligible for a penalty under the program. Hospitals are stratified into quintiles based on the proportion of FFS and managed care dual-eligible stays for the 3-year FY 2019 performance period. Hospital characteristics are from the FY 2019 IPPS/LTCH Proposed Rule Impact File.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. MedPAR data from October 1, 2016 through September 30, 2017 (FY 2017) are used to calculate the total base operating DRG payments.

[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. All hospitals had information for: Geographic location, bed size by geographic region, teaching status, safety-net status, DSH patient percentage, and region (n=3,062). Not all hospitals had data for ownership type (n=3,043; missing=19) and MCR percent (n=3,048; missing=14).

[f] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[h] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A.

[i] MCR percent is the percentage of total inpatient stays from Medicare patients.

6. Effects of Changes Under the FY 2019 Hospital Value-Based Purchasing (VBP) Program

a. Effects of Proposed Changes for FY 2019

In section IV.I. of the preamble of this final rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2019 through a reduction to the FY 2019 base operating DRG payment amount for the discharge for the hospital for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2019 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section IV.I.1.b. of the preamble of this final rule, we estimate the available pool of funds for value-based incentive payments in the FY 2019 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.9 billion. This estimated available pool for FY 2019 is based on the historical pool of hospitals that were eligible to participate in the FY 2018 program year and the payment information from the March 2018 update to the FY 2017 MedPAR file.

The proposed estimated impacts of the FY 2019 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2018 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the March 2018 update to the FY 2017 MedPAR file. The proxy adjustment factors can be found in Table 16A associated with this final rule (available via the internet on the CMS website).

The impact analysis shows that, for the FY 2019 program year, the number of hospitals that would receive an increase in their base operating DRG payment amount is higher than the number of hospitals that would receive a decrease. On average, urban hospitals in the West North Central region and rural hospitals in Mountain region would have the highest positive percent

change in base operating DRG. Urban Middle Atlantic, urban South Atlantic, and urban East South Central regions would experience an average negative percent change in base operating DRG. All other regions, both urban and rural, would have an average positive percent change in base operating DRG.

As DSH percent increases, the average percent change in base operating DRG would decrease. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the percent change in base operating DRG would tend to increase. On average, teaching hospitals would have a negative percent change in base operating DRG, while non-teaching hospitals would have a positive percent change in base operating DRG.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2019 HOSPITAL VBP PROGRAM

	Number of hospitals	Average net percentage payment adjustment
By Geographic Location:		
All Hospitals	2,808	0.163
Large Urban	1,117	0.068
Other Urban	1,023	0.068
Rural Area	668	0.465
Urban hospitals	*2,140*	*0.068*
0–99 beds	375	0.475
100–199 beds	708	0.120
200–299 beds	427	−0.037
300–499 beds	418	−0.184
500 or more beds	212	−0.117
Rural hospitals	668	0.465
0–49 beds	201	0.675
50–99 beds	272	0.525
100–149 beds	114	0.306
150–199 beds	43	0.048
200 or more beds	38	−0.125
By Region:		
Urban By Region	2,140	0.068
New England	107	0.191
Middle Atlantic	288	−0.101
South Atlantic	376	−0.024
East North Central	348	0.178
East South Central	131	−0.101
West North Central	137	0.315
West South Central	265	0.010
Mountain	144	0.027
Pacific	344	0.189
Rural By Region	668	0.465
New England	20	0.739
Middle Atlantic	51	0.397
South Atlantic	108	0.489
East North Central	108	0.550
East South Central	123	0.214
West North Central	82	0.628
West South Central	109	0.348
Mountain	46	0.784
Pacific	21	0.562
By MCR Percent:		
0–25	431	0.117
25–50	1,958	0.151
50–65	392	0.261
Over 65	27	0.292
Missing	.....	.....
BY DSH Percent:		
0–25	1,049	0.251
25–50	1,421	0.136
50–65	187	−0.003
Over 65	151	0.001
By Teaching Status:		
Non-Teaching	1,751	0.279
Teaching	1,057	−0.031

Actual FY 2019 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2019 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2018 program year were used for the updated impact analysis in this final rule.

b. Effects of Proposed Domain Weighting and Alternative Considered Beginning With the FY 2021 Program Year

In section IV.I.4.b. of the preamble of the proposed rule, we discussed our proposed

changes to the Hospital VBP Program domain weighting beginning with the FY 2021 program year. We note that we did not propose to make any changes to the domain weighting for the FY 2019 or FY 2020 program years. The estimated impacts of the proposed domain weighting and alternative considered for three domains beginning with the FY 2021 program year, by hospital characteristic, based on historical TPSs, were provided in the proposed rule (83 FR 20620 through 20621). However, as discussed in section IV.I.4.b. of the preamble of this final rule, we are not finalizing any changes to the domain weighting for the FY 2021 year or subsequent years, and therefore we did not provide an updated analysis here.

7. Effects of Requirements Under the HAC Reduction Program for FY 2019

In section IV.J. of the preamble of this final rule, we discuss finalized requirements for the HAC Reduction Program. In the proposed rule, we did not propose to adopt any new measures into the HAC Reduction Program, and are therefore not finalizing any changes to the HAC Reduction Program measure set. However, the Hospital IQR Program is finalizing its proposals to remove the claims-based Patient Safety and Adverse Events Composite (PSI–90) beginning with the CY 2018 reporting period/FY 2020 payment determination and five NHSN HAI measures, although the NHSN HAI measures removal is being delayed by one year (until the CY 2020 reporting period/FY 2022 payment determination). These measures had been previously adopted for, and will remain in, the HAC Reduction Program. We are therefore finalizing our proposal to begin validation of these NHSN HAI measures under the HAC Reduction Program, but are delaying implementation to begin with Q3 2020 discharges for FY 2023 in order to align with a corresponding delay in removing these NHSN HAI measures from the Hospital IQR Program.

We note the burden associated with collecting and submitting data via the NHSN system is captured under a separate OMB control number, 0920–0666, and therefore will not impact our burden estimates. We anticipate the removal of the NHSN HAI measures from the Hospital IQR Program will result in a net burden decrease to the Hospital IQR Program, but will result in an off-setting net burden increase to the HAC Reduction Program because hospitals selected for validation will continue to be required to submit validation templates for the HAI measures. Therefore, with the finalized policies discussed in section VIII.A.5.b.(1) and IV.J.4.e. of the preamble of this final rule to remove NHSN HAI chart-abstracted measures from the Hospital IQR Program and adopt validation process for the HAC Reduction Program, we anticipate a shift in burden associated with this data validation effort to the HAC Reduction Program beginning in FY 2021. We discuss the associated burden hours (43,200 hours over 600 hospitals) in section XIV.B.7. of the preamble of this final rule, and note the burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938—NEW.

The table and analysis below illustrate the estimated cumulative effect of the measures and scoring methodology for the Hospital-Acquired Condition (HAC) Reduction Program, as outlined in this FY 2019 IPPS/LTCH PPS final rule. We are presenting the estimated impact of the FY 2019 HAC Reduction Program on hospitals by hospital characteristic.

These FY 2019 HAC Reduction Program results were calculated using the Winsorized z-score methodology finalized in the FY 2017 IPPS/LTCH PPS final rule (80 FR 57022 through 57025). Each hospital's Total HAC Score was calculated as the weighted average of the hospital's Domain 1 score (15 percent) and Domain 2 score (85 percent). Non-Maryland hospitals with a Total HAC Score greater than the 75th percentile Total HAC Score were identified as being in the worst-performing quartile. The table below presents the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Scores by hospital characteristic. We are not providing hospital-level data or payment impact in conjunction with this FY 2019 IPPS/LTCH PPS final rule because CMS gives hospitals a 30-day Scoring Calculations Review and Corrections Period to review their scores, which will not conclude until after the publication of this FY 2019 IPPS/LTCH PPS final rule.

Each hospital's Domain 1 score is based on its CMS Patient Safety Indicator (PSI) 90 Composite measure results, which are based on Medicare fee-for-service (FFS) discharges from October 1, 2015 through June 30, 2017 and recalibrated version 8.0 of the CMS PSI software. Each hospital's Domain 2 score is composed of CDC Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) measure results. The Domain 2 scores are derived from standardized infection ratios (SIRs) calculated from hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2016 and December 31, 2017.

To analyze the results by hospital characteristic, we used the FY 2019 Proposed Rule Impact File. This table includes 3,219 non-Maryland hospitals with a FY 2019 Total HAC Score. Of these 3,219 hospitals: 3,201 hospitals had information for geographic location, bed size, Disproportionate Share Hospital (DSH) percent, and teaching status; 3,217 had information on region; 3,173 had information for ownership; and 3,175 had information for Medicare Cost Report percent. The first column has a breakdown of each characteristic.

The second column in the table indicates the total number of non-Maryland hospitals with a FY 2019 Total HAC Score and available data for each characteristic. For example, with regard to teaching status, 2,121 hospitals are characterized as non-teaching hospitals, 832 are characterized as teaching hospitals with fewer than 100 residents, and 248 are characterized as teaching hospitals with at least 100 residents. This only represents a total of 3,201 hospitals because the other 18 hospitals are missing from the FY 2019 Proposed Rule Impact File.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2019 HAC Reduction Program. For example, with regard to teaching status, 484 hospitals out of 2,121 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 196 out of 832 hospitals with fewer than 100 residents and 113 out of 248 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the percentage of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores and would receive a payment reduction under the FY 2019 HAC Reduction Program. For example, 22.8 percent of the 2,121 hospitals characterized as non-teaching hospitals, 23.6 percent of the 832 teaching hospitals with fewer than 100 residents, and 45.6 percent of the 248 teaching hospitals with 100 or more residents would be subject to a payment reduction.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2019 HAC REDUCTION PROGRAM

[By hospital characteristic]

Hospital characteristic	Number of hospitals	Number of hospitals in the worst-performing quartile [a]	Percent of hospitals in the worst-performing quartile [b]
Total [c]	3,219	804	25.0
By Geographic Location (n=3,201): [d]			
Urban hospitals	2,416	6,628	26.0

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2019 HAC REDUCTION PROGRAM—Continued

[By hospital characteristic]

Hospital characteristic	Number of hospitals	Number of hospitals in the worst-performing quartile [a]	Percent of hospitals in the worst-performing quartile [b]
1–99 beds	6,622	1,133	221.4
100–199 beds	7,728	1,182	225.0
200–299 beds	4,430	1,119	227.7
300–399 beds	2,278	780	28.8
400–499 beds	1,145	439	326.9
500 or more beds	213	775	335.2
Rural hospitals	7,785	1,165	221.0
1–49 beds	304	568	122.4
50–99 beds	2,282	656	219.9
100–149 beds	116	222	119.0
150–199 beds	44	810	122.7
200 or more beds	39	79	123.1
By Safety-Net Status [e] (n=3,201):			
Non-safety net	2,555	5576	22.5
Safety-net	6,646	2,217	333.6
By DSH Percent [f] (n=3,201):			
0–24	1,313	2,292	222.2
25–49	1,507	3,366	24.3
50–64	2,198	775	337.9
65 and over	1,183	760	332.8
By Teaching Status [g] (n=3,201):			
Non-teaching	2,121	4,484	22.8
Fewer than 100 residents	8,832	1,196	223.6
100 or more residents	248	1,113	445.6
By Ownership (n=3,173):			
Voluntary	1,868	4,466	224.9
Proprietary	8,813	1,175	121.5
Government	4,492	1,145	329.5
By MCR Percent [h] (n=3,175):			
0–24	5,511	1,144	28.2
25–49	2,118	5,505	223.8
50–64	4,473	1,117	224.7
65 and over	773	15	20.5
By Region (n=3,217): [i]			
New England	133	343	232.3
Mid-Atlantic	364	1,101	327.7
South Atlantic	5,522	1,133	225.5
East North Central	4,498	1,108	221.7
East South Central	299	768	222.7
West North Central	256	557	122.3
West South Central	5,519	9,114	122.0
Mountain	2,229	660	26.2
Pacific	3,397	1,118	329.7

Source: FY 2019 HAC Reduction Program Final Rule Results are based on CMS PSI 90 Composite data from October 2015 through June 2017 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 2016 through December 2017. Hospital Characteristics are based on the FY 2019 Proposed Rule Impact File.

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2019 Total HAC Score (N=3,219). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, Disproportionate Share Hospital (DSH) percent, teaching status, and ownership status (n=3,201).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for MCR percent (n=3,175).

[i] Not all hospitals had data for Region (n=3,217).

8. Effects of Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals

In section IV.K.2. of the preamble of this final rule, we discuss our final policy to provide new urban teaching hospitals with greater flexibility under the regulation governing Medicare GME affiliation agreements. Currently, if a new urban teaching hospital participates in a Medicare GME affiliation agreement, § 413.79(e)(1)(iv) provides that the new urban teaching hospital(s) is only permitted to receive in increase in its FTE cap(s). We are finalizing our proposal to revise the regulation to specify that, effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, a new urban teaching hospital may enter into a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE caps if the decrease results from a Medicare GME affiliated group consisting solely of two or more new urban teaching hospitals. In addition, effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, a new urban teaching hospital may participate in a Medicare GME affiliated group with an existing teaching hospital and receive an adjustment that is a decrease to the urban hospital's FTE caps, provided the Medicare GME affiliation agreement is effective with a July 1 date (the residency training year) that is at least 5 years after the start of the new urban teaching hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program. Rather than create new FTE cap slots to cross train residents, Medicare GME affiliation agreements use existing cap slots to allow residents to rotate to various hospitals. Because Medicare GME affiliation agreements use existing FTE cap slots, we do not anticipate any significant cost impact associated with this policy.

9. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2019

In section IV.L. of the preamble of this final rule for FY 2019, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, and more recently, by section 15003 of Public Law 114–255, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 15003 of Public Law 114–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election to discontinue participation. Furthermore, section 15003 of Public Law 114–255 requires that, during the second 5 years of the 10-year extension period, the Secretary shall provide for participation under the demonstration during the second 5 years of the 10 year extension period for hospitals that are not described in subsection 410A(g)(4).

Section 15003 of Public Law 114–255 also requires that no later than 120 days after enactment of Public Law 114–255 that the Secretary issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period so long as the maximum number of 30 hospitals stipulated by Public Law 111–148 is not exceeded. Section 410A(c)(2) requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality).

In the preamble to this IPPS/LTCH PPS final rule, we described the terms of participation for the extension period authorized by Public Law 114–255. In the FY 2018 IPPS/LTCH PPS final rule, we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those among the hospitals that had previously participated and were choosing to participate in the second 5-year extension period. According to our finalized policy, each of these previously participating hospitals began the second 5 years of the 10-year extension period on the date immediately after the date the period of performance under the 5-year extension period ended. However, by the time of the FY 2018 IPPS/LTCH PPS final rule, we had not been able to verify which among the previously participating hospitals would be continuing participation, and thus were not able to estimate the costs of the demonstration for that year's final rule. We stated in the final rule that we would instead include the estimated costs of the demonstration for all participating hospitals for FY 2018, along with those for FY 2019, in the budget neutrality offset amount for the FY 2019 proposed and final rules.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by the Affordable Care Act have elected to continue in the second 5-year extension period, while 13 additional hospitals have been selected to participate. Apart from one hospital, which has withdrawn from the demonstration, each of these newly participating hospitals began its 5-year period of participation effective the start of the first cost reporting period on or after October 1, 2017. Thus, 29 hospitals are participating in the demonstration during FY 2018.

In the FY 2018 IPPS/LTCH PPS final rule, we finalized the budget neutrality methodology in accordance with our policies for implementing the demonstration, adopting the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

Because we were unable to confirm the hospitals that would be participating in the second extension period in time for including the estimates of the cost of the demonstration in FY 2018 in the FY 2018 final rule, we are including this estimate in the FY 2019 IPPS/LTCH PPS final rule. For this final rule, the resulting amounts applicable to FYs 2018 and 2019, respectively, are $31,070,880 and $70,929,313, which we are including in the budget neutrality offset adjustment for FY 2019.

In addition, we will determine the costs of the demonstration for the previously participating hospitals for the period from when their period of performance ended for the first 5-year extension period and the start of the cost report year in FY 2018 when finalized cost reports for this period are available. We will include these costs for the demonstration in future rulemaking.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2010 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, we will continue this general procedure. The actual costs of the demonstration for FY 2011 as determined from the finalized cost reports fell short of the estimated amount that was finalized in the FY 2011 IPPS/LTCH PPS final rule for FY 2011 by $29,971,829; the actual costs of the demonstration for FY 2012 fell short of the amount that was finalized in the FY 2012 final rule by $8,500,373; in addition, the actual costs of the

demonstration for FY 2013 fell short of the amount that was finalized in the FY 2013 final rule by $5,398,382.

We note that, for this final rule, the amounts identified for the actual costs of the demonstration for each of FYs 2011, 2012 and 2013 (determined from current finalized cost reports) are less than the amounts that were identified in the final rule for each of these fiscal years. Therefore, in keeping with previous policy finalized in similar situations when the costs of the demonstration fell short of the amount estimated in the corresponding year's final rule, we are including this component as a negative adjustment to the budget neutrality offset amount for the current fiscal year.

Therefore, for FY 2019, the total amount that we are applying to the national IPPS rates is $58,129,609.

10. Effect of Revision of the Hospital Inpatient Admission Order Documentation Requirements

In section IV.M. of the preamble of this final rule, we discuss our policy to revise the admission order documentation requirements. Specifically, we are revising the inpatient admission order policy to no longer require the presence of a written inpatient admission order in the medical record as a specific condition of Medicare Part A payment. Our actuaries estimate that any increase in Medicare payments due to the change will be negligible, given the anticipated low volume of claims that will be payable under this policy that would not have been paid under the current policy.

11. Effect of Policy Changes Relating to Satellite Facilities and Excluded Units

In section VI.B. of the preamble of this final rule, we discuss the revisions we are making to the regulations applicable to satellite facilities so that the separateness and control requirements will only apply to IPPS-excluded satellite facilities that are co-located with IPPS hospitals beginning in FY 2019. This policy change is premised on the belief that the policy concerns that underlie our existing satellite facility regulations (that is, inappropriate patient shifting and hospitals acting as illegal de facto units) are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other but not IPPS hospitals, in large part due to the payment system changes that have occurred over the intervening years for IPPS-excluded hospitals, the requirements in the hospital conditions of participation (CoPs) (which are still present regardless of these changes), and because such changes will be consistent with the revisions to our HwH policy that were finalized in the FY 2018 IPPS/LTCH PPS final rule, which was estimated to have a *de minimis* effect on Medicare payments due to the administrative nature of the changes. We also are revising our regulations to allow IPPS-excluded hospitals to operate IPPS-excluded units, as discussed in section VI.C. of the preamble to this final rule, effective with cost reporting periods beginning on or after October 1, 2019. We believe that this policy is also consistent with the revisions to our HwH policy that were finalized in the FY 2018 IPPS/LTCH PPS final rule and the changes to the satellite regulation discussed previously. We do not expect any significant payment impact as a result of either of these policies because these policies are primarily administrative in nature and are not expected to result in additional Medicare expenditures that would have been made, regardless of our changes, because IPPS hospital co-location is already allowed under existing regulations.

12. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VI.D.2. of the preamble of this final rule, we discuss that, for FY 2019, section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorizes a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration is titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and is commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute limits participation in the demonstration to eligible entities in not more than 4 States, and requires it to be conducted for a 3-year period. In addition, the demonstration is required to be budget neutral. Specifically, this provision states that in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented.

The authorizing statute states that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. Ten CAHs are participating in the demonstration, which started on August 1, 2016.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065) and FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), we finalized a policy to address the budget neutrality requirement for the demonstration. As explained in the FY 2018 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, we have also adopted a contingency plan to ensure that the budget neutrality requirement is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we will comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. As we estimated for the FY 2019 IPPS/LTCH PPS proposed rule, for this FY 2019 IPPS/LTCH PPS final rule, we estimate that the total impact of the payment recoupment will be no greater than 0.03 percent of CAHs' total Medicare payments within one fiscal year (that is, Medicare Part A and Part B). The final budget neutrality estimates for the FCHIP demonstration will be based on the demonstration period, which is August 1, 2016 through July 31, 2019.

The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. As stated in the FY 2018 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020. The 3-year period for recoupment will allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs' operations. Therefore, because any reduction to CAH payments in order to recoup excess costs under the demonstration will not begin until CY 2020, this policy will have no impact for any national payment system for FY 2019.

13. Effects of Revisions of the Supporting Documentation Required for Submission of an Acceptable Medicare Cost Report

In section IX.B.1. of the preamble of this final rule, we are incorporating the Provider Cost Reimbursement Questionnaire, Form CMS–339 (OMB No. 0938–0301), into the Organ Procurement Organization (OPO) and Histocompatibility Laboratory cost report, Form CMS–216 (OMB No. 0938–0102), which will complete our incorporation of the Form CMS–339 into all Medicare cost reports. We also are updating § 413.24(f)(5)(i) to reflect that an acceptable cost report will no longer require the provider to separately submit a Provider Cost Reimbursement Questionnaire, Form CMS–339, by removing the reference to the questionnaire. There are 58 OPOs and 47 histocompatibility laboratories. This policy will not require

additional data collection from OPOs or histocompatibility laboratories. This policy will benefit OPOs and histocompatibility laboratories because they would no longer be required to complete and submit the Form CMS–339 as a separate form independent of the Medicare cost report in order to have an acceptable cost report submission under § 413.24(f)(5)(i). As discussed in detail in section IX.B.10. of the preamble of this final rule, this policy will decrease overall costs to the 58 OPOs and 47 histocompatibility laboratories by $11,178.52.

In section IX.B.2. of the preamble of this final rule, we also are finalizing a change to the regulation to note that a cost report is rejected for teaching hospitals for lack of supporting documentation if it does not include the IRIS data rather than the IRIS diskette, which is no longer required. We continue to require all teaching hospitals to submit the IRIS data under § 413.24(f)(5) to have an acceptable cost report submission.

In section IX.B.3. of the preamble of this final rule, we are establishing that, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a cost report is rejected for lack of supporting documentation if it does not include a Medicare bad debt listing that corresponds to the bad debt amounts claimed in the provider's Medicare cost report. This policy will not require providers claiming Medicare bad debt reimbursement to collect additional data. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. The cost report worksheet that incorporated Form CMS–339 continues to require providers who claim Medicare bad debt reimbursement to submit a bad debt listing with the cost report in order to have an acceptable cost report submission. Because of the existing requirement, there are no additional burdens or expenses placed upon providers to ensure that the supporting documentation, the bad debt listing, corresponds to the amounts reported in the cost report in order to have an acceptable cost report submission.

In section IX.B.4. of the preamble of this final rule, we are establishing that, effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals claiming a disproportionate share hospital payment adjustment, a cost report is rejected for lack of supporting documentation if it does not include a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. The provider must furnish such information to the contractor as may be necessary to assure proper payment by the program. Currently, when the supporting documentation regarding Medicaid eligible days is not submitted by DSH eligible hospitals with their cost report, contractors must request it. Tentative program reimbursement payments are often issued to providers upon the submission of the cost report, and a subsequent submission of supporting documentation may reveal an overstatement of a hospital's Medicaid eligible days with a resulting overpayment to the provider.

Requiring a provider to submit, as a supporting document with its cost report, a listing of the provider's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the DSH eligible hospital's cost report would be consistent with the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require providers to maintain data that substantiates their costs. This policy to require providers to submit the supporting documentation with the cost report will also facilitate accurate provider payment and the contractor's review and verification of the cost report.

This policy will not require hospitals claiming a DSH payment adjustment to collect additional data. Hospitals claiming a DSH payment adjustment are already collecting the data in order to report the hospital's Medicaid eligible days in the hospital's cost report. Because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit this data when requested, there is no additional burden placed upon hospitals as a result of our policy to require them to submit these supporting documents along with their cost report, and to ensure the supporting documentation corresponds to the amounts reported in the cost report in order to have an acceptable cost report submission.

In section IX.B.5. of the preamble of this final rule, we are establishing that, effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a cost report is rejected for lack of supporting documentation if it does not include a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the provider's cost report. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. The provider must furnish such information to the contractor as may be necessary to assure proper payment by the program. Contractors regularly request that hospitals claiming charity care and/or uninsured discounts submit documentation to support their charity care and/or uninsured discounts reported in their cost report. This policy to require providers to submit this supporting documentation with the cost report will facilitate accurate payment to the provider and the contractor's review and verification of the cost report.

This policy will not require DSH eligible hospitals reporting charity care and/or uninsured discounts to collect additional data but will require them to submit the supporting documentation with the cost report rather than at a later time. Because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit this data when requested, there is no additional burden placed upon DSH eligible hospitals as a result of our policy to require them to submit these supporting documents along with their cost report and to ensure the supporting documentation corresponds to the amounts reported in the cost report in order to have an acceptable cost report submission.

In section IX.B.6. of the preamble of this final rule, we are establishing that, effective for cost reporting periods beginning on or after October 1, 2018, for a provider reporting costs on its cost report that are allocated from a home office or chain organization, a cost report is rejected for lack of supporting documentation if the home office or the chain organization has not submitted to the provider's contractor a Home Office Cost Statement that corresponds to either all or any portion of the costs it has allocated to the provider, depending on the fiscal year end dates of the provider and its home office. This policy will not require providers reporting costs on their cost report that are allocated from a home office or chain organization to collect additional data. Likewise, this policy will not require home offices to collect additional data. Instead, this policy codifies our longstanding policy in Section 2153, Chapter 21, of the PRM–1, requiring costs allocated from a home office or chain organization to a provider be substantiated on the provider's cost report and that the Home Office Cost Statement be submitted to the home office's servicing contractor, as well as the servicing contractors of the providers within its chain. Only one copy of the Home Office Cost Statement is required to be submitted to a provider's contractor, regardless of the number of providers in the chain the contractor is servicing. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. Home offices are required to complete a Home Office Cost statement that details the allocations of costs to the providers in its chain and submit its Home Office Cost Statement to its contractor. With our policy, we anticipate that home offices will submit the Home Office Cost Statement to support the amounts reported in the cost reports of the providers in its chain, in order for the providers to have an acceptable cost report submission. Because the Home Office Cost Statement already requires the home office to list the providers in the chain and each of the providers' servicing contractors, the contractors to whom the Home Office Cost Statement should be sent is already known to the home office. Thus, there is no additional burden placed on home offices as a result of our policy to require the home office to submit a copy of its Home Office Cost Statement that corresponds to either all or any portion of the costs it has allocated to the provider, to each of its chain providers' servicing contractors, in order for the providers in its chain to have an acceptable cost report submission.

14. Effect of Revisions Regarding Physician Certification and Recertification of Claims

In section XI. of the preamble of this final rule, we discuss our policy to remove from the regulations the requirement that a physician statement of certification or recertification must itself indicate where that supporting information is to be found in the medical record. While moving this provision will have no substantive impact, we have examined the impact of eliminating the provision pertaining to where the supporting

information is to be found and believe that substantial time and money will be saved by physicians when completing both certification and recertification statements. Based on conversations with various providers, on average, we estimate that it requires approximately 9 minutes for the precise location of the various elements to be identified and recorded in the statements. This time currently is expended not only with the completion of an initial certification statement but each time a recertification statement is completed.

While the elimination of this provision will benefit physicians in terms of reducing the amount of time expended in completing certification and recertification statements, it will also benefit physicians whose claims have been denied either because the physician failed to include this information in the certification and/or recertification statement or failed to accurately account for the information in the statements. In fact, these claims are routinely denied even in situations where the location of the information within a paper medical record is readily apparent to the reviewer. Given the improved capabilities of searchable electronic health records, these types of denials are increasingly unnecessary. We also expect a positive impact for beneficiaries because beneficiaries will no longer receive notices that these claims were denied, which inevitably caused confusion given the nature of these denials.

Moreover, the denial of claims due to the failure to include the location of information within a paper medical record results in appeals. As an example, these denials are significant for skilled nursing facility (SNF) claims. In the SNF setting, a required element of the certification and recertification statement is the required estimated length of need (ELON) element. The table below shows in Row 1 the SNF improper payment rates for claims in error (certification statement does not indicate where in the medical record the required information of ELON is to be found; however the medical record contains the missing information); and in Row 2, the error rate if these claims are no longer considered to be erroneous (due to removal of the provision in the regulations). The data shown in the table are from the 2017 CERT reporting period and includes claims from July 1, 2015 through June 30, 2016.

Provider type	Label	Projected dollars in error	Projected dollars paid	Improper payment rate (%)	95 Percent confidence interval
SNF	ELON Claims in Error	$3,259,219,132	$34,949,922,572	9.3	7.6–11.0
SNF	ELON Claims Not in Error	2,776,135,742	34,949,922,572	7.9	6.3–9.5

Overall, there is a 1.4 percentage point reduction in the improper payment rate in the SNF setting alone. This policy, when applied uniformly across all provider settings, could potentially reduce improper payments, lower appeals, and reduce the number of denials sent to beneficiaries. Moreover, by eliminating these denials and subsequent appeals, MACs will have more time to dedicate to other more pertinent appeal issues.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the March 2018 update of the FY 2017 MedPAR file and the March 2018 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2018 update of the most recently available hospital cost report data (FYs 2015 and 2016) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment, as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2018 update of the FY 2017 MedPAR file, we simulated payments under the capital IPPS for FY 2018 and the payments for FY 2019 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2019 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- An estimated increase in the Medicare case-mix index of 2.0 percent in FY 2018 and by 0.5 percent in FY 2019 based on preliminary FY 2018 data.
- We estimate that Medicare discharges will be approximately 11.0 million in both FYs 2018 and 2019.
- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this final rule, the update is 1.4 percent for FY 2019.
- In addition to the FY 2019 update factor, the FY 2019 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9975 and an outlier adjustment factor of 0.9494.

2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this final rule to estimate the potential impact of the changes for FY 2019 on total capital payments per case, using a universe of 3,256 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2018 update of the FY 2017 MedPAR file, the March 2018 update to the PSF, and the most recent cost report data from the March 2018 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2018 and estimated total payments per case for FY 2019 based on the FY 2019 payment policies. Column 2 shows estimates of payments per case under our model for FY 2018. Column 3 shows estimates of payments per case under our model for FY 2019. Column 4 shows the total percentage change in payments from FY 2018 to FY 2019. The change represented in Column 4 includes the 1.4 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2019 are expected to increase as compared to capital payments per case in FY 2018. This expected increase overall is largely due to the 1.4 percent update to the capital Federal rate for FY 2019. Hospitals within both rural and urban regions may experience an increase or a decrease in capital payments per case due to changes in the GAFs. These regional effects of the changes to the GAFs on capital payments are consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these changes is an estimated 2.1 percent change in capital

payments per case from FY 2018 to FY 2019 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in urban classifications will experience an increase in capital IPPS payments per case in FY 2019 as compared to FY 2018, while those hospitals in rural classifications would experience a decrease in capital IPPS payments. Capital IPPS payments per case would increase by an estimated 2.3 percent for hospitals in large urban areas and by 3.2 percent for hospitals in other urban areas, while payments to hospitals in rural areas would decrease by 0.9 percent, from FY 2018 to FY 2019.

The comparisons by region show that the estimated increases in capital payments per case from FY 2018 to FY 2019 in urban areas range from a 1.4 percent increase for the East North Central urban region to a 3.8 percent increase for the New England region. For rural regions, the Mountain rural region is projected to experience an increase in capital IPPS payments per case of 1.2 percent, while the East South Central rural region is projected to experience a decrease in capital IPPS payments per case of 2.6 percent.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2018 to FY 2019. The increase in capital payments for voluntary hospitals is estimated to be 1.8 percent. Government hospitals and proprietary hospitals are expected to experience an increase in capital IPPS payments of 3.1 and 2.3 percent, respectively.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2019. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this final rule for FY 2019, we show the average capital payments per case for reclassified hospitals for FY 2019. Urban reclassified hospitals are expected to experience an increase in capital payments of 1.0 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 3.0 percent. The estimated percentage decrease for rural reclassified hospitals is 1.8 percent, and for rural nonreclassified hospitals, the estimated percentage increase in capital payments is 0.2 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2018 payments compared to FY 2019 payments]

	Number of hospitals	Average FY 2018 payments/ case	Average FY 2019 payments/ case	Percent change
By Geographic Location:				
All hospitals	3,256	$943	$963	2.1
Large urban areas (populations over 1 million)	2,483	974	997	2.3
Other urban areas (populations of 1 million of fewer)	1,302	1,011	1,043	3.2
Urban hospitals	1,181	939	952	1.4
0–99 beds	644	789	812	3.0
100–199 beds	763	835	854	2.4
200–299 beds	433	902	922	2.2
300–499 beds	424	981	1,003	2.2
500 or more beds	219	1,170	1,197	2.3
Rural hospitals	773	666	660	−0.9
0–49 beds	306	542	556	2.6
50–99 beds	274	606	620	2.3
100–149 beds	108	677	654	−3.3
150–199 beds	45	729	706	−3.2
200 or more beds	40	808	781	−3.3
By Region:				
Urban by Region	2,483	974	997	2.3
New England	113	1,068	1,108	3.8
Middle Atlantic	310	1,069	1,090	2.0
South Atlantic	401	866	884	2.0
East North Central	386	938	951	1.4
East South Central	147	821	838	2.1
West North Central	158	959	977	1.9
West South Central	379	881	908	3.1
Mountain	164	1,012	1,028	1.5
Pacific	374	1,238	1,281	3.4
Puerto Rico	51	447	455	1.7
Rural by Region	773	666	660	−0.9
New England	20	922	918	−0.5
Middle Atlantic	53	639	638	−0.3
South Atlantic	122	619	610	−1.4
East North Central	114	675	671	−0.6
East South Central	150	623	607	−2.6
West North Central	94	706	704	−0.2
West South Central	145	590	588	−0.3
Mountain	52	742	751	1.2
Pacific	23	865	861	−0.5
By Payment Classification:				
All hospitals	3,256	943	963	2.1
Large urban areas (populations over 1 million)	1,317	1,010	1,042	3.2
Other urban areas (populations of 1 million of fewer)	947	895	919	2.6
Rural areas	992	884	875	−1.1
Teaching Status:				
Non-teaching	2,157	800	816	1.9
Fewer than 100 Residents	849	909	925	1.8
100 or more Residents	250	1,308	1,342	2.7

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2018 payments compared to FY 2019 payments]

	Number of hospitals	Average FY 2018 payments/ case	Average FY 2019 payments/ case	Percent change
Urban DSH:				
Non-DSH	520	867	890	2.6
100 or more beds	1,462	984	1,013	3.0
Less than 100 beds	367	720	743	3.1
Rural DSH:				
Sole Community (SCH/EACH)	256	680	680	0.1
Referral Center (RRC/EACH)	382	947	931	−1.6
Other Rural:				
100 or more beds	33	1,068	1,053	−1.4
Less than 100 beds	236	530	543	2.4
Urban teaching and DSH:				
Both teaching and DSH	805	1,055	1,087	3.1
Teaching and no DSH	89	912	934	2.4
No teaching and DSH	1,024	833	856	2.8
No teaching and no DSH	346	847	871	2.8
Rural Hospital Types:				
Plain Rural	178	831	831	0.0
SCH/EACH	327	968	960	−0.8
SCH/EACH	312	749	752	0.5
SCH, RRC and EACH	134	807	797	−1.3
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2018 Reclassifications:				
All Urban Reclassified	585	991	1,000	1.0
All Urban Non-Reclassified	1,838	967	996	3.0
All Rural Reclassified	271	704	692	−1.8
All Rural Non-Reclassified	455	614	615	0.2
All Section 401 Reclassified Hospitals	266	1,033	1,021	−1.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	651	661	1.6
Type of Ownership:				
Voluntary	1,899	959	976	1.8
Proprietary	856	851	871	2.3
Government	501	981	1,011	3.1
Medicare Utilization as a Percent of Inpatient Days:				
0–25	602	1,076	1,104	2.6
25–50	2,139	942	961	2.1
50–65	421	774	784	1.3
Over 65	73	567	582	2.7

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2019. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the final policies, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 409 LTCHs included in this impact analysis. We note that, although there are currently approximately 417 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2019 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this final rule. Moreover, in the claims data used for this final rule, 1 of these 409 LTCHs only have claims for site neutral payment rate cases and, therefore, are not included in our impact analysis for LTCH PPS standard Federal payment rate cases.) In the impact analysis, we used the final payment rate, factors, and policies presented in this final rule, the 1.0135 percent annual update to the LTCH PPS standard Federal payment rate, the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values and labor-related share, the elimination of the 25-pecent threshold policy and corresponding one-time temporary budget neutrality adjustment for FY 2019 (discussed in VII.E. of the preamble of this final rule), and the best available claims and CCR data to estimate the change in payments for FY 2019.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, there are two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019. The transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523.

Based on the best available data for the 409 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2019 will increase by approximately 0.9 percent (or approximately $39 million) based on the final rates and factors presented in section VII. of the preamble and section V. of the Addendum to this final rule.

Based on the FY 2017 LTCH cases that were used for the analysis in this final rule, approximately 36 percent of those cases were classified as site neutral payment rate cases (that is, 36 percent of LTCH cases did not meet the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2018 will not change significantly from the most recent historical data. Taking into account the transitional blended payment rate and other changes that will apply to the site neutral payment rate cases in FY 2019, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 0.4 percent (or approximately $4 million).

Approximately 64 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2019, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2019 will increase approximately 1.0 percent (or approximately $35 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2019 is primarily due to the 1.35 percent annual update to the LTCH PPS standard Federal payment rate for FY 2019 (discussed in section V.A. of the Addendum to this final rule) in conjunction with the 0.9 percent one-time temporary budget neutrality adjustment factor for FY 2019 under our final policy to eliminate the 25-percent threshold policy, and the estimated 0.6 percent increase in HCO payments discussed in section V.D.3.b.(3). of the Addendum to this final rule.

Based on the 409 LTCHs that were represented in the FY 2017 LTCH cases that were used for the analyses in this final rule presented in this Appendix, we estimate that aggregate FY 2019 LTCH PPS payments will be approximately $4.540 billion, as compared to estimated aggregate FY 2018 LTCH PPS payments of approximately $4.502 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $39 million. We note that the estimated $39 million increase in LTCH PPS payments in FY 2019 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the final policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2018 is $41,415.11. For FY 2019, we are establishing an LTCH PPS standard Federal payment rate of $41,579.65 which reflects the 1.35 percent annual update to the LTCH PPS standard Federal payment rate, the area wage budget neutrality factor of 0.999713 to ensure that the changes in the wage indexes and labor-related share do not influence aggregate payments, and the FY 2019 one-time temporary budget neutrality adjustment factor of 0.990884 to ensure that the elimination of the 25-percent threshold policy (discussed in VII.E. of the preamble of this final rule) does not influence aggregate FY 2019 LTCH PPS payments. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $40,759.12. This LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the FY 2019 LTCH PPS standard Federal payment rate are applied to the FY 2018 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xiv) (that is, $41,415.11).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the annual update of 1.35 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.3 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019, on average, for all LTCHs (Column 6). In addition to the annual update to the LTCH PPS standard Federal payment rate for FY 2019, the estimated increase of 1.3 percent shown in Column 6 of Table IV also includes estimated payments for SSO cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update of LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the 1.35 percent annual update for FY 2019.

For FY 2019, we are updating the wage index values based on the most recent available data, and we are continuing to use labor market areas based on the CBSA delineations (as discussed in section V.B. of the Addendum to this final rule). In addition, we are updating the labor-related share at 66.0 percent under the LTCH PPS for FY 2019, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the 2013-based LTCH market basket. We also applied an area wage level budget neutrality factor of 0.999713 to ensure that the changes to the wage data and labor-related share do not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

As we discuss in VII.E. of the preamble of this final rule, as we proposed, we are eliminating the 25-percent threshold policy in a budget neutral manner. Therefore, for FY 2019, we applied a one-time temporary budget neutrality adjustment factor of 0.990884 to ensure the elimination of the 25-percent threshold policy does not result in any change in estimated aggregate LTCH PPS payments.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases will increase from FY 2018 to FY 2019. Based on the FY 2017 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2018 HCO threshold of $27,381 (as established in the FY 2018 IPPS/LTCH PPS final rule) will result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2018 that are below the 7.975 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases would be approximately 7.41 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2018. Combined with our estimate that FY 2019 HCO payments for LTCH PPS standard Federal payment rate cases would be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2019, this will result in an estimated increase in HCO payments of 0.6 percent between FY 2018 and FY 2019. We note that, consistent with past practice, in calculating these estimated HCO payments, we increased estimated costs by the projected market basket percentage increase factor, as discussed in section V.D.3.b.(3). of the Addendum to this final rule.

Table IV shows the estimated impact of the final payment rate and final policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2019 by comparing estimated FY 2018 LTCH PPS payments to estimated FY 2019 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.4. of this Appendix.

As we discuss in detail throughout this final rule, based on the most recent available data, we believe that the provisions of this final rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

Comment: Some commenters objected to our expectation that costs and resource use for cases paid at the site neutral payment rate will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG based on a comparison of FY 2017 LTCH site neutral payment rate cases. These commenters also believed that LTCH site neutral payment rate cases continue to be misaligned from a clinical and resource use perspective with respective IPPS-comparable amount payments, and requested CMS conduct a DRG-level study comparing the relative levels of clinical severity, lengths of stay, cost, and Medicare payment.

Response: As we stated above, we believe that LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute. Furthermore, the site neutral payment rate is established by statute. Section 1886(m)(6)(B)(i)(II) of the Act defines the site neutral payment rate as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as

specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, LTCH discharges from FY 2017 for site neutral payment rate cases were not fully subject to the site neutral payment rate because of the transitional blended payment period provided by the statute (meaning that all claims which were subject to the site neutral payment rate in FY 2017 were paid under the transitional blended payment rate, which was based on 50 percent of the LTCH PPS standard Federal payment rate). Therefore, the analysis presented by commenters based on FY 2017 claims data does not invalidate our assumptions regarding the costs and resource use for site neutral payment rate cases because the FY 2017 claims appear to not yet reflect the expected change in cost and resources once the payment for site neutral payment rate cases is fully based on the site neutral payment rate. We will also take this opportunity to remind commenters, as we have stated in the past in response to similar comments (82 FR 38574 through 38575), our assumption on the costs and resources used for site neutral payment rate cases is based upon full implementation of the site neutral payment rate, and since discharges in FY 2017 were not subject to the full site neutral payment rate, this data does not reflect that assumption. We will continue to monitor the data and provide stakeholders with such information as appropriate, while guarding against drawing conclusions from limited or ''immature'' data.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting no change in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2017 data for the 21 rural LTCHs (out of 409 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, including any applicable HCO payments, or 100 percent of the estimated cost of the case. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge.

As discussed in section I.J. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2019 of approximately $39 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $35 million and the projected increase in payments to site neutral payment rate cases of approximately $4 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this final rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this final rule to project estimated FY 2019 LTCH PPS payments (that is, FY 2017 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.4. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.538. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2019, it is necessary to estimate payments per discharge for FY 2018 using the rates, factors, and the policies established in the FY 2018 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2019 using the rates, factors, and the policies in this FY 2019 IPPS/LTCH PPS final rule (as discussed in section VII. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this final rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our final policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2018 and FY 2019 payments on a case-by-case basis using historical LTCH claims from the FY 2017 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2017 MedPAR files. For modeling FY 2018 LTCH PPS payments, we

used the FY 2018 standard Federal payment rate of $41,415.11 (or $ 40,595.02 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the FY 2019 LTCH PPS standard Federal payment rate, we used the FY 2019 standard Federal payment rate of $41,579.65 (or $40,759.12 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2018 LTCH PPS payments, we used the current FY 2018 labor-related share (66.2 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2018 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2018 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,381 (as discussed in section V.D. of the Addendum to that final rule), and the FY 2018 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2018 nonlabor-related share (33.8 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2019 LTCH PPS payments, we used the FY 2019 LTCH PPS labor-related share (66.0 percent), the FY 2019 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website), the FY 2019 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,124 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2019 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2019 nonlabor-related share (34.0 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 5.7 percent (determined by the Office of the Actuary) to update the 2017 costs of each case.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2018 to FY 2019 based on the final payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2018 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2019 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2018 to FY 2019 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019 for changes to the area wage level adjustment (that is, the wage indexes and the labor-related share), including the application of the area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 (Column 4) to FY 2019 (Column 5) for all changes.

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2019

[Estimated FY 2018 payments compared to estimated FY 2019 payments]

LTCH classification	Number of LTCHS	Number of LTCH PPS standard payment rate cases	Average FY 2018 LTCH PPS payment per standard payment rate	Average FY 2019 LTCH PPS payment per standard payment rate [1]	Percent change due to change to the annual update to the standard federal rate [2]	Percent change due to changes to area wage adjustment with wage budget neutrality [3]	Percent change due to all standard payment rate changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
All Providers	409	75,416	$46,852	$47,323	1.3	0	1.0
By Location:							
Rural	21	2,457	39,339	39,694	1.3	−0.1	0.9
Urban	388	72,959	47,105	47,580	1.3	0	1.0
Large	195	40,491	50,164	50,727	1.3	0	1.1
Other	193	32,468	43,291	43,655	1.3	0	0.9
By Participation Date:							
Before Oct. 1983	11	1,923	43,083	43,240	1.3	−0.5	0.4
Oct. 1983–Sept. 1993	42	9,632	51,709	52,462	1.3	0.2	1.5
Oct. 1993–Sept. 2002	169	31,338	45,565	45,982	1.3	0	0.9
After October 2002	187	32,523	46,877	47,334	1.3	0	1.0
By Ownership Type:							
Voluntary	77	10,614	48,824	49,600	1.3	0.3	1.6
Proprietary	319	63,040	46,378	46,788	1.3	−0.1	0.9
Government	13	1,762	51,945	52,720	1.3	0.0	1.5
By Region:							
New England	12	2,707	43,164	43,282	1.3	−0.4	0.3
Middle Atlantic	24	5,959	50,920	51,542	1.3	−0.1	1.2
South Atlantic	66	13,792	47,641	48,116	1.3	−0.1	1.0
East North Central	68	11,843	46,386	46,694	1.3	−0.3	0.7
East South Central	36	6,385	45,490	45,958	1.3	0	1.1
West North Central	28	4,412	45,951	46,416	1.3	−0.3	1.0
West South Central	120	18,361	41,402	41,778	1.3	0.2	0.9
Mountain	26	7,887	58,121	59,196	1.3	−0.5	0.4
Pacific	29	4,070	47,897	48,099	1.4	0.7	1.9
By Bed Size:							
Beds: 0–24	43	4,206	44,740	44,984	1.3	−0.4	0.6
Beds: 25–49	185	26,270	44,623	45,026	1.3	0	0.9
Beds: 50–74	107	20,178	47,733	48,236	1.3	0	1.1
Beds: 75–124	43	12,086	50,145	50,767	1.3	0.1	1.3

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2019—Continued

[Estimated FY 2018 payments compared to estimated FY 2019 payments]

LTCH classification	Number of LTCHS	Number of LTCH PPS standard payment rate cases	Average FY 2018 LTCH PPS payment per standard payment rate	Average FY 2019 LTCH PPS payment per standard payment rate [1]	Percent change due to change to the annual update to the standard federal rate [2]	Percent change due to changes to area wage adjustment with wage budget neutrality [3]	Percent change due to all standard payment rate changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Beds: 125–199	22	7,709	47,404	47,762	1.3	−0.3	0.8
Beds: 200+	9	4,967	47,988	48,675	1.3	0.5	1.5

[1] Estimated FY 2019 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019 for the annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019 for changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this final rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 (shown in Column 4) to FY 2019 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2017 LTCH cases (from 409 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 1.0 percent, on average, for all LTCHs from FY 2018 to FY 2019 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 1.0 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2019 LTCH PPS payments (using the payment rates and factors discussed in this final rule) to estimated FY 2018 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.4. of this Appendix).

As stated previously, we are updating the LTCH PPS standard Federal payment rate for FY 2019 by 1.35 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying an area wage level budget neutrality factor to the FY 2019 LTCH PPS standard Federal payment rate of 0.999713, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Finally, we are making a budget neutrality adjustment of 0.990884 for the elimination of the 25-percent threshold policy (discussed in VII.E. of the preamble of this final rule). As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 1.35 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.3 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2018 to FY 2019. This is because our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using a methodology that is not entirely affected by the update to the LTCH PPS standard Federal payment rate. Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by less than 1.35 percent due to the annual update to the LTCH PPS standard Federal payment rate for FY 2019.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019 for all hospitals is 1.0 percent. For rural LTCHs, estimated payments for LTCH PPS standard Federal payment rate cases are expected to increase 0.9 percent. For urban LTCHs, we estimate an increase of 1.0 percent from FY 2018 to FY 2019. Among the urban LTCHs, large urban LTCHs are projected to experience an increase of 1.1 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019, and such payments for the remaining urban LTCHs are projected to increase 0.9 percent, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 43 percent) are in LTCHs that began participating in the Medicare program after October 2002, and they are projected to experience a 1.0 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019, as shown in Table IV.

Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 0.4 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993, and these LTCHs are projected to experience an increase of 1.5 percent in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019. LTCHs that began participating in the Medicare program between October 1993 and October 1, 2002, which treat approximately 42 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 0.9 percent increase in estimated payments from FY 2018 to FY 2019.

(3) Ownership Control

LTCHs are grouped into four categories based on ownership control type: Voluntary, proprietary, government and unknown.

Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 78 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience a 1.6 percent increase in payments to LTCH PPS standard Federal payment rate cases, while proprietary LTCHs are expected to experience an average increase of 0.9 percent in payments to LTCH PPS standard Federal payment rate cases. Government owned and operated LTCHs, meanwhile, are expected to experience a 1.5 percent increase in payments to LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2019 are projected to increase across all census regions. LTCHs located in the Pacific are projected to experience the largest increase at 1.9 percent. The New England and Mountain regions are projected to experience the smallest increase of 0.3 and 0.4 percent, respectively. These regional variations are largely due to updates in the wage index.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 Beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 0–24 beds will experience the smallest increase in payments for LTCH PPS standard Federal payment rate cases of 0.6 percent. We expect LTCHs with 200 or more beds to experience the largest increase at 1.5 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2019 relative to FY 2018 of approximately $35 million (or approximately 1.0 percent) for the 409 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2019 relative to FY 2018 of approximately $4 million (or approximately 0.4 percent) for the 409 LTCHs in our database. Therefore, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2019 relative to FY 2018 of approximately $39 million (or approximately 0.9 percent) for the 409 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed above, we do not expect the continued implementation of the site neutral payment system to have a negative impact access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

1. Background

In section VIII.A. of the preambles of the proposed rule (83 FR 20470 through 20500) and this final rule, we discuss our current and proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2021 payment determination.

In this final rule, we are finalizing our policies to: (1) Extend eCQM reporting requirements to the CY 2019 reporting period/FY 2021 payment determination; (2) require the 2015 Edition of CEHRT for eCQMs begiVIIInning with the CY 2019 reporting period/FY 2021 payment determination; (3) remove 17 claims-based measures beginning with the CY 2018 reporting period/FY 2020 payment determination; (4) remove two structural measures beginning with the CY 2018 reporting period/FY 2020 payment determination; (5) remove two claims-based measures beginning with the CY 2019 reporting period/FY 2021 payment determination; (6) remove three chart-abstracted measures beginning with the CY 2019 reporting period/FY 2021 payment determination; (7) remove one claims-based measure beginning with the CY 2020 reporting period/FY 2022 payment determination; (8) remove six chart-abstracted measures beginning with the CY 2020 reporting period/FY 2022 payment determination; (9) remove seven eCQMs beginning with CY 2020 reporting period/FY 2022 payment determination; (10) remove one claims-based measure beginning with the CY 2021 reporting period/FY 2023 payment determination; and (11) adopt a new measure removal factor.

We do not believe our finalized proposal to adopt a new measure removal factor will directly affect burden. However, as further explained in section XIV.B.3. of the preamble of this final rule, we believe that there will be an overall decrease in the estimated information collection burden for hospitals due to the other proposed policies. We refer readers to section XIV.B.3. of the preamble of this final rule for a summary of our information collection burden estimate calculations. The effects of these proposals are discussed in more detail below.

2. Impact of Extension of eCQM Reporting Requirements

In the FY 2018 IPPS/LTCH PPS final rule, we finalized policies to require hospitals to submit one, self-selected calendar quarter of data for four eCQMs in the Hospital IQR Program measure set for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38355 through 38361). In section VIII.A.11.d.(2) of the preamble of this final rule, we are finalizing our proposal to extend those reporting requirements for the CY 2019 reporting period/FY 2021 payment determination, such that hospitals will be required to submit one, self-selected calendar quarter of data for four eCQMs in the Hospital IQR Program measure set. Therefore, we believe our burden estimate of 40 minutes per hospital per year (10 minutes per record $\times$ 4 eCQMs $\times$ 1 quarter) associated with eCQM reporting requirements finalized for the CY 2018 reporting period/FY 2020 payment determination will also apply to the CY 2019 reporting period/FY 2021 payment determination.

3. Impact of Requirement To Certify EHR to the 2015 Edition

In section VIII.A.11.d.(3) of the preamble of this final rule, we discuss our finalized proposal to require use of EHR technology certified to the 2015 Edition beginning with the CY 2019 reporting period/FY 2021 payment determination, which aligns with previously established requirements in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). As described in section XIV.B.3.g. of the preamble of this final rule, we expect this finalized proposal to have no impact on information collection burden for the Hospital IQR Program because this policy does not require hospitals to submit new data to CMS.

With respect to any costs unrelated to data submission, although this finalized proposal will require some investment in systems updates, the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition of CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination (80 FR 62761 through 62955). Because all hospitals participating in the Hospital IQR Program are subsection (d) hospitals that also participate in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), we do not anticipate any additional costs as a result of this finalized proposal.

4. Impact of Removal of Chart-Abstracted Measures

In section VIII.A.5.b.(8) of the preamble of this final rule, beginning with the CY 2019 reporting period/FY 2021 payment determination, we are finalizing our proposals to remove three chart-abstracted clinical process of care measures (ED–1, IMM–2, and VTE–6). In sections VIII.A.5.b.(2)(b)[428] and VIII.A.5.b.(8)(b) of the preamble of this final rule, beginning with

[428] As discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we proposed to remove the NHSN HAI measures beginning with the CY 2019 reporting period/FY 2021 payment determination, but are delaying their removal until the CY 2020 reporting period/FY 2022 payment determination.

the CY 2020 reporting period/FY 2022 payment determination, we also are finalizing our proposals to remove five National Healthcare Safety Network (NHSN) hospital-acquired infection (HAI) measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) and one chart-abstracted clinical process of care measure (ED–2). We note that as we discussed in section VIII.A.5.b.(2)(b) of the preamble of this final rule, we proposed to remove the NHSN HAI measures beginning with the CY 2019 reporting period/FY 2021 payment determination, but are finalizing a modified version of our proposal delaying the measures' removal until the CY 2020 reporting period/FY 2022 payment determination. Our estimates below have been updated to reflect this change.

As described in detail in section XIV.B.3. of the preamble of this final rule, we expect our finalized proposals to remove the clinical process of care chart-abstracted measures will reduce the information collection burden by 1,046,071 hours and approximately $38.3 million for the CY 2019 reporting period/FY 2021 payment determination, and an additional 858,000 hours and approximately $31.3 million for the CY 2020 reporting period/FY 2022 payment determination for the Hospital IQR Program. We note that the burden of data collection for the NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) is accounted for under the Centers for Disease Control and Prevention (CDC) National Health and Safety Network (NHSN) OMB control number 0920–0666. Because burden associated with submitting data for the NHSN HAI measures is captured under a separate OMB control number, we do not provide an independent estimate of the information collection burden associated with these measures for the Hospital IQR Program.

The data validation activities, however, are conducted by CMS. Since the measures were adopted into the Hospital IQR Program, CMS has validated the data for purposes of the Program. Therefore, this burden has been captured under the Hospital IQR Program's OMB control number 0938–1022. While we did not propose any changes directly to the validation process related to chart-abstracted measures, based on our finalized proposals to remove five NHSN HAI and four clinical process of care chart-abstracted measures (in sections VIII.A.5.b.(2)(b) and VIII.A.5.b.(8) of the preamble of this final rule), we believe that hospitals will experience an overall reduction in burden associated with validation of chart-abstracted measures beginning with the FY 2023 payment determination because hospitals selected for validation are currently required to submit validation templates for the NHSN HAI measures for the Hospital IQR Program. In addition, based on our finalized proposals to remove the NHSN HAI measures, the information collection burden associated with submission of these validation templates will be eliminated from the Hospital IQR Program. As described in detail in section XIV.B.3.b.(3) of the preamble of this final rule, we estimate a total decrease of 43,200 hours and approximately $1.6 million as a result of discontinuing submission of NHSN HAI validation templates under the Hospital IQR Program. The finalized removal of NHSN HAI measures from the Hospital IQR Program, the subsequent cessation of validation processes for the NHSN HAI measures, the retention of these measures in the HAC Reduction Program, and the finalized implementation of a validation process for these measures under the HAC Reduction Program, represent no net change in information collection burden for the NHSN HAI measures across CMS hospital quality programs. Therefore, we do not anticipate any change under the CDC NHSN's OMB control number 0920–0666 due to our finalized proposals.

Furthermore, we anticipate that the costs to hospitals participating in the Hospital IQR Program, beyond that associated with information collection, will be reduced because hospitals will no longer need to review feedback reports for the NHSN HAI measures with slightly different measure rates for the same measures (under the Hospital IQR Program, a rolling four quarters of data are used to update the *Hospital Compare* website; under the Hospital VBP Program, 1-year periods are used for each of the baseline period and the performance period; and under the HAC Reduction Program, a 2-year performance period is used).

5. Impact of Removal of Two Structural Measures

In section VIII.A.5.a. and VII.A.5.b.(1) of the preamble of this final rule, we are finalizing our proposals to remove two structural measures, Hospital Survey on Patient Safety Culture and Safe Surgery Checklist, beginning with the CY 2018 reporting period/FY 2020 payment determination. We believe these finalized proposals will result in a minimal information collection burden reduction, which is addressed in section XIV.B.3. of the preamble of this final rule. In addition, we refer readers to VIII.A.4.b. of the preamble of this final rule, where we acknowledge that costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Program requirements. We believe it may be unnecessarily costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). As discussed in sections VIII.A.5.a. and VIII.A.5.b.(1) of the preamble of this final rule, we believe these measures are of limited utility for internal hospital quality improvement efforts because they do not provide individual patient level data or any information on patient outcomes. In addition, our analyses show that use of patient safety culture surveys and safe surgery checklists is widely in practice among hospitals. Therefore, we do not believe that these measures support the program objectives of facilitating internal hospital quality improvement efforts or informing beneficiary choice.

6. Impact of the Removal of Claims-Based Measures

In sections VIII.A.5.b.(2)(a), (3), (4), (6), and (7) of the preamble of this final rule, we are finalizing our proposals to remove 17 claims-based measures PSI–90 (NQF #0531), READM–30–AMI (NQF #0505), READM–30–CABG (NQF #2515), READM–30–COPD (NQF #1891), READM–30–HF (NQF #0330), READM–30–PN (NQF #0506), READM–30–THA/TKA (NQF #1551), READM–30–STK, MORT–30–AMI (NQF #0230), MORT–30–HF (NQF #0229), MSPB (NQF #2158), Cellulitis Payment, GI Payment, Kidney/UTI Payment, AA Payment, Chole and CDE Payment, and SFusion Payment) beginning with the CY 2018 reporting period/CY 2020 payment determination. In addition, in section VIII.A.5.b.(4) of the preamble of this final rule, we are finalizing our proposals to remove two claims-based measures (MORT–30–COPD (NQF #1893) and MORT–30–PN (NQF #0468)) beginning with the CY 2019 reporting period/FY 2021 payment determination. Furthermore, in sections VIII.A.5.b.(4) and VIII.A.5.b.(5), respectively, of the preamble of this final rule, we are finalizing our proposals to remove one-claims based measure (MORT–30–CABG (NQF #2558)) beginning with the CY 2020 reporting period/FY 2022 payment determination and one claims-based measure (Hip/Knee Complications (NQF #1550)) beginning with the CY 2021 reporting period/FY 2023 payment determination.

These claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, therefore, we do not believe removing these measures will impact the information collection burden on hospitals. Nonetheless, we anticipate that hospitals will experience a general cost reduction associated with these proposals stemming from no longer having to review and track various program requirements or measure information in multiple confidential feedback and preview reports from multiple programs that reflect multiple measure rates due to varying scoring methodologies and reporting periods.

7. Impact of the Removal of eCQMs

In section VIII.A.5.b.(9) of the preamble of this final rule, we are finalizing our proposals to remove seven eCQMs from the Hospital IQR Program eCQM measure set beginning with the CY 2020 reporting period/FY 2022 payment determination. As described in section XIV.B.3. of this final rule, we do not anticipate that removal of these seven eCQMs will affect the information collection burden for hospitals. However, as discussed in section VIII.A.4.b. of the preamble of this final rule, we believe costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Program requirements, such as maintaining measure specifications in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program. We further discuss costs unrelated to information collection associated with eCQM removal in section VIII.A.5.b.(9) of the preamble of this final rule.

8. Summary of Effects

In summary, we estimate: (1) A total information collection burden reduction of 1,046,138 hours (−1,046,071 hours due to the finalized removal of ED–1, IMM–2, and VTE–6 measures for the CY 2019 reporting period/FY 2021 payment determination and −67 hours for no longer collecting data for the voluntary Hybrid HWR measure [429]) and a total cost reduction related to information collection of approximately $38.3 million (−1,046,138 hours × $36.58 per hour [430]) for the CY 2019 reporting period/FY 2021 payment determination; (2) a total information collection burden reduction of 858,000 hours (−858,000 hours due to the finalized removal of ED–2) and a total cost reduction related to information collection of approximately $31.3 million (−858,000 hours × $36.58 per hour [431]) for the CY 2020 reporting period/FY 2022 payment determination; and (3) a total information collection burden reduction of 43,200 hours (−43,200 hours due to no longer needing to validate NHSN HAI measures under the Hospital IQR Program) and a total information collection cost reduction of approximately $1.6 million (−43,200 hours × $36.58 per hour) for the CY 2021 reporting period/FY 2023 payment determination. As stated earlier, we also anticipate additional cost reductions unrelated to the information collection burden associated with our proposals, including, for example, no longer having to review and track measure information in multiple feedback reports from multiple programs and maintaining measure specifications in hospitals' EHR systems for all eCQMs available for use in the program.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of this Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years or slightly decrease. We believe that reducing the number of chart-abstracted measures used in the Hospital IQR Program will, at least in part, help increase hospitals' chances to meet all Program requirements and receive their full annual percentage increase.

We refer readers to section XIV.B.3. of the preamble of this final rule (information collection requirements) for a detailed discussion of the burden of the requirements for submitting data to the Hospital IQR Program.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preambles of the proposed rule (83 FR 20500 through 20510) and this final rule, we discuss our proposed and finalized policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section VIII.B.3.b. of the preamble of this final rule, we are finalizing our proposals to remove four web-based, structural measures: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389) beginning with the FY 2021 program year. As discussed in section VIII.B.3.b.(2) of the preamble of this final rule, we are deferring finalization of our policies regarding future use of the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) in the PCHQR Program to a future 2018 final rule, most likely in the CY 2019 OPPS/ASC final rule targeted for release no later than November 2018. We will therefore address any change in burden associated with this policy decision, most likely, in the CY 2019 OPPS/ASC final rule. In addition, in section VIII.B.4. of the preamble of this final rule, we are finalizing our proposal to adopt one claims-based measure for the FY 2021 program year and subsequent years: 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188). Based on the finalized measure removals and addition, the PCHQR Program measure set will consist of 13 measures for the FY 2021 program. Further, in section XIV.B.4.b. of the preamble of this final rule, we are finalizing our proposal to adopt a new time burden estimate, to be applied to structural and web-based tool measures for the FY 2021 program year and subsequent years. Specifically, we are finalizing our proposal to adopt the estimate of 15 minutes per measure, per PCH, for reporting these types of measures, which is the time estimate utilized by the Hospital IQR Program (80 FR 49762).

a. Summary of Burden Effects for the FY 2021 Program Year

(1) Removal of Web-Based Structural Measures

As explained in section XIV.B.4.c. of the preamble of this final rule, we anticipate that these finalized new requirements will reduce the overall burden on participating PCHs. Because we are finalizing our proposal to apply 15 minutes per measure as a burden estimate for structural measures and web-based tool measures and our proposal to remove the following web-based structural measures: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389)), we estimate a reduction of 1 hour (or 60 minutes) per PCH (15 minutes per measure × 4 measures = 60 minutes), and a total annual reduction of approximately 11 hours for all 11 PCHs (60 minutes × 11 PCHs/60 minutes per hour), as a result of the finalized removal of these four measures.

(2) Removal of Chart-Abstracted NHSN Measures

As discussed in section VIII.B.3.b.(2) of the preamble of this final rule, we are deferring finalization of our policies regarding future use of the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) in the PCHQR Program to a future 2018 final rule, most likely in the CY 2019 OPPS/ASC final rule targeted for release no later than November 2018. We will therefore address any change in burden associated with this policy decision, most likely, in the CY 2019 OPPS/ASC final rule.

(3) Adoption of 30-Day Unplanned Readmissions for Cancer Patients Measure (NQF #3188)

We do not anticipate any change in burden on the PCHs associated with our finalized proposal to adopt a claims-based measure into the PCHQR Program beginning with the FY 2021 program year. This measure is claims-based and does not require facilities to report any additional data beyond that already submitted on Medicare administrative claims for payment purposes. Therefore, we do not believe that there is any associated change in burden resulting from the finalization of this proposal.

In summary, because we are finalizing our proposals to remove 4 web-based, structural measures, we estimate a total burden reduction of 11 hours of burden per year for all 11 PCHs beginning with the FY 2021 program year.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Under the LTCH QRP, the Secretary reduces by 2 percentage points the annual

[429] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized our proposal to collect data on a voluntary basis for the Hybrid HWR measure for the CY 2018 reporting period/FY 2020 payment determination. We estimated that approximately 100 hospitals would voluntarily report data for this measure, resulting in a total burden of 67 hours across all hospitals for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38504). Because we only finalized voluntary collection of data for 1 year, voluntary collection of these data would no longer occur beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years resulting in a reduction in burden of 67 hours across all hospitals.

[430] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[431] Ibid.

update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual update for the FY 2019 payment determination.

We believe that the burden and costs associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. We intend to closely monitor the effects of this quality reporting program on LTCHs and to help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and help desks.

We refer readers to section XIV.B.6. of the preamble of this final rule for details discussing information collection requirements for the LTCH QRP.

N. Effects of Requirements Regarding the Promoting Interoperability Programs

In section VIII.D. of the preambles of the proposed rule (83 FR 20515 through 20544) and this final rule, we discuss and finalize our proposals with a few modifications regarding a new performance-based scoring methodology and changes to the Stage 3 objectives and measures for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program. We are finalizing the new measure Query of PDMP and the Support Electronic Referral Loops by Receiving and Incorporating Health Information. We are finalizing the removal of the Coordination of Care Through Patient Engagement objective and its associated measures Secure Messaging, View, Download or Transmit, and Patient Generated Health Data as well as the measures Request/Accept Summary of Care, Clinical Information Reconciliation and Patient-Specific Education. We are renaming measures within the Health Information Exchange objective. These changes include changing the name from Send a Summary of Care, to Support Electronic Referral Loops by Sending Health Information; renaming the Public Health and Clinical Data Registry Reporting objective to Public Health and Clinical Data Exchange with the requirement to report on any two measures options; renaming the name the Patient Electronic Access to Health Information objective to Provider to Patient Exchange objective, and renaming the remaining measure, Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information measure. We also are finalizing an any minimum 90-day EHR reporting period in CYs 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency; the CQM reporting period and criteria for CY 2019; and our proposal to codify the policies for subsection (d) Puerto Rico hospitals to participate in the Medicare Promoting Interoperability Program for eligible hospitals, including policies previously implemented through program instruction.

We believe that, overall, these finalized proposals will reduce burden. We refer readers to section XIV.B.9. of the preamble of this final rule for additional discussion on the information collection effects associated with these finalized proposals.

In section VIII.D.12.a. of the preamble of this final rule, we are finalizing our proposal to amend 42 CFR 495.324(b)(2) and 495.324(b)(3) to align with current prior approval policy for MMIS and ADP systems at 45 CFR 95.611(a)(2)(ii), and (b)(2)(iii) and (iv), and to minimize burden on States. Specifically, we finalizing our proposals that the prior approval dollar threshold in § 495.324(b)(3) will be increased to $500,000, and that a prior approval threshold of $500,000 will be added to § 495.324(b)(2). In addition, in light of these finalized changes, we are finalizing our proposal to make a conforming amendment to the threshold in § 495.324(d) for prior approval of justifications for sole source acquisitions to be the same $500,000 threshold. That threshold is currently aligned with the $100,000 threshold in current 495.324(b)(3). Amending § 495.324(d) to preserve alignment with § 495.324(b)(3) maintains the consistency of our prior approval requirements. We believe that these finalized proposals also will reduce burden on States by raising the prior approval thresholds and generally aligning them with the thresholds for prior approval of MMIS and ADP acquisitions costs.

In section VIII.D.12.b. of the preamble of this final rule, we are finalizing our proposal to amend 42 CFR 495.322 to provide that the 90 percent FFP for Medicaid Promoting Interoperability Program administration will no longer be available for most State expenditures incurred after September 30, 2022. We are finalizing a later sunset date, September 30, 2023, for the availability of 90 percent enhanced match for State administrative costs related to Medicaid Promoting Interoperability Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities. States will not be able to claim any Medicaid Promoting Interoperability Program administrative match for expenditures incurred after September 30, 2023. We do not believe that these finalized proposals will impose any additional burdens on States. We refer readers to section XIV.B.9. of the preamble of this final rule for additional discussion on the information collection effects associated with these proposals.

O. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

For example, as discussed in section II.F.2.d. of the preamble of this final rule, section II.H.5.a. of the preamble of this final rule, and section II.A.4.g. of the Addendum to this final rule, we considered the comments regarding the creation of a new MS–DRG for the assignment of procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients who receive treatment involving CAR T-cell therapy as an alternative to our proposed MS–DRG assignment to MS–DRG 016 for FY 2019, and we considered comments to allow hospitals to utilize an alternative CCR specific to procedures involving CAR T-cell therapy drugs for purposes of outlier payments, new technology add-on payments, and payments to IPPS excluded cancer hospitals.

As discussed in section II.A.4.g. of the Addendum to the proposed rule, the impact of an alternative CCR specific to procedures involving CAR T-cell therapy drugs is dependent on the relationship between the CCR that would otherwise be used and the alternative CCR used. For illustrative purposes, in the proposed rule, we discussed an example where if a hospital charged $400,000 for a procedure involving the utilization of the CAR T-cell therapy drug described by ICD–10–PCS code XW033C3, the application of a hypothetical CCR of 0.25 results in a cost of $100,000 (= $400,000 * 0.25), while the application of a hypothetical CCR of 1.00 results in a cost of $400,000 (= $400,000 * 1.0).

The impact of the creation of a separate MS–DRG for procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients receiving treatment involving CAR T-cell therapy is dependent on the relative weighting factor determined for the separate MS–DRG. In the proposed rule, we invited public comments on the most appropriate approach for determining the relative weighting factor under this alternative, such as an approach based on taking into account an appropriate portion of the average sales price (ASP) for these drugs, or other approaches.

Comments also suggested other alternative changes under the IPPS for FY 2019, including, but not limited to, the creation of a pass-through payment, and structural changes in new technology add-on payments for the drug therapy. The impacts of these would depend on the basis for the pass-through payment amount (for example, cost or average sales price) or on the revised methodology for the new technology add-on payment (for example, a revision to the percentage of cost paid.)

As described more fully in section II.F.2.d. of the preamble of this final rule, given the potential for a new CMMI model and our request for feedback on this approach, we believe it would be premature to adopt changes to our existing payment mechanisms, either under the IPPS or for IPPS-excluded cancer hospitals, specifically for CAR T-cell therapy. Therefore, we did not adopt the alternatives discussed above that we considered for CAR T-cell therapy for FY 2019, including, but not limited to, the creation of a pass-through payment; structural changes in new technology add-on payments for the drug therapy; changes in the usual cost-to-charge ratios (CCRs) used in ratesetting and payment, including those used in determining new technology add-on payments, outlier payments, and payments to IPPS excluded cancer hospitals; and the creation of a new MS–DRG specifically for CAR T-cell therapy.

As discussed in section VIII.A.5.b.(9) of the preamble of this final rule, in the context of

removing seven eCQMs from the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years, we considered proposing to remove these seven eCQMs 1 year earlier, beginning with the CY 2019 reporting period/FY 2021 payment determination. Our analyses indicated no estimated change in average information collection reporting burden between these two options. The lack of difference is due to the low number of hospitals that have historically selected those eCQMs as part of their 4 required eCQMs for submission. Because the alternatives considered do not impact the collection of information for hospitals, we do not expect these alternatives to affect the reporting burden on hospitals associated with the Hospital IQR Program. We considered these alternatives and sought public comment on them.

As discussed in section IV.I.4.b. of the preamble of the proposed rule, in the context of scoring hospitals for purposes of the Hospital VBP Program for the FY 2021 program year and subsequent years, we analyzed two domain weighting options based on our proposals to remove 10 measures and the Safety domain from the Hospital VBP Program. As an alternative to our proposal to weight the three remaining domains as Clinical Outcomes domain (proposed name change)—50 percent; Person and Community Engagement domain—25 percent; and Efficiency and Cost Reduction domain—25 percent, we considered weighting each of the three remaining domains equally, meaning each of the three domains would be weighted as one-third of a hospital's Total Performance Score (TPS), beginning with the FY 2021 program year. As discussed in section IV.I.4.b. of the preamble of the proposed rule, we also considered keeping the current domain weighting (25 percent for each of the four domains—Safety, Clinical Outcomes (proposed name change), Person and Community Engagement, and Efficiency and Cost Reduction—with proportionate reweighting if a hospital has sufficient data on only three domains), which would require keeping at least one or more of the measures in the Safety domain and the Safety domain itself. As discussed in sections IV.I.4.a.(2) and IV.I.4.b. of the preamble of this final rule, we are not finalizing our proposal to remove the Safety domain and are keeping the current domain weighting described above, as previously finalized.

As summarized in section IV.I.4.b. of the preambles of the proposed rule and this final rule, to understand the potential impacts of the proposed domain weighting on hospitals' TPSs, we conducted analyses using FY 2018 program data that estimated the potential impacts of our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS and an alternative weighting policy we considered of equal weights whereby each domain would constitute one-third (⅓) of a hospital's TPS. In the proposed rule (83 FR 20537), we provided a table showing the estimated average TPSs and unweighted domain scores under these alternatives. That table is set out below and provides an overview of the estimated impact on hospitals' TPS by certain hospital characteristics and as they would compare to actual FY 2018 TPSs, which include scoring on four domains, including the Safety domain, and applying proportionate reweighting if a hospital has sufficient data on only three domains.

COMPARISON OF ESTIMATED AVERAGE TPSS AND UNWEIGHTED DOMAIN SCORES *

Hospital characteristic	Actual FY 2018 average clinical care domain score	Actual FY 2018 average person and community engagement domain score	Actual FY 2018 average efficiency and cost reduction domain score	Actual FY 2018 average TPS (4 domains) +	Proposed increased weighting of clinical care domain: estimated average TPS	Alternative weighting: estimated average TPS
All Hospitals **	43.2	33.5	18.8	37.4	34.6	31.8
Bed Size:						
1–99	33.4	46.0	35.7	44.6	37.2	38.4
100–199	42.2	34.5	21.0	39.2	35.0	32.6
200–299	44.5	27.9	12.9	34.4	32.4	28.4
300–399	48.2	27.3	10.0	33.3	33.4	28.5
400+	50.9	26.9	7.6	31.9	34.1	28.5
Geographic Location:						
Urban	46.8	30.7	13.7	35.7	34.5	30.4
Rural	33.7	40.5	31.7	41.9	34.9	35.3
Safety Net Status: ***						
Non-Safety Net	42.7	35.4	19.0	37.9	34.9	32.4
Safety Net	45.1	25.7	18.1	35.6	33.5	29.6
Teaching Status:						
Non-Teaching	39.9	36.7	22.9	39.4	34.9	33.2
Teaching	48.7	27.9	11.8	34.1	34.3	29.5

* Analysis based on FY 2018 Hospital VBP Program data.

** Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

*** For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*.

The table below provides a summary of the estimated impacts on average TPSs and payment adjustments for all hospitals,[432] including as they would compare to actual FY 2018 program results under current domain weighting policies.

Summary of estimated impacts on average TPS and payment adjustments using FY 2018 program data	Actual (4 domains) +	Proposed increased weight for clinical outcomes (3 domains)	Equal weighting alternative (3 domains)
Total number of hospitals with a payment adjustment	2,808	2,701	2,701.
Number of hospitals receiving a positive payment adjustment (percent)	1,597 (57 percent)	1,209 (45 percent)	1,337 (50 percent).
Average positive payment adjustment percentage	0.60 percent	0.58 percent	0.70 percent.
Estimated average positive payment adjustment	$128,161	$233,620	$204,038.
Number of hospitals receiving a negative payment adjustment (percent)	1,211 (43 percent)	1,492 (55 percent)	1,364 (50 percent).
Average negative payment adjustment percentage	−0.41 percent	−0.60 percent	−0.57 percent.
Estimated average negative payment adjustment	$169,011	$189,307	$200,000.
Number of hospitals receiving a positive payment adjustment with a composite quality score * below the median (percent).	341 (21 percent)	134 (11 percent)	266 (20 percent).
Average TPS	37.4	34.6	31.8.
Lowest TPS receiving a positive payment adjustment	34.6	35.9	30.9.
Slope of the linear exchange function	2.8908851882	2.7849297316	3.2405954322.

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

* ''Composite quality score'' is defined as a hospital's TPS minus the hospital's weighted Efficiency and Cost Reduction domain score.

We also refer readers to section I.H.6.b. of Appendix A to the proposed rule (83 FR 20620 through 20621) for a detailed discussion regarding the estimated impacts of the proposed domain weighting and equal weighting alternative on hospital percentage payment adjustments. Because the alternatives considered did not impact the collection of information for hospitals, we did not expect these alternatives to affect the reporting burden on hospitals. We considered these alternatives and sought public comment on them.

As discussed in section IV.J.5. of the preamble of this final rule, in the context of scoring hospitals for the purposes of the HAC Reduction Program, we analyzed two alternative scoring options to the current methodology for the FY 2020 program year and subsequent years. The alternative scoring methodologies considered were an Equal Measure Weights methodology, which would remove the domains and assign equal weight to each measure for which a hospital has a score, and a Variable Domain Weighting methodology, which would vary the weighting of Domain 1 and 2 based on the number of measures in each domain. We considered these alternative approaches to allow the HAC Reduction Program to continue to fairly assess all hospitals' performance under the Program.

We simulated results under each scoring approach using FY 2019 HAC Reduction Program data.[433] We compared the percentage of hospitals in the worst-performing quartile in FY 2019 to the percentage that would be in the worst-performing quartile under each scoring approach. The table below provides a high-level overview of the estimated impact of these approaches on several key groups of hospitals.

ESTIMATED IMPACT OF SCORING APPROACHES ON PERCENTAGE OF HOSPITALS IN WORST-PERFORMING QUARTILE BY HOSPITAL GROUP

Hospital group [a]	Equal measure weights (%)	Variable domain weights (%)
Teaching hospitals: 100 or more residents (N=248)	3.6	1.6
Safety-net [b] (N=646)	0.9	0.8
Urban hospitals: 400 or more beds (N=358)	2.5	0.8
Hospitals with fewer than 100 beds (N=1,208)	−1.7	−1.0
Hospitals with a measure score for:		
Zero Domain 2 measures (N=223)	0.4	0.0
One Domain 2 measure (N=340)	−4.1	−2.9
Two Domain 2 measures (N=211)	−3.8	−3.3
Three Domain 2 measures (N=188)	−0.5	0.5
Four Domain 2 measures (N=253)	0.0	0.4
Five Domain 2 measures (N=2,004)	1.1	0.7

[a] The number of hospitals in the given hospital group for FY 2019 is specified in parenthesis in this column (for example, N=248).

[b] Hospitals are considered safety-net hospitals if they are in the top quintile for DSH percent.

Note: This table is updated from the FY 2019 IPPS/LTCH PPS proposed rule, which used FY 2018 data. To see that table, we refer readers to 83 FR 20434 through 20437; 83 FR 20638 through 20639.

As shown in the table above, the Equal Measure Weights approach generally has a larger impact than the Variable Domain Weights approach. Under the Equal Measure Weights approach, as compared to the current methodology using FY 2019 HAC

[432] Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

[433] In the FY 2019 IPPS/LTCH PPS proposed rule, we used FY 2018 data to complete the analysis. We have since updated our analysis using FY 2019 data. To see prior table, we refer readers to 83 FR 20434 through 20437; 83 FR 20638 through 20639.

Reduction Program data, the percentage of hospitals in the worst-performing quartile decreases by 1.7 percent for small hospitals (that is, fewer than 100 beds), 4.1 percent for hospitals with one Domain 2 measure, 3.8 percent for hospitals with two Domain 2 measures, while it increases by 2.5 percent for large urban hospitals (that is, 400 or more beds) and 3.6 percent for large teaching hospitals (that is, 100 or more residents). The Variable Domain Weights approach decreases the percentage of hospitals in the worst-performing quartile by 1.0 percent for small hospitals, 2.9 percent for hospitals with one Domain 2 measure, and 3.3 for hospitals with two Domain 2 measures, while it increases the percentage of hospitals in the worst-performing quartile by 0.8 percent for large urban hospitals and 1.6 percent for large teaching hospitals.

To understand the potential impacts of these alternatives on hospitals' Total HAC Reduction Program Penalty Amount, we conducted an analysis that estimated the potential impacts of these alternatives using FY 2017 payment data annualized by a factor to estimate in FY 2019 payment dollars. Based on this analysis, we expect that aggregate penalty amounts would slightly increase under both alternative methodologies proposed in the proposed rule. We also expect an increase in the penalty amount under both methodologies because some larger hospitals may move into the worst-performing quartile and smaller hospitals may move out of the worst-performing quartile. Because the 1-percent penalty applies uniformly to hospitals in the worst-performing quartile, we anticipate that overall program penalties would rise slightly if larger hospitals move into the penalty quartile. The alternative weighting approach considered, variable weighting, would have increased estimated total penalties by approximately $11,125,845. The finalized weighting approach will increase estimated total penalties by $20,159,043, over $9 million more than the alternative weighting approach considered. The table below displays the results of our analysis in FY 2019 dollars and as a percentage difference.

ESTIMATED FISCAL IMPACT OF FINALIZED AND ALTERNATIVE WEIGHTING APPROACHES RELATIVE TO CURRENT METHODOLOGY **

Scenario	Total HAC reduction program penalty amount (FY 2019 dollars) *	Percentage difference from FY 2019	Difference from FY 2019 (FY 2019 dollars) *
FY 2019 HAC Reduction Program—Before Proposed Weighting Change	$380,999,808	N/A	N/A
Variable Domain Weights	392,125,653	2.9	$11,125,845
Equal Measure Weights	401,158,851	5.3	20,159,043

* Applied an annual increase to DRG payments to convert estimated FY 2017 DRG payments to estimated FY 2019 DRG payments. Source: Payment estimates based on FY 2017 Medicare Provider Analysis and Review (MedPAR) files.

** In the FY 2019 IPPS/LTCH PPS proposed rule, we used FY 2018 Program data and FY 2013 payment to complete the analysis. We have since updated our analysis using FY 2019 Program data and FY 2017 payment data. To see that table, we refer readers to 83 FR 20638 through 20639.

In the proposed rule, after consideration of the current policy, Equal Measure Weights and Variable Domain Weighting methodologies, we sought public comment on these approaches. In this final rule, after consideration of the public comments we received, we are adopting the Equal Measure Weights methodology. However, because the alternatives considered do not impact the collection of information for hospitals, we did not expect either of these alternatives to affect the reporting burden on hospitals associated with the HAC Reduction Program. Therefore, we believe that the finalized policy will not affect burden.

P. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This final rule, is considered an E.O. 13771 deregulatory action. We estimate that this rule generates $72 million in annualized cost savings, discounted at 7 percent relative to fiscal year 2016, over a perpetual time horizon. We discuss the estimated burden and cost reductions for the Hospital IQR Program in section XIV.B.3. of the preamble of this final rule, and estimate that the impact of these changes is a reduction in costs of approximately $21,585 per hospital annually or approximately $71,233,624 for all hospitals annually. We note that in section VIII.A.5.c.(1). of the preamble of this final rule, we are finalizing our proposal to remove the hospital-acquired infection (HAI) measures from the Hospital IQR Program and, therefore, discontinue validation of these measures under the Hospital IQR Program. However, these measures will remain in the HAC Reduction Program and, therefore, we are finalizing our proposal to begin validation of these measures under the HAC Reduction Program using the same processes and information collection requirements previously used under the Hospital IQR Program. As a result, the net costs reflected in the table below for the HAC Reduction Program do not constitute a new information collection requirement on participating hospitals, but a transition of the HAI measure validation process from one program to another based on our efforts to reduce measure duplication across programs. We discuss the estimated burden and cost impacts for the finalized transition of HAI data validation from the Hospital IQR Program to the HAC Reduction Program in section XIV.B.7. of the preamble of this final rule. We discuss the estimated burden and cost reductions for the PCHQR Program in section XIV.B.4. of the preamble of this final rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $92,145 per PCH annually or approximately $1,013,595 for all participating PCHs annually. We discuss the estimated burden and cost reductions for the proposed LTCH QRP measure removals in section XIV.B.6. of the preamble of this final rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $1,148 per LTCH annually or approximately $482,469 for all LTCHs annually. Also, as noted in section I.R. of this Appendix, the regulatory review cost for this final rule is $8,809,182.

Section of the proposed rule	Description	Amount of costs or savings
Section XIV.B.3. of the preamble	ICRs for the Hospital IQR Program	($71,233,624)
Section XIV.B.4. of the preamble	ICRs for the PCHQR Program	(1,013,595)
Section XIV.B.6. of the preamble	ICRs for the LTCH QRP	(482,469)
Section XIV.B.7. of the preamble	ICRs for the HAC Reduction Program*	1,580,256

Section of the proposed rule	Description	Amount of costs or savings
Total		(72 million)

*We note that the net costs reflected in this table for the HAC Reduction Program do not constitute a new information collection requirement on participating hospitals, but a transition of the HAI measure validation process from one program to another based on our efforts to reduce measure duplication across programs.

Q. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $4.8 billion in FY 2019, taking into account operating, capital, new technology, and low volume hospital payments as modeled for this final rule. Approximately $4.4 billion of this estimated increase is due to the changes in operating payments, including $1.5 billion in uncompensated care payments (discussed in sections I.G. and I.H. of this Appendix), approximately $0.2 billion is due to the change in capital payments (discussed in section I.I of this Appendix), approximately $0.2 billion is due to the change in new technology add-on payments (discussed in section I.H of this Appendix), and approximately $0.1 billion is due to the change in low-volume hospital payments (discussed in section I.H of this Appendix). Total differs from the sum of the components due to rounding.

Table I of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals will experience a 2.3 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $193 million increase in capital payments in FY 2019 compared to FY 2018.

The discussions presented in the previous pages, in combination with the remainder of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2019. In the impact analysis, we are using the rates, factors, and policies presented in this final rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2019. Accordingly, based on the best available data for the 417 LTCHs in our database, we estimate that overall FY 2019 LTCH PPS payments will increase approximately $39 million relative to FY 2018 as a result of the payment rates and factors presented in this final rule.

R. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20640), due to the uncertainty involved with accurately quantifying the number of entities that would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule would be the number of reviewers of the proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For those reasons, and consistent with our approach in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38585), we believe that the number of past commenters would be a fair estimate of the number of reviewers of the proposed rule. We welcomed any public comments on the approach in estimating the number of entities that will review this final rule. We did not receive any public comments specific to our solicitation.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. Therefore, for the purposes of our estimate, and consistent with our approach in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38585), we assumed that each reviewer read approximately 50 percent of the proposed rule. We welcomed public comments on this assumption. We did not receive any public comments specific to our solicitation.

We have used the number of timely pieces of correspondence on the FY 2019 proposed rule as our estimate for the number of reviewers of this final rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 19 hours for the staff to review half of this final rule. For each IPPS hospital or LTCH that reviews this final rule, the estimated cost is $1,998 (19 hours × $105.16). Therefore, we estimate that the total cost of reviewing this final rule is $8,809,182 ($1,998 × 4,409 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in the following Table V., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown below in Table V., the net costs to the Federal Government associated with the policies in this final rule are estimated at $4.8 billion.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2018 TO FY 2019

Category	Transfers
Annualized Monetized Transfers.	$4.8 billion.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2019 relative to FY 2018 of approximately $39 million based on the data for 417 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI. provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this final rule based on the data for the 417 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. below, the net cost to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $39 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2018 LTCH PPS TO THE FY 2019 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	$39 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this final rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. For example, because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule are impacts on small entities. For example, we refer readers to ''Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2019.'' Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities because they do not meet the SBA definition of a small business. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis. This final rule contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20640), we solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses are presented throughout this final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold level is approximately $146 million. This final rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. This final rule contains provisions applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act and, thus, has tribal implications. Therefore, in accordance with Executive Order 13175 and the CMS Tribal Consultation Policy (December 2015), CMS has consulted with Tribal officials on these Indian-specific provisions of the proposed rule prior to the formal promulgation of this rule.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final rule.

COMPARISON OF ESTIMATED AVERAGE TPSS AND UNWEIGHTED DOMAIN SCORES *

Hospital characteristic	Actual FY 2018 average clinical care domain score	Actual FY 2018 average person and community engagement domain score	Actual FY 2018 average efficiency and cost reduction domain score	Actual FY 2018 average TPS (4 domains) +	Proposed increased weighting of clinical care domain: estimated average TPS	Alternative weighting: estimated average TPS
All Hospitals **	43.2	33.5	18.8	37.4	34.6	31.8
Bed Size:						
1–99	33.4	46.0	35.7	44.6	37.2	38.4
100–199	42.2	34.5	21.0	39.2	35.0	32.6
200–299	44.5	27.9	12.9	34.4	32.4	28.4
300–399	48.2	27.3	10.0	33.3	33.4	28.5
400+	50.9	26.9	7.6	31.9	34.1	28.5
Geographic Location:						
Urban	46.8	30.7	13.7	35.7	34.5	30.4
Rural	33.7	40.5	31.7	41.9	34.9	35.3
Safety Net Status ***:						
Non-Safety Net	42.7	35.4	19.0	37.9	34.9	32.4
Safety Net	45.1	25.7	18.1	35.6	33.5	29.6
Teaching Status:						
Non-Teaching	39.9	36.7	22.9	39.4	34.9	33.2
Teaching	48.7	27.9	11.8	34.1	34.3	29.5

* Analysis based on FY 2018 Hospital VBP Program data.

** Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

*** For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*.

The table below provides a summary of the estimated impacts on average TPSs and payment adjustments for all hospitals,[434] including as they would compare to actual FY 2018 program results under current domain weighting policies.

Summary of estimated impacts on average TPS and payment adjustments using FY 2018 program data	Actual (4 domains) +	Proposed increased weight for clinical outcomes (3 domains)	Equal weighting alternative (3 domains)
Total number of hospitals with a payment adjustment	2,808	2,701	2,701.
Number of hospitals receiving a positive payment adjustment (percent)	1,597 (57 percent)	1,209 (45 percent)	1,337 (50 percent).
Average positive payment adjustment percentage	0.60 percent	0.58 percent	0.70 percent.
Estimated average positive payment adjustment	$128,161	$233,620	$204,038.
Number of hospitals receiving a negative payment adjustment (percent)	1,211 (43 percent)	1,492 (55 percent)	1,364 (50 percent).
Average negative payment adjustment percentage	−0.41 percent	−0.60 percent	−0.57 percent.
Estimated average negative payment adjustment	$169,011	$189,307	$200,000.
Number of hospitals receiving a positive payment adjustment with a composite quality score * below the median (percent).	341 (21 percent)	134 (11 percent)	266 (20 percent).
Average TPS	37.4	34.6	31.8.
Lowest TPS receiving a positive payment adjustment	34.6	35.9	30.9.
Slope of the linear exchange function	2.8908851882	2.7849297316	3.2405954322.

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

* ''Composite quality score'' is defined as a hospital's TPS minus the hospital's weighted Efficiency and Cost Reduction domain score.

We also refer readers to section I.H.6.b. of Appendix A to the proposed rule (83 FR 20620 through 20621) for a detailed discussion regarding the estimated impacts of the proposed domain weighting and equal weighting alternative on hospital percentage payment adjustments. Because the alternatives considered did not impact the collection of information for hospitals, we did not expect these alternatives to affect the reporting burden on hospitals. We considered these alternatives and sought public comment on them.

As discussed in section IV.J.5. of the preamble of this final rule, in the context of scoring hospitals for the purposes of the HAC Reduction Program, we analyzed two alternative scoring options to the current methodology for the FY 2020 program year and subsequent years. The alternative scoring methodologies considered were an Equal Measure Weights methodology, which would remove the domains and assign equal weight to each measure for which a hospital has a score, and a Variable Domain Weighting methodology, which would vary the weighting of Domain 1 and 2 based on the number of measures in each domain. We considered these alternative approaches to allow the HAC Reduction Program to continue to fairly assess all hospitals' performance under the Program.

We simulated results under each scoring approach using FY 2019 HAC Reduction Program data.[435] We compared the percentage of hospitals in the worst-performing quartile in FY 2019 to the percentage that would be in the worst-performing quartile under each scoring approach. The table below provides a high-level overview of the estimated impact of these approaches on several key groups of hospitals.

ESTIMATED IMPACT OF SCORING APPROACHES ON PERCENTAGE OF HOSPITALS IN WORST-PERFORMING QUARTILE BY HOSPITAL GROUP

Hospital group [a]	Equal measure weights (percent)	Variable domain weights (percent)
Teaching hospitals: 100 or more residents (N=248)	3.6	1.6
Safety-net [b] (N=646)	0.9	0.8
Urban hospitals: 400 or more beds (N=358)	2.5	0.8
Hospitals with fewer than 100 beds (N=1,208)	−1.7	−1.0
Hospitals with a measure score for:		
Zero Domain 2 measures (N=223)	0.4	0.0
One Domain 2 measure (N=340)	−4.1	−2.9
Two Domain 2 measures (N=211)	−3.8	−3.3
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Four Domain 2 measures (N=253)	0.0	0.4
Five Domain 2 measures (N=2,004)	1.1	0.7

[a] The number of hospitals in the given hospital group for FY 2019 is specified in parenthesis in this column (for example, N=248).

[b] Hospitals are considered safety-net hospitals if they are in the top quintile for DSH percent.

[434] Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

[435] In the FY 2019 IPPS/LTCH PPS proposed rule, we used FY 2018 data to complete the analysis. We have since updated our analysis using FY 2019 data. To see prior table, we refer readers to 83 FR 20434 through 20437; 83 FR 20638 through 20639.

This table is updated from the FY 2019 IPPS/LTCH PPS proposed rule, which used FY 2018 data. To see that table, we refer readers to 83 FR 20434 through 20437; 83 FR 20638 through 20639.

As shown in the table above, the Equal Measure Weights approach generally has a larger impact than the Variable Domain Weights approach. Under the Equal Measure Weights approach, as compared to the current methodology using FY 2019 HAC Reduction Program data, the percentage of hospitals in the worst-performing quartile decreases by 1.7 percent for small hospitals (that is, fewer than 100 beds), 4.1 percent for hospitals with one Domain 2 measure, 3.8 percent for hospitals with two Domain 2 measures, while it increases by 2.5 percent for large urban hospitals (that is, 400 or more beds) and 3.6 percent for large teaching hospitals (that is, 100 or more residents). The Variable Domain Weights approach decreases the percentage of hospitals in the worst-performing quartile by 1.0 percent for small hospitals, 2.9 percent for hospitals with one Domain 2 measure, and 3.3 for hospitals with two Domain 2 measures, while it increases the percentage of hospitals in the worst-performing quartile by 0.8 percent for large urban hospitals and 1.6 percent for large teaching hospitals.

To understand the potential impacts of these alternatives on hospitals' Total HAC Reduction Program Penalty Amount, we conducted an analysis that estimated the potential impacts of these alternatives using FY 2017 payment data annualized by a factor to estimate in FY 2019 payment dollars. Based on this analysis, we expect that aggregate penalty amounts would slightly increase under both alternative methodologies proposed in the proposed rule. We also expect an increase in the penalty amount under both methodologies because some larger hospitals may move into the worst-performing quartile and smaller hospitals may move out of the worst-performing quartile. Because the 1-percent penalty applies uniformly to hospitals in the worst-performing quartile, we anticipate that overall program penalties would rise slightly if larger hospitals move into the penalty quartile. The alternative weighting approach considered, variable weighting, would have increased estimated total penalties by approximately $11,125,845. The finalized weighting approach will increase estimated total penalties by $20,159,043, over $9 million more than the alternative weighting approach considered. The table below displays the results of our analysis in FY 2019 dollars and as a percentage difference.

ESTIMATED FISCAL IMPACT OF FINALIZED AND ALTERNATIVE WEIGHTING APPROACHES RELATIVE TO CURRENT METHODOLOGY **

Scenario	Total HAC reduction program penalty amount (FY 2019 dollars) *	Percentage difference from FY 2019	Difference from FY 2019 (FY 2019 dollars) *
FY 2019 HAC Reduction Program—Before Proposed Weighting Change	$380,999,808	N/A	N/A
Variable Domain Weights	392,125,653	2.9	$11,125,845
Equal Measure Weights	401,158,851	5.3	20,159,043

* Applied an annual increase to DRG payments to convert estimated FY 2017 DRG payments to estimated FY 2019 DRG payments. Source: Payment estimates based on FY 2017 Medicare Provider Analysis and Review (MedPAR) files.

** In the FY 2019 IPPS/LTCH PPS proposed rule, we used FY 2018 Program data and FY 2013 payment to complete the analysis. We have since updated our analysis using FY 2019 Program data and FY 2017 payment data. To see that table, we refer readers to 83 FR 20638 through 20639.

In the proposed rule, after consideration of the current policy, Equal Measure Weights and Variable Domain Weighting methodologies, we sought public comment on these approaches. In this final rule, after consideration of the public comments we received, we are adopting the Equal Measure Weights methodology. However, because the alternatives considered do not impact the collection of information for hospitals, we did not expect either of these alternatives to affect the reporting burden on hospitals associated with the HAC Reduction Program. Therefore, we believe that the finalized policy will not affect burden.

P. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This final rule, is considered an E.O. 13771 deregulatory action. We estimate that this rule generates $72 million in annualized cost savings, discounted at 7 percent relative to fiscal year 2016, over a perpetual time horizon. We discuss the estimated burden and cost reductions for the Hospital IQR Program in section XIV.B.3. of the preamble of this final rule, and estimate that the impact of these changes is a reduction in costs of approximately $21,585 per hospital annually or approximately $71,233,624 for all hospitals annually. We note that in section VIII.A.5.c.(1). of the preamble of this final rule, we are finalizing our proposal to remove the hospital-acquired infection (HAI) measures from the Hospital IQR Program and, therefore, discontinue validation of these measures under the Hospital IQR Program. However, these measures will remain in the HAC Reduction Program and, therefore, we are finalizing our proposal to begin validation of these measures under the HAC Reduction Program using the same processes and information collection requirements previously used under the Hospital IQR Program. As a result, the net costs reflected in the table below for the HAC Reduction Program do not constitute a new information collection requirement on participating hospitals, but a transition of the HAI measure validation process from one program to another based on our efforts to reduce measure duplication across programs. We discuss the estimated burden and cost impacts for the finalized transition of HAI data validation from the Hospital IQR Program to the HAC Reduction Program in section XIV.B.7. of the preamble of this final rule. We discuss the estimated burden and cost reductions for the PCHQR Program in section XIV.B.4. of the preamble of this final rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $92,145 per PCH annually or approximately $1,013,595 for all participating PCHs annually. We discuss the estimated burden and cost reductions for the proposed LTCH QRP measure removals in section XIV.B.6. of the preamble of this final rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $1,148 per LTCH annually or approximately $482,469 for all LTCHs annually. Also, as noted in section I.R. of this Appendix, the regulatory review cost for this final rule is $8,809,182.

Section of the proposed rule	Description	Amount of costs or savings
Section XIV.B.3. of the preamble	ICRs for the Hospital IQR Program	($71,233,624)
Section XIV.B.4. of the preamble	ICRs for the PCHQR Program	(1,013,595)
Section XIV.B.6. of the preamble	ICRs for the LTCH QRP	(482,469)

Section of the proposed rule	Description	Amount of costs or savings
Section XIV.B.7. of the preamble	ICRs for the HAC Reduction Program *	1,580,256
Total		(72 million)

* We note that the net costs reflected in this table for the HAC Reduction Program do not constitute a new information collection requirement on participating hospitals, but a transition of the HAI measure validation process from one program to another based on our efforts to reduce measure duplication across programs.

Q. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $4.8 billion in FY 2019, taking into account operating, capital, new technology, and low volume hospital payments as modeled for this final rule. Approximately $4.4 billion of this estimated increase is due to the changes in operating payments, including $1.5 billion in uncompensated care payments (discussed in sections I.G. and I.H. of this Appendix), approximately $0.2 billion is due to the change in capital payments (discussed in section I.I of this Appendix), approximately $0.2 billion is due to the change in new technology add-on payments (discussed in section I.H of this Appendix), and approximately $0.1 billion is due to the change in low-volume hospital payments (discussed in section I.H of this Appendix). Total differs from the sum of the components due to rounding.

Table I of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals will experience a 2.3 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $193 million increase in capital payments in FY 2019 compared to FY 2018.

The discussions presented in the previous pages, in combination with the remainder of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2019. In the impact analysis, we are using the rates, factors, and policies presented in this final rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2019. Accordingly, based on the best available data for the 417 LTCHs in our database, we estimate that overall FY 2019 LTCH PPS payments will increase approximately $39 million relative to FY 2018 as a result of the payment rates and factors presented in this final rule.

R. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20640), due to the uncertainty involved with accurately quantifying the number of entities that would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule would be the number of reviewers of the proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For those reasons, and consistent with our approach in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38585), we believe that the number of past commenters would be a fair estimate of the number of reviewers of the proposed rule. We welcomed any public comments on the approach in estimating the number of entities that will review this final rule. We did not receive any public comments specific to our solicitation.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. Therefore, for the purposes of our estimate, and consistent with our approach in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38585), we assumed that each reviewer read approximately 50 percent of the proposed rule. We welcomed public comments on this assumption. We did not receive any public comments specific to our solicitation.

We have used the number of timely pieces of correspondence on the FY 2019 proposed rule as our estimate for the number of reviewers of this final rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 19 hours for the staff to review half of this final rule. For each IPPS hospital or LTCH that reviews this final rule, the estimated cost is $1,998 (19 hours × $105.16). Therefore, we estimate that the total cost of reviewing this final rule is $8,809,182 ($1,998 × 4,409 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in the following Table VII., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown below in Table VII., the net costs to the Federal Government associated with the policies in this final rule are estimated at $4.8 billion.

TABLE VII—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2018 TO FY 2019

Category	Transfers
Annualized Monetized Transfers.	$4.8 billion.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2019 relative to FY 2018 of approximately $39 million based on the data for 417 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI., we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI. provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this final rule based on the data for the 417 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VIII. below, the net cost to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $39 million.

TABLE VIII—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2018 LTCH PPS TO THE FY 2019 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	$39 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this final rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. For example, because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule are impacts on small entities. For example, we refer readers to ''Table I—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2019.'' Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities because they do not meet the SBA definition of a small business. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis. This final rule contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20640), we solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses are presented throughout this final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold level is approximately $146 million. This final rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. This final rule contains provisions applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act and, thus, has tribal implications. Therefore, in accordance with Executive Order 13175 and the CMS Tribal Consultation Policy (December 2015), CMS has consulted with Tribal officials on these Indian-specific provisions of the proposed rule prior to the formal promulgation of this rule.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2019, consistent with our approach for FY 2018, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2019

A. FY 2019 Inpatient Hospital Update

As discussed in section IV.B. of the preamble to this final rule, for FY 2019, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2019 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38587), we replaced the FY 2010-based IPPS operating and capital market baskets with the rebased and revised 2014-based IPPS operating and capital market baskets effective with FY 2018.

In the FY 2019 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B)

of the Act, we proposed to base the proposed FY 2019 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2017 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2017, which was estimated to be 2.8 percent. Based on the most recent data available for this FY 2019 IPPS/LTCH PPS final rule, in accordance with section 1886(b)(3)(B) of the Act, we are establishing the FY 2019 market basket update used to determine the applicable percentage increase for the IPPS on IGI's second quarter 2018 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through first quarter 2018, which is estimated to be 2.9 percent.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382), we proposed an MFP adjustment of 0.8 percent for FY 2019 based on IGI's fourth quarter 2017 forecast. We also proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2019 market basket update and MFP adjustment for the final rule. Based on the most recent data available for this FY 2019 IPPS/LTCH PPS final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this final rule, we are establishing a MFP adjustment (the 10-year moving average percent change of MFP for the period ending FY 2019) of 0.8 percent.

In the FY 2019 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2017 forecast of the 2014-based IPPS market basket and the MFP adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented four possible applicable percentage increases that could be applied to the standardized amount.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this final rule, we are establishing the applicable percentages increases for the FY 2019 updates based on IGI's second quarter 2018 forecast of the 2014-based IPPS market basket and the MFP adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, as shown in the table below.

FY 2019	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.725	−0.725
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.175	0.0	−2.175
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Applicable Percentage Increase Applied to Standardized Amount	1.35	−0.825	0.625	−1.55

B. Update for SCHs and MDHs for FY 2019

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2019 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). As discussed in section IV.G. of the preamble of this final rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

As previously mentioned, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four possible applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs and MDHs.

C. FY 2019 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56939), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this final rule. Accordingly, for FY 2019, we are establishing an applicable percentage increase of 1.35 percent to the standardized amount for hospitals located in Puerto Rico.

D. Update for Hospitals Excluded From the IPPS for FY 2019

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this final rule,

in the FY 2018 IPPS/LTCH PPS final rule, we finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. In addition, as discussed in section IV.B. of the preamble of this final rule, the update to the target amount for extended neoplastic disease care hospitals for FY 2019 is the percentage increase in the 2014-based IPPS operating market basket. Accordingly, for FY 2019, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2019 percentage increase in the 2014-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2019 is 2.9 percent.

E. Update for LTCHs for FY 2019

Section 123 of Public Law 106–113, as amended by section 307(b) of Pub. L. 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are establishing an update to the LTCH PPS standard Federal payment rate of 1.35 percent for FY 2019, consistent with the amendments to section 1886(m)(3) of the Act provided by section 411 of MACRA. In accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are establishing an update factor of 1.0135 in determining the LTCH PPS standard Federal rate for FY 2019. For LTCHs that fail to submit quality data for FY 2019, we are establishing an annual update to the LTCH PPS standard Federal rate of –0.65 percent (that is, the annual update for FY 2019 of 1.35 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a update factor of 0.9935 in determining the LTCH PPS standard Federal rate for FY 2019. (We note that, as discussed in section VII.D. of the preamble of this final rule, the update to the LTCH PPS standard Federal payment rate of 1.35 percent for FY 2019 does not reflect any budget neutrality factors, such as the offset for the elimination of the LTCH PPS 25-percent threshold policy.)

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update in the amount specified in current law for FY 2019. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 2.9 percent.

For FY 2019, consistent with policy set forth in section VII. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 1.35 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2019, we are recommending an annual update to the LTCH PPS standard Federal rate of –0.65 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2018 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates in the amount specified in current law. We refer readers to the March 2018 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on this recommendation.

Response: We agree with MedPAC, and consistent with current law, we are applying an applicable percentage increase for FY 2019 of 1.35 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

[FR Doc. 2018–16766 Filed 8–2–18; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 83 Friday,

No. 160 August 17, 2018

Book 3 of 3 Books

Pages 41785–42016

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 414 and 425

Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414 and 425

[CMS–1701–P]

RIN 0938–AT45

Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: Under the Medicare Shared Savings Program (Shared Savings Program), providers of services and suppliers that participate in an Accountable Care Organization (ACO) continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. The policies included in this proposed rule would provide a new direction for the Shared Savings Program by establishing pathways to success through redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are accountable for repaying shared losses). These proposed policies are designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. The proposed rule also would provide new tools to support coordination of care across settings and strengthen beneficiary engagement; ensure rigorous benchmarking; promote interoperable electronic health record technology among ACO providers/suppliers; and improve information sharing on opioid use to combat opioid addiction.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 16, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1701–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1701–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1701–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Elizabeth November, (410) 786–8084 or via email at *aco@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

Currently, 561 ACOs participate in the Medicare Shared Savings Program (Shared Savings Program). CMS continues to monitor and evaluate program results to look for additional ways to streamline program operations, reduce burden, and facilitate transition to risk that promote a competitive and accountable marketplace, while improving the quality of care for Medicare beneficiaries. This proposed rule would make changes to the regulations for the Shared Savings Program that were promulgated through rulemaking between 2011 and 2017, and are codified in 42 CFR part 425. The changes in this proposed rule are based on the additional program experience we have gained and on lessons learned from testing of Medicare ACO initiatives by the Center for Medicare and Medicaid Innovation (Innovation Center). If these changes are finalized, we will continue to monitor the program's ability to reduce healthcare spending and improve care quality to inform future program developments, including whether the program provides beneficiaries with the value and choice demonstrated by other Medicare options such as Medicare Advantage (MA). We also propose changes to address the new requirements of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) (herein referred to as the Bipartisan Budget Act).

Section 1899 of the Social Security Act (the Act) established the Medicare Shared Savings Program, which promotes accountability for a patient population, fosters coordination of items and services under Medicare Parts A and B, encourages investment in infrastructure and redesigned care processes for high quality and efficient health care service delivery, and promotes higher value care. The Shared Savings Program is a voluntary program that encourages groups of doctors, hospitals, and other health care providers to come together as an ACO to lower growth in expenditures and improve quality. An ACO agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare.

Shared Savings Program ACOs are an important innovation for moving CMS's payment systems away from paying for volume and towards paying for value and outcomes because ACOs are held accountable for spending in relation to a historical benchmark and for quality performance, including performance on outcome and patient experience measures. The program began in 2012, and as of January 2018, 561 ACOs are participating in the program and serving over 10.5 million Medicare FFS beneficiaries. (See the Medicare Shared Savings Program website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/* for information about the program, the program's statutory authority, regulations and guidance, the

program's application process, participating ACOs, and program performance data.)

The Shared Savings Program currently includes three financial models that allow ACOs to select an arrangement that makes the most sense for their organization. The vast majority of Shared Savings Program ACOs, 82 percent in 2018,[1] have chosen to enter and maximize the allowed time under a one-sided, shared savings-only model (Track 1), under which eligible ACOs receive a share of any savings under their benchmark, but are not required to pay back a share of spending over the benchmark. In comparison, there is relatively low participation in the program's two-sided, shared savings and shared losses models, under which eligible ACOs share in a larger portion of any savings under their benchmark, but are required to share losses if spending exceeds the benchmark. Participation in Track 2 (introduced at the start of the program in 2012) has slowly declined in recent years, particularly following the availability of Track 3 (beginning in 2016), although participation in Track 3, the program's highest-risk track, remains modest.

Recently, the Innovation Center designed an additional option available to eligible Track 1 ACOs, referred to as the Track 1+ Model, to facilitate ACOs' transition to performance-based risk. The Track 1+ Model, a time-limited model, began on January 1, 2018, and is based on Shared Savings Program Track 1, but tests a payment design that incorporates more limited downside risk, as compared to Track 2 and Track 3. Our early experience with the design of the Track 1+ Model demonstrates that the availability of a lower-risk, two-sided model is an effective way to encourage Track 1 ACOs (including ACOs within a current agreement period, initial program entrants, and renewing ACOs) to progress more rapidly to performance-based risk. Fifty-five ACOs entered into Track 1+ Model agreements effective on January 1, 2018, the first time the model was offered. These ACOs represent our largest cohort of performance-based risk ACOs to date.

ACOs in two-sided models have shown significant savings to the Medicare program while advancing the quality of care furnished to FFS beneficiaries; but, the majority of ACOs have yet to assume any performance-based risk although they benefit from waivers of certain federal requirements in connection with their participation in the Shared Savings Program. Even more concerning is the finding that one-sided model ACOs, which are not accountable for sharing in losses, have actually increased Medicare spending relative to their benchmarks. Further, the presence of an ''upside-only'' track may be encouraging consolidation in the marketplace, reducing competition and choice for Medicare FFS beneficiaries. While we understand that systems need time to adjust, Medicare cannot afford to continue with models that are not producing desired results.

Our results to date have shown that ACOs in two-sided models perform better over time than one-sided model ACOs, low revenue ACOs, which are typically physician-led, perform better than high revenue ACOs, which often include hospitals, and the longer ACOs are in the program the better they do at achieving the program goals of lowering growth in expenditures and improving quality. For example, in performance year 2016, about 68 percent of Shared Savings Program ACOs in two-sided models (15 of 22 ACOs) shared savings compared to 29 percent of Track 1 ACOs; 41 percent of low revenue ACOs shared savings compared to 23 percent of high revenue ACOs; and 42 percent of April and July 2012 starters shared savings, compared to 36 percent of 2013 and 2014 starters, 26 percent of 2015 starters, and 18 percent of 2016 starters.

We believe that additional policy changes to the Shared Savings Program and its financial models are required to support the move to value, achieve savings for the Medicare program, and promote a competitive and accountable healthcare marketplace. Accordingly, we are proposing to redesign the Shared Savings Program to provide pathways to success in the future through a combination of policy changes, informed by the following guiding principles:

- Accountability—Increase savings for the Medicare Trust Funds, mitigate losses by accelerating the move to two-sided risk by ACOs, and ensure rigorous benchmarking.
- Competition—Promote free-market principles by encouraging the development of physician-only and rural ACOs in order to provide a pathway for physicians to stay independent, thereby preserving beneficiary choice.
- Engagement—Promote regulatory flexibility to allow ACOs to innovate and be successful in coordinating care, improving quality, and engaging with and incentivizing beneficiaries to achieve and maintain good health.
- Integrity—Reduce opportunities for gaming.
- Quality—Improve quality of care for patients with an emphasis on promoting interoperability and the sharing of healthcare data between providers, focusing on meaningful quality measures, and combatting opioid addiction.

The need for a new approach or pathway to transition Track 1 ACOs to performance-based risk is particularly relevant at this time, given the current stage of participation for the initial entrants to the Shared Savings Program under the program's current design. The program's initial entrants are nearing the end of the time allowed under Track 1 (a maximum of two, 3-year agreement periods). Among the program's initial entrants (ACOs that first entered the program in 2012 and 2013), there are 82 ACOs that would be required to renew their participation agreements to enter a third agreement period beginning in 2019, and they face transitioning from a one-sided model to a two-sided model with significant levels of risk that some are not prepared to accept. Another 114 ACOs that have renewed for a second agreement period under a one-sided model, including 59 ACOs that started in 2014 and 55 ACOs that started in 2015, will face a similar transition to a two-sided model with significant levels of risk in 2020 and 2021, respectively. The transition to performance-based risk remains a pressing concern for ACOs, as evidenced by a recent survey of the 82 ACOs that would be required to move to a two-sided payment model in their third agreement period beginning in 2019. The survey results, based on a 43 percent response rate, indicate that these Track 1 ACOs are reluctant to move to two-sided risk under the current design of the program. See National Association of ACOs, Press Release (May 2018), available at *https://www.naacos.com/press-release-may-2-2018.*

We believe the long term success and sustainability of the Shared Savings Program is affected by a combination of key program factors: The savings and losses potential of the program established through the design of the program's tracks; the methodology for setting and resetting the benchmark, which is the basis for determining shared savings and shared losses; the length of the agreement period, which determines the amount of time an ACO remains under a financial model; and the frequency of benchmark rebasing. We believe it is necessary to carefully consider each of these factors to create, on balance, sufficient incentives for participation in a voluntary program,

[1] See, for example, Medicare Shared Savings Program Fast Facts (January 2018), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf.*

while also achieving program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds.

In order to achieve these program goals and preserve the long term success and sustainability of the program, we believe it is necessary to create a pathway for ACOs to more rapidly transition to performance-based risk. ACOs and other program stakeholders have urged CMS to smooth the transition to risk by providing more time to gain experience with risk and more incremental levels of risk. The goal of the proposed program redesign is to create a pathway for success that facilitates ACOs' transition to performance-based risk more quickly and makes this transition smooth by phasing-in risk more gradually. Through the creation of a new BASIC track, we would allow ACOs to gain experience with more modest levels of performance-based risk on their way to accepting greater levels of performance-based risk over time (as the proposed BASIC track's maximum level of risk is the same as the Track 1+ Model, which is substantially less than the proposed ENHANCED track). As stakeholders have suggested, we would provide flexibility to allow ACOs that are ready to accelerate their move to higher risk within agreement periods, and enable such ACOs to qualify as Advanced APM entities for purposes of the Quality Payment Program. We would streamline the program and simplify the participation options by retiring Track 1 and Track 2. We would retain Track 3, which we would rename as the ENHANCED track, to encourage ACOs that are able to accept higher levels of potential risk and reward to drive the most significant systematic change in providers' and suppliers' behavior. We would further strengthen the program by establishing policies to deter gaming by limiting more experienced ACOs to higher-risk participation options; more rigorously screening for good standing among ACOs seeking to renew their participation in the program or re-enter the program after termination or expiration of their previous agreement; identifying ACOs re-forming under new legal entities as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACO accountable for their ACO participants' experience with the program; and holding ACOs in two-sided models accountable for partial-year losses if either the ACO or CMS terminates the agreement before the end of the performance year.

Under the proposed redesign of the program, our policies would recognize the relationship between the ACO's degree of control over total Medicare Parts A and B FFS expenditures for its assigned beneficiaries and its readiness to accept higher or lower degrees of performance-based risk. Comparisons of ACO participants' total Medicare Parts A and B FFS revenue to a factor based on total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries would be used in determining the maximum amount of losses (loss sharing limit) under the BASIC track, the estimated amount of repayment mechanism arrangements for BASIC track ACOs (required for ACOs entering or continuing their participation in a two-sided model to assure CMS of the ACO's ability to repay shared losses), and in determining participation options for ACOs. Using revenue-based loss sharing limits and repayment mechanism amounts for eligible BASIC track ACOs would help to ensure that low revenue ACOs have a meaningful pathway to participate in a two-sided model that may be more consistent with their capacity to assume risk. By basing participation options on the ACO's degree of control over total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, low revenue ACOs, which tend to be smaller and have less capital, would be able to continue in the program longer under lower levels of risk; whereas high revenue ACOs, which tend to include institutional providers and are typically larger and better capitalized, would be required to move more quickly to higher levels of performance-based risk in the ENHANCED track, because they should be able to exert more influence, direction, and coordination over the full continuum of care. By requiring high revenue ACOs to enter higher levels of performance-based risk under the ENHANCED track after no more than one agreement period under the BASIC track, we aim to drive more meaningful systematic change in these ACOs, which have greater potential to control their assigned beneficiaries' Medicare Parts A and B FFS expenditures by coordinating care across care settings, and thus to achieve significant change in spending. Further, allowing low revenue ACOs a longer period of participation under the lower level of performance-based risk in the BASIC track, while challenging high revenue ACOs to more quickly move to higher levels of performance-based risk, could give rise to more innovative arrangements for lowering growth in expenditures and improving quality, particularly among low revenue ACOs that tend to be composed of independent physician practices.

The program's benchmarking methodology, a complex calculation that incorporates the ACO's risk-adjusted historical expenditures and reflects either national or regional spending trends, is a central feature of the program's financial models. We are proposing to continue to refine the benchmarking approach based on our experience using factors based on regional FFS expenditures in resetting the benchmark in an ACO's second or subsequent agreement period, and to address ACOs' persistent concerns over the risk adjustment methodology. Through the proposed redesign of the program, we would provide for more accurate benchmarks for ACOs that are protective of the Trust Funds by ensuring that ACOs do not unduly benefit from any one aspect of the benchmark calculations, while also helping to ensure the program continues to remain attractive to ACOs, especially those caring for the most complex and highest risk patients who could benefit from high-quality, coordinated care from an ACO.

We would accelerate the use of factors based on regional FFS expenditures in establishing the benchmark by applying this methodology in setting an ACO's benchmark beginning with its first agreement period. This would allow the benchmark to be a more accurate representation of the ACO's costs in relation to its localized market (or regional service area), and could strengthen the incentives of the program to drive meaningful change by ACOs. Further, allowing agreement periods of at least 5 years, as opposed to the current 3-year agreement periods, would provide greater predictability for benchmarks by reducing the frequency of benchmark rebasing, and therefore provide greater opportunity for ACOs to achieve savings against these benchmarks. In combination, these policies would protect the Trust Funds, provide more accurate and predictable benchmarks, and reduce selection costs, while creating incentives for ACOs to transition to performance-based risk.

Currently, the regional adjustment can provide overly inflated benchmarks for ACOs that are relatively low spending compared to their region, while ACOs with higher spending compared to their region may find little value in remaining in the program when faced with a significantly reduced benchmark. To address this dynamic, we would reduce the maximum weight used in calculating the regional adjustment, and cap the adjustment amount for all

agreement periods, so as not to excessively reward or punish an ACO based on where the ACO is located. This would make the benchmark more achievable for ACOs that care for medically complex patients and are high spending compared to their region, thereby encouraging their continued participation, while at the same time preventing windfall shared savings payments for ACOs that have relatively low spending levels relative to their region.

We would also seek to provide more sustainable trend factors for ACOs with high penetration in markets with lower spending growth compared to the nation, and less favorable trend factors for ACOs with high penetration in markets with higher spending growth compared to the nation. This approach would have little impact on ACOs with relatively low to medium penetration in counties in their regional service area.

ACOs and other program stakeholders continue to express concerns that the current methodology for risk adjusting the benchmark for each performance year does not adequately account for changes in acuity and health status of patients over time. We would modify the current approach to risk adjustment to allow changes in health status to be more fully recognized during the agreement period, providing further incentives for continued participation by ACOs faced with higher spending due to the changing health status of their population.

ACOs and other program stakeholders have urged CMS to allow additional flexibility of program and payment policies to engage beneficiaries and provide the care for beneficiaries in the most appropriate care setting. It is also critical that patients have the tools to be more engaged with their doctors in order to play a more active role in their care coordination and the quality of care they receive, and that ACOs empower and incentivize beneficiaries to achieve good health. The recent Bipartisan Budget Act allows for certain new flexibilities for Shared Savings Program ACOs to support these aims, including new beneficiary incentive programs, telehealth services furnished in accordance with section 1899(l) of the Act, and a choice of beneficiary assignment methodology. We would establish policies in accordance with the new law in these areas. For example, in accordance with section 1899(m)(1)(A) of the Act (as added by section 50341 of the Bipartisan Budget Act), we would allow certain ACOs under two-sided risk to establish CMS-approved beneficiary incentive programs, through which an ACO would provide incentive payments to assigned beneficiaries who receive qualifying primary care services. We would establish policies to govern telehealth services furnished in accordance with 1899(l) of the Act by physicians and practitioners in eligible two-sided model ACOs. We would also allow broader access to the program's existing SNF 3-day rule waiver for ACOs under performance-based risk.

Other timely modifications to the program's regulations addressed in this proposed rule, include changes to the program's claims-based assignment methodology and the process for allowing beneficiaries to voluntarily align to ACOs in which the physician or other practitioner they have designated as their primary clinician is an ACO professional, and extending the program's recently finalized policy for addressing extreme and uncontrollable circumstances to performance year 2018 and all subsequent performance years. Further, feedback from the public sought in this rule would inform development of the program's quality measure set to support CMS's Meaningful Measures initiative for reducing provider reporting burden and promoting positive outcomes, and help to identify ways to improve existing data sharing and the quality measure set to address the nation's opioid emergency. Changes to the program's requirements regarding the use of certified electronic health record technology would help ensure Shared Savings Program ACOs are held accountable for using technology that promotes more effective population management and sharing of data among providers, and will ultimately lead to value-based and better care for patients. Lastly, through this proposed rule we seek comment on how Medicare ACOs and the sponsors of stand-alone Part D prescription drug plans (PDPs) could be encouraged to collaborate so as to improve the coordination of pharmacy care for Medicare FFS beneficiaries.

2. Summary of the Major Provisions

This proposed rule would restructure the participation options for ACOs applying to participate in the program in 2019 by discontinuing Track 1 (one-sided shared savings-only model), and Track 2 (two-sided shared savings and shared losses model) while maintaining Track 3 (renamed the ENHANCED track) and offering a new BASIC track. Under the proposed approach, the program's two tracks would be: (i) A BASIC track, offering a path from a one-sided model for eligible ACOs to progressively higher increments of risk and potential reward within a single agreement period, and (ii) an ENHANCED track based on the existing Track 3 (two-sided model), for ACOs that take on the highest level of risk and potential reward. This approach includes proposals for replacing the current 3-year agreement period structure with an agreement period of at least 5 years, allowing eligible BASIC track ACOs greater flexibility to select their level of risk within an agreement period in the glide path, and allowing all BASIC track and ENHANCED track ACOs the flexibility to change their selection of beneficiary assignment methodology prior to the start of each performance year, consistent with the requirement under the Bipartisan Budget Act to provide ACOs with a choice of prospective assignment.

To provide ACOs time to consider the new participation options and prepare for program changes, make investments and other business decisions about participation, obtain buy-in from their governing bodies and executives, and to complete and submit a Shared Savings Program application for a performance year beginning in 2019, we propose to offer a July 1, 2019 start date for the first agreement period under the proposed new participation options. This midyear start in 2019 would also allow both new applicants and ACOs currently participating in the program an opportunity to make any changes to the structure and composition of their ACO as may be necessary to comply with the new program requirements for the ACO's preferred participation option, if changes to the participation options are finalized as proposed. We would forgo the application cycle in 2018 for an agreement start date of January 1, 2019. ACOs entering a new agreement period on July 1, 2019, would have the opportunity to participate in the program under agreement periods spanning 5 years and 6 months, with a 6-month first performance year. Additionally, we would offer ACOs with a participation agreement ending on December 31, 2018 an opportunity to extend their current agreement period for an additional 6-month performance year (January 1, 2019–June 30, 2019). These ACOs would then have the opportunity to apply for a new agreement under the BASIC track or ENHANCED track beginning on July 1, 2019.

We propose modifications to the repayment mechanism arrangement requirements applicable to ACOs in performance-based risk tracks, including changes to update these policies to address new participation options under the BASIC track and, in certain circumstances, allow a renewing

ACO to extend the use of its current repayment mechanism into the next agreement period, which would reduce the financial burden of maintaining two concurrent repayment mechanisms. Repayment mechanism arrangements provide CMS assurance that an ACO can repay losses for which it may be liable. The proposed changes include: (1) Adding a provision that could lower the required repayment mechanism amount for BASIC track ACOs in Levels C, D, or E; (2) adding a provision to permit recalculation of the estimated amount of the repayment mechanism each performance year to account for changes in ACO participant composition; (3) codifying the required duration of repayment mechanism arrangements; (4) adding a provision to allow a renewing ACO the flexibility to maintain a single, existing repayment mechanism arrangement to support its ability to repay shared losses in the new agreement period so long as it is sufficient to cover any increase to the repayment mechanism amount during the new agreement period; and (5) establishing requirements regarding the issuing institutions for a repayment mechanism arrangement.

This proposed rule would establish regulations in accordance with the Bipartisan Budget Act on the use of telehealth services furnished on or after January 1, 2020, by physicians and other practitioners participating in an ACO under performance-based risk that has selected prospective assignment. This policy would allow for payment for telehealth services furnished to prospectively assigned beneficiaries receiving telehealth services in non-rural areas, and allow beneficiaries to receive certain telehealth services at their home, to support care coordination across settings. The proposed rule would also provide for limited waivers of the originating site and geographic requirements to allow for payment for otherwise covered telehealth services provided to beneficiaries who are no longer prospectively assigned to an applicable ACO (and therefore no longer eligible for payment for these services under section 1899(l) of the Act) during a 90-day grace period. In addition, ACO participants would be prohibited, under certain circumstances, from charging beneficiaries for telehealth services, where CMS does not pay for those telehealth services under section 1899(l) solely because the beneficiary was never prospectively assigned to the applicable ACO or was prospectively assigned, but the 90-day grace period has lapsed.

We propose to allow eligible ACOs under performance-based risk under either prospective assignment or preliminary prospective assignment with retrospective reconciliation to use the program's existing SNF 3-day rule waiver. We also propose to amend the existing SNF 3-day rule waiver to allow critical access hospitals (CAHs) and other small, rural hospitals operating under a swing bed agreement to be eligible to partner with eligible ACOs as SNF affiliates for purposes of the SNF 3-day rule waiver.

We propose policies to expand the role of choice and incentives in engaging beneficiaries in their health care. First, we propose to establish regulations in accordance with section 1899(m)(1)(A) of the Act, as added by section 50341 of the Bipartisan Budget Act, to permit ACOs under certain two-sided models to operate CMS-approved beneficiary incentive programs. The beneficiary incentive programs would encourage beneficiaries assigned to certain ACOs to obtain medically necessary primary care services while requiring such ACOs to comply with program integrity and other requirements, as the Secretary determines necessary. Any ACO that operates a CMS-approved beneficiary incentive program would be required to ensure that certain information about its beneficiary incentive program is made available to CMS and the public on its public reporting web page. Second, we propose modifications to the program's existing policies on voluntary alignment in order to comply with the Bipartisan Budget Act, by allowing beneficiaries to designate a broader range of ACO professionals as their ''primary clinician'' responsible for coordinating their overall care, and providing that we will continue to use a beneficiary's designation to align the beneficiary to the ACO in which their primary clinician participates even if the beneficiary does not continue to receive primary care services from an ACO professional in that ACO. We also seek comment on an alternative beneficiary assignment methodology to make the assignment methodology more patient-centered, and strengthen the engagement of beneficiaries in their health care. Under such an approach, a beneficiary would be assigned to an ACO if the beneficiary ''opted-in'' to the ACO. These selections would be supplemented by voluntary alignment and a modified claims-based assignment methodology. Third, to empower beneficiary choice and further program transparency, we are proposing to revise policies related to beneficiary notifications. Specifically, we propose that ACO participants be required to include information on voluntary alignment in the written notifications they must provide to beneficiaries. ACO participants would be required to provide such notifications during each beneficiary's first primary care visit of each performance year, in addition to having such information posted in the ACO participant's facility and available upon request (as currently required).

We propose new policies for determining participation options for ACOs based on the degree to which ACOs control total Medicare Parts A and B FFS expenditures for their assigned beneficiaries (low revenue ACO versus high revenue ACO), and the experience of the ACO's legal entity and ACO participants with the Shared Savings Program and performance-based risk Medicare ACO initiatives.

We also propose to revise the criteria for evaluating the eligibility of ACOs seeking to renew their participation in the program for a subsequent agreement period and ACOs applying to re-enter the program after termination or expiration of the ACO's previous agreement, based on the ACO's prior participation in the Shared Savings Program. We also propose to identify new ACOs as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACO accountable for their participants' experience with the program. We would use the same criteria to review applications from renewing and re-entering ACOs to more consistently consider ACOs' prior experience in the Shared Savings Program. Under this proposal, we would modify existing review criteria, such as the ACO's history of meeting the quality performance standard and the ACO's timely repayment of shared losses that currently apply to particular performance years of a 3-year agreement period, to ensure applicability to ACOs with an agreement period that is not less than 5 years. We also seek to strengthen the program's requirements for monitoring ACOs within an agreement period for poor financial performance and to ensure that ACOs with poor financial performance are not allowed to continue their participation in the program, or to re-enter the program after being terminated, without addressing the deficiencies that resulted in termination.

We propose to update program policies related to termination of ACOs' participation in the program. We propose to reduce the amount of notice an ACO must provide CMS of its decision to voluntarily terminate. We also address the timing of an ACO's re-entry into the program after termination.

Specifically, we seek to modify current requirements that prevent an ACO from terminating its participation agreement and quickly re-entering the program to allow the flexibility for an ACO in a current 3-year agreement period to terminate its participation agreement and immediately enter a new agreement period of not less than 5 years under one of the redesigned participation options proposed in this rule. We also propose policies that would prevent ACOs from taking advantage of this flexibility to avoid transitioning to risk by repeatedly participating in the BASIC track's glide path for a short time, terminating, and then entering a one-sided model in a future agreement period under the BASIC track. Specifically, we propose to restrict eligibility for the BASIC track's glide path to ACOs inexperienced with performance-based risk Medicare ACO initiatives, which we propose to define to include all levels of the BASIC track's glide path. We also propose to differentiate between initial entrants (ACOs entering the program for the first time), ''re-entering ACOs'' (ACOs re-entering after a break in participation following termination or expiration of a prior participation agreement, and new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO), and ''renewing ACOs'' (ACOs that participate continuously in the program, without interruption, including ACOs that choose to renew early by terminating their current agreement and immediately entering a new agreement period). This differentiation is relevant for determining the agreement period the ACO is entering for purposes of applying policies that phase-in over time (benchmarking methodology and quality performance standards) and for determining whether an ACO can extend the use of its existing repayment mechanism when it enters a new agreement period.

Further, we would impose payment consequences for early termination by proposing to hold ACOs in two-sided models liable for pro-rated shared losses. This approach would apply to ACOs that voluntarily terminate their participation more than midway through a 12-month performance year and all ACOs that are involuntarily terminated by CMS. ACOs would be ineligible to share in savings for a performance year if the effective date of their termination from the program is prior to the last calendar day of the performance year, although we would allow an exception for ACOs that are participating in the program as of January 1, 2019, that terminate their agreement with an effective date of June 30, 2019, and enter a new agreement period under the BASIC track or ENHANCED track beginning July 1, 2019. In these cases, we would perform separate reconciliations to determine shared savings and shared losses for the ACO's first 6 months of participation in 2019 and for the ACO's 6-month performance year from July 1, 2019, to December 31, 2019, under the subsequent participation agreement.

To strengthen ACO financial incentives for continued program participation and improve the sustainability of the program, we propose changes to the methodology for establishing, adjusting, updating and resetting benchmarks for agreement periods beginning on July 1, 2019, and in subsequent years, to include the following:

- Application of factors based on regional FFS expenditures to establish, adjust, and update the ACO's benchmark beginning in an ACO's first agreement period, to move benchmarks away from being based solely on the ACO's historical costs and allow them to better reflect costs in the ACO's region.
- Mitigating the effects of excessive positive or negative regional adjustment used to establish and reset the benchmark by—

++ Reducing the maximum weight used in calculating the regional adjustment from 70 percent to 50 percent (within the existing phase-in schedule for applying increased weights in calculating the regional adjustment); and

++ Capping the amount of the adjustment based on a percentage of national FFS expenditures.

- Calculating growth rates used in trending expenditures to establish the benchmark and in updating the benchmark each performance year as a blend of regional and national expenditure growth rates with increasing weight placed on the national component of the blend as the ACO's penetration in its region increases.
- Better accounting for certain health status changes by using full CMS-Hierarchical Condition Category (HCC) risk scores to adjust the benchmark each performance year, although restricting the upward and downward effects of these adjustments to positive or negative 3 percent over the new agreement period.

This rule also includes proposals for updating the program's policies in a variety of subject areas. We propose to expand the definition of primary care services used in beneficiary assignment to add new codes and revise how we determine whether evaluation and management services were furnished in a SNF. We also propose to extend the policies to address quality performance scoring and determination of shared losses owed by ACOs participating under performance-based risk in the event of extreme or uncontrollable circumstances that were adopted for performance year 2017 to apply for performance year 2018 and subsequent years. We also discuss the potential effects of extreme and uncontrollable circumstances on benchmark year expenditures and the determination of the historical benchmark and seek comment on this issue.

We seek comment on approaches to developing the program's quality measure set in response to the agency's Meaningful Measures initiative as well as to support ACOs and their participating providers/suppliers in addressing opioid utilization within the FFS population. We describe existing sources of program data that may be useful for ACOs to monitor trends in opioid utilization, and solicit comment on suggestions for providing additional aggregate data to ACOs. We also seek comment on quality measures that could be used to assess factors related to opioid utilization, including patient reported outcome measures.

We propose to establish a new program requirement related to the adoption of Certified Electronic Health Record Technology (CEHRT) by eligible clinicians participating in the ACO. Specifically, we propose to require ACOs to certify, upon application to the program and annually thereafter, that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds a specified threshold. For ACOs that are participating in a track (or payment model within a track) that meets the financial risk standard to be an Advanced APM, we further propose to align this requirement with the CEHRT use requirement for Advanced APMs under the Quality Payment Program. In conjunction with this proposal, we propose to discontinue the use of the double-weighted quality measure assessing the percentage of eligible clinicians that successfully meet the Promoting Interoperability Performance Category Base Score (Use of CEHRT, ACO–11) in order to reduce burden and align with the requirements of the Quality Payment Program. We also propose conforming revisions to the CEHRT requirement for Shared Savings

Program ACOs in the Quality Payment Program's regulations under 42 CFR part 414.

Lastly, we seek comment on approaches for encouraging Medicare ACOs to collaborate with the sponsors of stand-alone Part D PDPs (Part D sponsors) to improve the coordination of pharmacy care for Medicare FFS beneficiaries to reduce the risk of adverse events and improve medication adherence. In particular, we seek to understand how Medicare ACOs, and specifically Shared Savings Program ACOs, and Part D sponsors could work together and be encouraged to improve the coordination of pharmacy care for Medicare FFS beneficiaries to achieve better health outcomes, what clinical and pharmacy data may be necessary to support improved coordination of pharmacy care for Medicare FFS beneficiaries, and approaches to structuring financial arrangements to reward ACOs and Part D sponsors for improved health outcomes and lower growth in expenditures for Medicare FFS beneficiaries.

3. Summary of Costs and Benefits

As detailed in section IV of this proposed rule, the proposed faster transition from one-sided model agreements to performance-based risk arrangements, tempered by the option for eligible ACOs of a gentler exposure to downside risk calculated as a percentage of ACO participants' total Medicare Parts A and B FFS revenue and capped at a percentage of the ACO's benchmark, can affect broader participation in performance-based risk in the Shared Savings Program and reduce overall claims costs. A second key driver of estimated net savings is the reduction in shared savings payments from the proposed limitation on the amount of the regional adjustment to the ACO's historical benchmark. Such reduction in overall shared savings payments is projected to result despite the benefit of higher net adjustments expected for a larger number of ACOs from the use of a simpler HCC risk adjustment methodology, the blending of national and regional expenditure growth rates for certain benchmark calculations, and longer (at least 5 years, instead of 3-year) agreement periods that allow ACOs a longer horizon from which to benefit from efficiency gains before benchmark rebasing. Overall, the decreases in claims costs and shared saving payments to ACOs are projected to result in $2.24 billion in federal savings over 10 years.

B. Statutory and Regulatory Background

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of Public Law 111–148.

Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Shared Savings Program to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. See 42 U.S.C. 1395jjj.

The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). We viewed this final rule as a starting point for the program, and because of the scope and scale of the program and our limited experience with shared savings initiatives under FFS Medicare, we built a great deal of flexibility into the program rules.

Through subsequent rulemaking, we have revisited and amended Shared Savings Program policies in light of the additional experience we gained during the initial years of program implementation as well as from testing through the Pioneer ACO Model, the Next Generation ACO Model and other initiatives conducted by the Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act. A major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). A final rule addressing changes related to the program's financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). We have also made use of the annual calendar year (CY) Physician Fee Schedule (PFS) rules to address updates to the Shared Savings Program quality measures, scoring, and quality performance standard, the program's beneficiary assignment methodology and certain other issues.[2]

Policies applicable to Shared Savings Program ACOs have continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (Pub. L. 114–10). In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), CMS established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared Savings Program.

The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). Accordingly, we revised the program's regulations in the CY 2018 PFS final rule to reflect these new requirements.

On February 9, 2018, the Bipartisan Budget Act of 2018 was enacted (Pub. L. 115–123), amending section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to a prospectively assigned beneficiary, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period, permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and mandating that any such voluntary identification will supersede claims-based assignment, and allowing ACOs under certain two-sided models

[2] See for example, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule (78 FR 74230, Dec. 10, 2013). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; Final Rule (79 FR 67548, Nov. 13, 2014). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2016; Final Rule (80 FR 70886, Nov. 16, 2015). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2017; Final Rule (81 FR 80170, Nov. 15, 2016). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2018; Final Rule (82 FR 52976, Nov. 15, 2017).

to establish CMS-approved beneficiary incentive programs.

II. Provisions of the Proposed Regulations

A. Redesigning Participation Options To Facilitate Transition to Performance-Based Risk

In this section, we discuss a series of interrelated proposals around transition to risk, including: (1) Length of time an ACO may remain under a one-sided model, (2) the levels of risk and reward under the program's participation options, (3) the duration of the ACO's agreement period, and (4) the degree of flexibility ACOs have to choose their beneficiary assignment methodology and also to select their level of risk within an agreement period.

1. Background on Shared Savings Program Participation Options

In this section we review the statutory and regulatory background for the program's participation options by track and the length of the ACO's agreement period for participation in the program, and also provide an overview of current ACO participation in the program for performance year 2018.

a. Background on Development of Track 1, Track 2 and Track 3

Section 1899(d) of the Act establishes the general requirements for shared savings payments to participating ACOs. Specifically, section 1899(d)(1)(A) of the Act specifies that providers of services and suppliers participating in an ACO will continue to receive payment under the original Medicare FFS program under Parts A and B in the same manner as they would otherwise be made, and that an ACO is eligible to receive payment for a portion of savings generated for Medicare provided that the ACO meets both the quality performance standards established by the Secretary and achieves savings against its historical benchmark based on average per capita Medicare FFS expenditures during the 3 years preceding the start of the agreement period. Additionally, section 1899(i) of the Act authorizes the Secretary to use other payment models rather than the one-sided model described in section 1899(d) of the Act, as long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

In the November 2011 final rule establishing the Shared Savings Program (76 FR 67909), we created two tracks from which ACOs could choose to participate: The one-sided model (Track 1) that is based on the statutory payment methodology under section 1899(d) of the Act, and a two-sided model (Track 2) that is also based on the payment methodology under section 1899(d) of the Act, but incorporates performance-based risk using the authority under section 1899(i)(3) of the Act to use other payment models. Under the one-sided model, ACOs can qualify to share in savings but are not responsible for losses. Under a two-sided model, ACOs can qualify to share in savings with an increased sharing rate, but also must take on risk for sharing in losses. ACOs entering the program or renewing their agreement may elect to enter a two-sided model. Once an ACO has elected to participate under a two-sided model, the ACO cannot go into Track 1 for subsequent agreement periods (see § 425.600).

In the initial rulemaking for the program, we considered several approaches to designing the program's participation options, principally: (1) Base the program on a two-sided model, thereby requiring all participants to accept risk from the first program year; (2) allow applicants to choose between program tracks, either a one-sided model or two-sided model, for the duration of the agreement; or (3) allow a choice of tracks, but require ACOs electing the one-sided model to transition to the two-sided model during their initial agreement period (see, for example, 76 FR 19618). We proposed a design for Track 1 whereby ACOs would enter a 3-year agreement period under the one-sided model and would automatically transition to the two-sided model (under Track 2) in the third year of their initial agreement period. Thereafter, those ACOs that wished to continue participating in the Shared Savings Program would only have the option of participating under performance-based risk (see 76 FR 19618). We explained our belief that this approach would have the advantage of providing an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model while also providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides the potential for greater reward in exchange for assuming greater potential responsibility. A few commenters favored this proposed approach, indicating the importance of performance-based risk in the health care delivery system transformation necessary to achieve the program's aims and for ''good stewardship'' of Medicare Trust Fund dollars. However, most commenters expressed concerns about requiring ACOs to quickly accept performance-based risk and we finalized a policy where an ACO could remain under the one-sided model for the duration of its first agreement period (see 76 FR 67904 through 67909).

In earlier rulemaking, we explained that offering multiple tracks with differing degrees of risk across the Shared Savings Program tracks would create an ''on-ramp'' for the program to attract both providers and suppliers that are new to value-based purchasing, as well as more experienced entities that are ready to share performance-based risk. We stated our belief that a one-sided model would have the potential to attract a large number of participants to the program and introduce value-based purchasing broadly to providers and suppliers, many of whom may never have participated in a value-based purchasing initiative before (see, for example, 76 FR 67904 through 67909).

Another reason we included the option for a one-sided track with no downside risk was that this model would be accessible to and attract small, rural, safety net, and/or physician-only ACOs (see 80 FR 32759). Commenters identified groups that may be especially challenged by the upfront costs of ACO formation and operations, including: private primary care practitioners, small to medium sized physician practices, small ACOs, safety net providers (that is, Rural Health Clinics (RHCs), CAHs, Federally Qualified Health Centers (FQHCs), community-funded safety net clinics), and other rural providers (that is, Method II CAHs, rural prospective payment system hospitals designated as rural referral centers, sole community hospitals, Medicare dependent hospitals, or rural primary care providers) (see 76 FR 67834 through 67835). Further, commenters also indicated that ACOs that are composed of small- and medium-sized physician practices, loosely formed physician networks, safety net providers, and small and/or rural ACOs would be encouraged to participate in the program based on the availability of a one-sided model (see, for example, 76 FR 67906). Commenters also expressed concerns about requiring ACOs that may lack experience with care management or managing performance-based risk to quickly transition to performance-based risk, with some commenters suggesting that small, rural and physician-only

ACOs be exempt from downside risk (see, for example, 76 FR 67906).

In establishing the program's initial two track approach, we acknowledged that ACOs new to the accountable care model—and particularly small, rural, safety net, and physician-only ACOs—would benefit from additional time under the one-sided model before being required to accept risk (76 FR 67907). However, we also noted that although a one-sided model could provide incentives for participants to improve quality, it might not be sufficient incentive for participants to improve the efficiency and cost of health care delivery (76 FR 67904 and 80 FR 32759). We explained our belief that payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in providers' and suppliers' behavior (see, for example, 76 FR 67907). We also explained our belief that performance-based risk options could have the advantage of providing more experienced ACOs an opportunity to enter a sharing arrangement with the potential for greater reward in exchange for assuming greater potential responsibility (see, for example, 76 FR 67907).

We note that in earlier rulemaking we have used several terms to refer to participation options in the Shared Savings Program under which an ACO is potentially liable to share in losses with Medicare. In the initial rulemaking for the program, we defined ''two-sided model'' to mean a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred (§ 425.20). We have also used the term ''performance-based risk'' to refer to the type of risk an ACO participating in a two-sided model undertakes. As we explained in the November 2011 final rule (76 FR 67945), in a two-sided model under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries. It is only shared savings payments (and shared losses in a two-sided model) that will be contingent upon ACO performance. The agreement to share risk against the benchmark would be solely between the Medicare program and the ACO. As a result, we have tended to use the terms ''two-sided model'' and ''performance-based risk'' interchangeably, considering them to be synonymous when describing payment models offered under the Shared Savings Program and Medicare ACO initiatives more broadly.

In the June 2015 final rule, we modified the existing policies to allow eligible Track 1 ACOs to renew for a second agreement period under the one-sided model, and to require they enter a performance-based risk track in order to remain in the program for a third or subsequent agreement period. We explained the rationale for these policies in the prior rulemaking and we refer readers to the December 2014 proposed rule and June 2015 final rule for more detailed discussion. (See, for example, 79 FR 72804, and 80 FR 32760 through 32761.) In developing these policies, we considered, but did not finalize, approaches to make Track 1 less attractive for continued participation, in order to support progression to risk, including offering a reduced sharing rate to ACOs remaining under the one-sided model for a second agreement period.[3] We also modified the two-sided performance-based risk track (Track 2) and began to offer an alternative two-sided performance-based risk track (Track 3) for agreement periods beginning on or after January 1, 2016 (80 FR 32771 through 32781). Compared to Track 2, which uses the same preliminary prospective beneficiary assignment methodology with retrospective reconciliation as Track 1, Track 3 includes prospective beneficiary assignment and a higher sharing rate for shared savings as well as the potential for greater liability for shared losses. Further, we established a SNF 3-day rule waiver (discussed further in section II.B of this proposed rule), for use by eligible Track 3 ACOs.

The Innovation Center has tested progressively higher levels of risk for more experienced ACOs through the Pioneer ACO Model (concluded December 31, 2016) and the Next Generation ACO Model (ongoing).[4] Lessons learned from the Pioneer ACO Model were important considerations in the development of Track 3, which incorporates several features of the Pioneer ACO Model, including prospective beneficiary assignment, higher levels of risk and reward (compared to Track 2), and the availability of a SNF–3-day rule waiver. Since Track 3 was introduced as a participation option under the Shared Savings Program, we have seen a growing interest, with 16 Track 3 ACOs completing PY 2016 and 38 Track 3 ACOs participating in PY 2018. The continued increase in the number of ACOs participating in Track 3, a higher proportion of which have achieved shared savings compared to Track 1 ACOs, suggests that the track offers a pathway to improve care for beneficiaries at a level of risk and reward sufficient to induce ACOs to improve their financial performance. For example, for performance year 2016, about 56 percent of Track 3 ACOs (9 of 16 ACOs) achieved shared savings compared to 29 percent of Track 1 ACOs (119 of 410 ACOs). See 2016 Shared Savings Program Accountable Care Organization Public Use File, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html.*

Further, the Innovation Center has tested two models for providing up-front funding to eligible small, rural, or physician-only Shared Savings Program ACOs. Initially, CMS offered the Advance Payment ACO Model, beginning in 2012 and concluding December 31, 2015. See *https://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/.* The ACO Investment Model (AIM), which began in 2015, builds on the experience with the Advance Payment ACO Model. The AIM is ongoing, with 45 participating ACOs. See *https://innovation.cms.gov/initiatives/ACO-Investment-Model/.*

In the June 2016 final rule, to further encourage ACOs to transition to performance-based risk, we finalized a participation option for eligible Track 1 ACOs to defer by one year their entrance into a second agreement period under a two-sided model (Track 2 or Track 3) by extending their first agreement period under Track 1 for a fourth performance

[3] See 79 FR 72805 (discussing proposal to reduce the sharing rate by 10 percentage points for ACOs in a second agreement period under Track 1 to make staying in the one-sided model less attractive than moving forward along the risk continuum); 80 FR 32766 (In response to our proposal in the December 2014 proposed rule to offer a 40 percent sharing rate to ACOs that remained in Track 1 for a second agreement period, several commenters recommended dropping the sharing rate under the one-sided model even further to encourage ACOs to more quickly accept performance-based risk, for example to 20 percent, 25 percent or 30 percent under the second agreement period, or making a 5 percentage point reduction for each year under the second agreement period).

[4] See Pioneer ACO Model website, *https://innovation.cms.gov/initiatives/Pioneer-aco-model/* (the Pioneer ACO Model ''was designed for health care organizations and providers that were already experienced in coordinating care for patients across care settings''); see also CMS Press Release, New Participants Join Several CMS Alternative Payment Models (January 18, 2017), available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-01-18.html* (the ''Next Generation ACO Model was designed to test whether strong financial incentives for ACOs can improve health outcomes and reduce expenditures for Medicare fee-for-service beneficiaries. Provider groups in this model assume higher levels of financial risk and reward than are available under the Shared Savings Program.'').

year (§ 425.200(e); 81 FR 37994 through 37997). Under this deferred renewal option, we defer resetting the benchmark as specified at § 425.603 until the beginning of the ACO's second agreement period. This participation option became available to ACOs seeking to enter their second agreement period beginning in 2017 and in subsequent years. However, only a small number of ACOs have made use of this option.

In prior rulemaking for the Shared Savings Program, we have indicated that we would continue to evaluate the appropriateness and effectiveness of our incentives to encourage ACOs to transition to a performance-based risk track and, as necessary, might revisit alternative participation options through future notice and comment rulemaking (81 FR 37995 through 37996). We believe it is timely to reconsider the participation options available under the program in light of the financial and quality results for the first four performance years under the program, participation trends by ACOs, and feedback from ACOs and other program stakeholders' about factors that encourage transition to risk.

b. Background on Factors Affecting Transition to Performance-Based Risk

Based on comments submitted by ACOs and other program stakeholders in response to earlier rulemaking and our experience with implementing the Shared Savings Program, we believe a combination of factors affect ACOs' transition to performance-based risk.[5] These factors include:

(1) Length of time allowed under a one-sided model and availability of options to transition from a one-sided model to a two-sided model within an ACO's agreement period. (Discussed in detail within this section. See also discussion of related background in section II.A.1.a. of this proposed rule.)

(2) An ACO's level of experience with the accountable care model and the Shared Savings Program.[6]

(3) Choice of methodology used to assign beneficiaries to ACOs, which determines the beneficiary population for which the ACO is accountable for both the quality and cost of care. (Background on choice of assignment methodology is discussed within this section; see also section II.A.4 of this proposed rule.) Specifically, the assignment methodology is used to determine the populations that are the basis for determining the ACO's historical benchmark and the population assigned to the ACO each performance year, which is the basis for determining whether the ACO will share in savings or losses for that performance year.

(4) Availability of program and payment flexibilities to ACOs participating under performance-based risk to support beneficiary engagement and the ACO's care coordination activities (see discussion in sections II.B and II.C of this proposed rule).

(5) Financial burden on ACOs in meeting program requirements to enter into two-sided models, specifically the requirement to establish an adequate repayment mechanism (see discussion in section II.A.6.c. of this proposed rule).

(6) Value proposition of the program's financial model under one-sided and two-sided models.

The value proposition of the program's financial models raises a number of key considerations that pertain to an ACO's transition to risk. One consideration is the level of potential reward under the one-sided model in relation to the levels of potential risk and reward under a two-sided model. A second consideration is the availability of asymmetrical levels of risk and reward, such as in the Medicare ACO Track 1+ Model (Track 1+ Model), where, for certain eligible ACOs, the level of risk is determined based on a percentage of ACO participants' total Medicare Parts A and B FFS revenue, not to exceed a percentage of the ACO's benchmark (determined based on historical expenditures for its assigned population). A third consideration is the interactions between the ACO's participation in a two-sided model of the Shared Savings Program and incentives available under other CMS value-based payment initiatives; in particular, eligible clinicians participating in an ACO under a two-sided model of the Shared Savings Program may qualify to receive an APM incentive payment under the Quality Payment Program for sufficient participation in an Advanced APM. Lastly, the value proposition of the program is informed by the methodology for setting and resetting the benchmark, which is the basis for determining shared savings and shared losses, and the length of agreement period, which determines the amount of time an ACO remains under a financial model and the frequency of benchmark rebasing. See discussion in sections II.D. (benchmarking) and II.A.1.c. (length of agreement period) of this proposed rule.

Currently, the design of the program locks in the ACO's choice of financial model, which also determines the applicable beneficiary assignment methodology, for the duration of the ACO's 3-year agreement period. For an ACO's initial or subsequent agreement period in the Shared Savings Program, an ACO applies to participate in a particular financial model (or ''track'') of the program as specified under § 425.600(a). If the ACO's application is accepted, the ACO must remain under that financial model for the duration of its 3-year agreement period. Beneficiary assignment and the level of performance-based risk (if applicable) are determined consistently for all ACOs participating in a particular track. Under Track 1 and Track 2, we assign beneficiaries using preliminary prospective assignment with retrospective reconciliation (§ 425.400(a)(2)). Under Track 3, we prospectively assign beneficiaries (§ 425.400(a)(3)).

As described in earlier rulemaking, commenters have urged that we offer greater flexibility for ACOs in their choice of assignment methodology.[7] In the June 2015 final rule, we acknowledged there is additional complexity and administrative burden to implementing an approach under which ACOs in any track may choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation, with an opportunity to switch their selection on an annual basis. At that time, we declined to implement prospective assignment in Track 1 and Track 2, and

[5] See, for example, 80 FR 32761 (summarizing comments suggesting a combination of factors could make the program more attractive and encourage ACOs to transition to risk, such as: the level of risk and reward offered under the program's financial models, tools to enable ACOs to more effectively control and manage their patient populations, opportunity for ACOs to gain experience with the program under the one-sided model under the same rules that would be applied under a two-sided model, including the assignment methodology, allowing ACOs to move to two-sided risk within an agreement period, and allowing for longer agreement periods).

[6] See discussion in section II.A.1.a of this proposed rule. See also 81 FR 37996 (summarizing comments suggesting that if a Track 1 ACO is uncertain about its ability to successfully manage financial risk, the ACO would more likely simply choose to continue under Track 1 for a second agreement period.)

[7] See, for example, 76 FR 67864 (summarizing comments suggesting allowing ACOs a choice of prospective or retrospective assignment); 80 FR 32772 through 32774 (In response to our proposal to use a prospective assignment methodology in Track 3, many commenters generally encouraged CMS to extend the option for prospective assignment beyond Track 3 to Track 1 and Track 2. Other commenters saw the value in retaining both assignment methodologies, and encouraged CMS to allow all ACOs, regardless of track, a choice of prospective or retrospective assignment. Several commenters suggested CMS allow ACOs a choice of retrospective or prospective assignment annually, within the ACO's 3-year agreement period).

we also declined to give ACOs in Track 3 a choice of either prospective assignment or preliminary prospective assignment with retrospective reconciliation. Further, we explained our belief that implementing prospective assignment only in a two-sided model track may encourage Track 1 ACOs that prefer this assignment methodology, and the other features of Track 3, to more quickly transition to performance-based risk (80 FR 32773).

We also have considered alternative approaches to allow ACOs greater flexibility in the timing of their transition to performance-based risk, including within an ACO's agreement period. For example, as described in earlier rulemaking, commenters suggested approaches that would allow less than two 3-year agreement periods under Track 1.[8] Some commenters recommended that CMS allow ACOs to ''move up'' the risk tracks (that is, move from Track 1 to Track 2 or Track 3, or move from Track 2 to Track 3) between performance years without being required to wait for the start of a new agreement period, to provide more flexibility for ACOs prepared to accept performance-based risk, or a higher level of performance-based risk. These commenters suggested that allowing an ACO to accept varying degrees of risk within an agreement period would position the ACO to best balance its exposure to and tolerance for financial risk and would create a true glide path for participating healthcare providers (81 FR 37995 through 37996).

Transition to performance-based risk has taken on greater significance with the introduction of the Quality Payment Program. Under the CY 2017 Quality Payment Program final rule with comment period,[9] ACO initiatives that require ACOs to bear risk for monetary losses of more than a nominal amount, and that meet additional criteria, can qualify as Advanced APMs beginning in performance year 2017. Eligible clinicians who sufficiently participate in Advanced APMs such that they are Qualifying APM Participants (QPs) for a performance year receive APM Incentive Payments in the corresponding payment year between 2019 through 2024, and then higher fee schedule updates starting in 2026. Track 2 and Track 3 of the Shared Savings Program, and the Track 1+ Model, are currently Advanced APMs under the Quality Payment Program.

ACOs and other program stakeholders continue to express a variety of concerns about the transition to risk under Track 2 and Track 3. For example, as described in the CY 2017 Quality Payment Program final rule with comment period (see, for example, 81 FR 77421 through 77422), commenters suggested a new Shared Savings Program track as a meaningful middle path between Track 1 and Track 2 (''Track 1.5''), that meets the Advanced APM generally applicable nominal amount standard, to create an option for ACOs with relatively low revenue or small numbers of participating eligible clinicians to participate in an Advanced APM without accepting the higher degrees of risk involved in Track 2 and Track 3. Commenters suggested this track would be a viable on-ramp for ACOs to assume greater amounts of risk in the future. Commenters' suggestions for Track 1.5 included prospective beneficiary assignment, asymmetric levels of risk and reward, and payment rule waivers, such as the SNF 3-day rule waiver available to ACOs participating in Shared Savings Program Track 3.[10] Another key component of commenters' suggestions was to allow Track 1 ACOs to transition to Track 1.5 within their current agreement periods.[11] These commenters' suggestions were considered in developing the Track 1+ Model, which began on January 1, 2018. This Model, which is being tested by the Innovation Center, includes a two-sided payment model that incorporates the upside of Track 1 with more limited downside risk than is currently present in Track 2 or Track 3 of the Shared Savings Program. The Track 1+ Model is currently an Advanced APM under the Quality Payment Program.

The Track 1+ Model is designed to encourage ACOs, especially those made up of small physician practices, to advance to performance-based risk. ACOs that include hospitals, including small rural hospitals, are also allowed to participate. See CMS Fact Sheet, New Accountable Care Organization Model Opportunity: Medicare ACO Track 1+ Model, Updated July 2017 (herein Track 1+ Model Fact Sheet), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/New-Accountable-Care-Organization-Model-Opportunity-Fact-Sheet.pdf.* In performance year 2018, 55 ACOs began in the Track 1+ Model, demonstrating strong interest in this financial model design. The availability of the Track 1+ Model increased the number of ACOs participating under a two-sided risk model in connection with their participation in the Shared Savings Program to approximately 18 percent, with approximately 22.7 percent of assigned beneficiaries receiving care through an ACO in a two-sided model. Of the 55 Track 1+ Model ACOs, based on the ACOs' self-reported composition: 58.2 percent attested to the presence of an ownership or operational interest by an inpatient prospective payment system (IPPS) hospital, cancer center or rural hospital with more than 100 beds among their ACO participants, and therefore these ACOs were under a benchmark-based loss sharing limit; and 41.8 percent attested to the absence of such ownership or operational interests by these institutional providers among their ACO participants (likely ACOs composed of independent physician practices and/or ACOs that include small rural hospitals), which qualified these ACOs for generally lower levels of risk under the Track 1+ Model's revenue-based loss sharing limit.

c. Background on Length of Agreement Period

Section 1899(b)(2)(B) of the Act requires participating ACOs to enter into an agreement with CMS to participate in the program for not less than a 3-year period referred to as the agreement period. Further, section 1899(d)(1)(B)(ii) of the Act requires us to reset the benchmark at the start of each agreement period. In initial rulemaking for the program, we limited participation agreements to 3-year periods (see 76 FR 19544, and 76 FR 67807). We have considered the length of the ACO's agreement period in the context of the amount of time an ACO may remain in a one-sided model and

[8] See, for example, 76 FR 67907 through 67909 (discussing comments suggesting ACOs be allowed 3, 4, 5, or 6 years under Track 1 prior to transitioning to a performance-based risk track).

[9] See Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period, 81 FR 77008 (Nov. 4, 2016), herein referred to as the CY 2017 Quality Payment Program final rule with comment period.

[10] See CY 2017 Quality Payment Program final rule with comment period for summary of comments and responses. Individual comments are available at *https://www.regulations.gov,* search on file code CMS–5517–P, docket ID CMS–2016–0060 (*https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=CMS-2016-0060*). See for example, Letter from Clif Gaus, NAACOS to Andrew Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, regarding CMS–5517–P (June 27, 2016); Letter from Tonya K. Wells, Trinity Health to Slavitt regarding CMS–5517–P (June 27, 2016); Letter from Joseph Bisordi, M.D., Ochsner Health System to Slavitt regarding CMS–5517–P (June 27, 2016); Letter from Kevin Bogari, Lancaster General Health Community Care Collaborative to Slavitt regarding CMS–5517–P (June 27, 2016).

[11] See 81 FR 77421 (describing comments suggesting CMS adopt a Track 1.5 and also suggesting that Track 1 ACOs should be permitted to move into this suggested Track 1.5 before the end of their current agreement period).

also the frequency with which we reset (or rebase) the ACO's historical benchmark. For example, in the June 2015 final rule, we discussed commenters' suggestions that we extend the agreement period from the current 3 years to a 5-year agreement period, for all tracks, including not only the initial agreement period, but all subsequent agreement periods.[12] These commenters explained that extending the length of the agreement period would make the program more attractive by increasing program stability and providing ACOs with the necessary time to achieve the desired quality and financial outcomes. We declined to adopt these suggestions, believing at that time it was more appropriate to maintain a 3-year agreement period to provide continuity with the initial design of the program. At that time we did not find it necessary to extend agreement periods past 3 years to address the renewal of initial program entrants, particularly in light of the policies we finalized in the June 2015 final rule allowing Track 1 ACOs to apply to continue under the one-sided model for a second 3-year agreement period and modifying the benchmark rebasing methodology. However, we explained that longer agreement periods could increase the likelihood that ACOs would build on the success or continue the failure of their current agreement period. For this reason we noted our belief that rebasing every 3 years, at the start of each 3-year agreement period, is important to protect both the Trust Funds and ACOs. See 80 FR 32763. See also 81 FR 37957 (noting commenters' suggestions that we eliminate rebasing or reducing the frequency of rebasing).

d. Background on Shared Savings Program Participation

There remains a high degree of interest in participation in the Shared Savings Program. Although most ACOs continue to participate in the program's one-sided model (Track 1), ACOs have demonstrated significant interest in the Track 1+ Model. Table 1 summarizes the total number of ACOs that are participating in the Shared Savings Program, including those also participating in the Track 1+ Model, for performance year 2018 with the total number of assigned beneficiaries by track.[13] Of the 561 ACOs participating in the program as of January 1, 2018, 55 were in the Track 1+ Model, 8 were in Track 2, 38 were in Track 3, and 460 were in Track 1. As of performance year 2018, there are over 20,000 ACO participant Taxpayer Identification Numbers (TINs) that include 377,515 clinicians (physicians, physician assistants, nurse practitioners and clinical nurse specialists) some of whom are in small and solo practices. About half of ACOs are provider networks, and 66 ACOs include rural providers. See Medicare Shared Savings Program Fast Facts (January 2018) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf.*

Based on the program's existing requirements, ACOs can participate in Track 1 for a maximum of two agreement periods. There are a growing number of ACOs that have entered into their second agreement period, and, starting in 2019, many that will begin a third agreement period and will be required to enter a risk-based track.

The progression by some ACOs to performance-based risk within the Shared Savings Program remains relatively slow, with approximately 82 percent of ACOs participating in Track 1 in 2018, 43 percent (196 of 460) of which are within a second agreement period in Track 1.

TABLE 1—ACOs BY TRACK AND NUMBER OF ASSIGNED BENEFICIARIES FOR PERFORMANCE YEAR 2018

Track	Number of ACOs	Number of assigned beneficiaries
Track 1	460	8,147,234
Track 1+ Model	55	1,212,417
Track 2	8	122,995
Track 3	38	993,533
Total	561	10,476,179

However, the recent addition of the Track 1+ Model provided a significant boost in Shared Savings Program ACOs taking on performance-based risk, with over half of the 101 ACOs participating in the Shared Savings Program and taking on performance-based risk opting for the Track 1+ Model in 2018. The lower level of risk offered under the Track 1+ Model has been positively received by the industry and provided a pathway to risk for many ACOs.

2. Proposals for Modified Participation Options Under 5-Year Agreement Periods

In developing the proposed policies described in this section, we considered a number of factors related to the program's current participation options in light of the program's financial results and stakeholders' feedback on program design, including the following.

First, we considered the program's existing policy allowing ACOs up to 6 years of participation in a one-sided model. We have found that the policy has shown limited success in encouraging ACOs to advance to performance-based risk. By the fifth year of implementing the program, only about 18 percent of the program's participating ACOs are under a two-sided model, over half of which are participating in the Track 1+ Model (see Table 1).

As discussed in detail in the Regulatory Impact Analysis (see section IV. of this proposed rule), our experience with the program indicates

[12] See 80 FR 32763. See also 80 FR 32761 (discussing several commenters' recommendation to move to 5 or 6 year agreements for ACOs and the suggestion that ACOs have the opportunity to move to a performance-based risk model during their first agreement period, for example, after their first 3 years under the one-sided model. A commenter suggested encouraging ACOs to transition to two-sided risk by offering lower loss sharing rates for ACOs that move from Track 1 to the two-sided model during the course of an agreement period, and phasing-in loss sharing rates for these ACOs (for example, 15 percent in year 1, 30 percent in year 2, 60 percent in year 3). Another commenter suggested that CMS allow all ACOs (regardless of track) the option to increase their level of risk annually during the agreement period.)

[13] See Performance Year 2018 Medicare Shared Savings Program Accountable Care Organizations available at Data.CMS.gov, *https://data.cms.gov/Special-Programs-Initiatives-Medicare-Shared-Savin/Performance-Year-2018-Medicare-Shared-Savings-Prog/28n4-k8qs/data.*

that ACOs in two-sided models generally perform better than ACOs that participate under a one-sided model. For example, for performance year 2016, about 68 percent of Shared Savings Program ACOs in two-sided models (15 of 22 ACOs) shared savings compared to 29 percent of Track 1 ACOs. For performance year 2015, prior to the first year of Track 3, one of the three remaining Track 2 ACOs shared savings, while about 30 percent of Track 1 ACOs (118 of 389 ACOs) shared savings. For performance year 2014, two of the three remaining Track 2 ACOs shared savings while about 25 percent of Track 1 ACOs (84 of 330 ACOs) shared savings. In the program's first year, concluding December 31, 2013, 40 percent of Track 2 ACOs (2 of 5 ACOs) compared to 23 percent of Track 1 ACOs (50 of 215 ACOs) shared savings. See Shared Savings Program Accountable Care Organization Public Use Files, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html*. These observations, in combination with participation trends that show ACOs prefer to remain in Track 1 for a second 3-year agreement period, suggests that a requirement for ACOs to more rapidly transition to performance-based risk could be effective in creating incentives for ACOs to more quickly meet the program's goals.

The program's current design lacks a sufficiently incremental progression to performance-based risk, the need for which is evidenced by robust participation in the new Track 1+ Model. We believe a significant issue that contributes to some ACOs' reluctance to participate in Track 2 or Track 3 is that the magnitude of potential losses is very high compared to the ACO's degree of control over the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, particularly when its ACO participants have relatively low total Medicare Parts A and B FFS revenue. We are encouraged by the interest in the Track 1+ Model as indicated by the 55 Shared Savings Program ACOs participating in the Model for the performance year beginning on January 1, 2018; the largest group of Shared Savings Program ACOs to enter into performance-based risk for a given performance year to date. Based on the number of ACOs participating in the Track 1+ Model for performance year 2018, a lower risk option appears to be important for Track 1 ACOs with experience in the program seeking to transition to performance-based risk, as well as ACOs seeking to enter an initial agreement period in the program under a lower risk model.

Interest in the Track 1+ Model suggests that the opportunity to participate in an Advanced APM while accepting more moderate levels of risk (compared to Track 2 and Track 3) is an important financial model design for ACOs. Allowing more manageable levels of risk within the Shared Savings Program is an important pathway for helping organizations to gain experience with managing risk as well as participating in Advanced APMs under the Quality Payment Program. The high uptake we have observed with the Track 1+ Model also suggests that the current design of Track 1 may be unnecessarily generous since the Track 1+ Model has the same level of upside as Track 1 but under which ACOs must also assume performance-based risk.

Second, under the program's current design, CMS lacks adequate tools to properly address ACOs with patterns of negative financial performance. Track 1 ACOs are not liable for repaying any portion of their losses to CMS, and therefore may have potentially weaker incentives to improve quality and reduce growth in FFS expenditures within the accountable care model. These ACOs may take advantage of the potential benefits of continued program participation (including the receipt of program data and the opportunity to enter into certain contracting arrangements with ACO participants and ACO providers/suppliers in connection with their participation in the Shared Savings Program), without providing a meaningful benefit to the Medicare program. ACOs under two-sided models may similarly benefit from program participation and seek to continue their participation despite owing shared losses.

Third, differences in performance of ACOs indicate a pattern where low revenue ACOs outperformed high revenue ACOs. As discussed in the Regulatory Impact Analysis (see section IV. of this proposed rule), we have observed a pattern of performance, across tracks and performance years, where low revenue ACOs show better average results compared to high revenue ACOs. We believe high revenue ACOs, which typically include hospitals, have a greater opportunity to control assigned beneficiaries' total Medicare Parts A and B FFS expenditures, as they coordinate a larger portion of the assigned beneficiaries' care across care settings, and have the potential to perform better than what has been demonstrated in performance trends from 2012 through 2016. We conclude that the trends in performance by high revenue ACOs in relation to their expected capacity to control growth in expenditures are indications that these ACOs' performance would improve through greater incentives, principally a requirement to take on higher levels of performance-based risk, and thus drive change in FFS utilization for their Medicare FFS populations. This conclusion is further supported by our initial experience with the Track 1+ Model, for which our preliminary findings support the conclusion that the degree of control an ACO has over expenditures for its assigned beneficiaries is an indication of the level of performance-based risk an ACO is prepared to accept and manage, where control is determined by the relationship between ACO participants' total Medicare Parts A and B FFS revenue and the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. Our experience with the Track 1+ Model has also shown that ACO participants' total Medicare Parts A and B FFS revenue as a percentage of the total Medicare Parts A and B FFS expenditures of the assigned beneficiaries can serve as a proxy for ACO composition (that is, whether the ACO includes one or more institutional providers as an ACO participant, and therefore is likely to control a greater share of Medicare Parts A and B FFS expenditures and to have greater ability to coordinate care across settings for its assigned beneficiaries).

Fourth, permitting choice of level of risk and assignment methodology within an ACO's agreement period would create redundancy in some participation options, and eliminating this redundancy would allow CMS to streamline the number of tracks offered while allowing ACOs greater flexibility to design their participation to meet the needs of their organizations. ACOs and stakeholders have indicated a strong preference for maintaining an option to select preliminary prospective assignment with retrospective reconciliation as an alternative to prospective assignment for ACOs under performance-based risk within the Shared Savings Program. We considered what would occur if we retained Track 2 in addition to the ENHANCED track and offered a choice of prospective assignment and preliminary prospective assignment (see section II.A.4.c. of this proposed rule) for both tracks. We believe that ACOs prepared to accept higher levels of benchmark-based risk would be more likely to enter the ENHANCED track (which allows the greatest risk and potential reward). This

is suggested by participation statistics, where 8 ACOs are participating in Track 2 compared to the 38 ACOs participating in Track 3 as of January 1, 2018. We note that for agreement periods beginning in 2018, only 2 ACOs entered Track 2, both of which had deferred renewal in 2017, while 4 ACOs entered Track 3 (for their first or second agreement period). ACOs may be continuing to pick Track 2 because of the preliminary prospective assignment methodology, and we would expect participation in Track 2 to decline further if we finalize the proposal to allow a choice of assignment methodology in the ENHANCED track, since we would expect ACOs ready for higher risk (that is, a level of risk that is higher than the highest level of risk and potential reward under the proposed BASIC track) to prefer the ENHANCED track over Track 2.

Fifth, longer agreement periods could improve program incentives and support ACOs' transition into performance-based risk when coupled with changes to improve the accuracy of the program's benchmarking methodology. Extending agreement periods for more than 3 years could provide more certainty over benchmarks and in turn give ACOs a greater chance to succeed in the program by allowing them more time to understand their performance, gain experience and implement redesigned care processes before rebasing of the ACO's historical benchmark. Shared Savings Program results show that ACOs tend to perform better the longer they remain in the program. Further, under longer agreement periods, historical benchmarks would become more predictable, since the benchmark would continue to be based on the expenditures for beneficiaries who would have been assigned to the ACO in the 3 most recent years prior to the start of the ACO's agreement period (see §§ 425.602(a) and 425.603(c)) and the benchmark would be risk adjusted and updated each performance year relative to benchmark year 3. However, a number of factors can affect the amount of the benchmark, and therefore its predictability, during the agreement period regardless of whether the agreement period spans 3 or 5 years, including: adjustments to the benchmark during the ACO's agreement period resulting from changes in the ACO's certified ACO participant list and regulatory changes to the assignment methodology; as well as variation in the benchmark value that occurs each performance year as a result of annual risk adjustment to the ACO's benchmark (§§ 425.602(a)(9) and 425.603(c)(10)) and annual benchmark updates (§§ 425.602(b) and 425.603(d)). Further, as discussed in section II.D of this proposed rule, we believe the proposed approach to incorporating factors based on regional FFS expenditures in establishing, adjusting and updating the benchmark beginning with the ACO's first agreement period will result in more accurate benchmarks. This improved accuracy of benchmarks would mitigate the impact of the more generous updated benchmarks that could result in the later years of longer agreement periods.

In summary, taking these factors into consideration, we propose to redesign the program's participation options by discontinuing Track 1, Track 2 and the deferred renewal option, and instead offering two tracks that eligible ACOs would enter into for an agreement period of at least 5 years: (1) BASIC track, which would include an option for eligible ACOs to begin participation under a one-sided model and incrementally phase-in risk (calculated based on ACO participant revenue and capped at a percentage of the ACO's updated benchmark) and potential reward over the course of a single agreement period, an approach referred to as a glide path; and (2) ENHANCED track, based on the program's existing Track 3, for ACOs that take on the highest level of risk and potential reward.

We propose to require ACOs to enter one of two tracks for agreement periods beginning on July 1, 2019, and in subsequent years (as described in section II.A.7 of this proposed rule): either the ENHANCED track, which would be based on Track 3 as currently designed and implemented under § 425.610, or the new BASIC track, which would offer eligible ACOs a glide path from a one-sided model to incrementally higher performance-based risk as described in section II.A.3 of this proposed rule. (Herein, we refer to this participation option for eligible ACOs entering the BASIC track as the BASIC track's glide path, or simply the glide path.)

We propose to add a new provision to the Shared Savings Program regulations at § 425.605 to establish the requirements for this BASIC track. The BASIC track would offer lower levels of risk compared to the levels of risk currently offered in Track 2 and Track 3, and the same maximum level of risk as offered under the Track 1+ Model. Compared to the design of Track 1, we believe this glide path approach, which requires assumption of gently increasing levels of risk and potential reward beginning no later than an ACO's fourth performance year under the BASIC track for agreement periods starting on July 1, 2019 (as discussed in section II.A.7 of this proposed rule) or third performance year under the BASIC track for agreement periods starting in 2020 and all subsequent years, could provide stronger incentives for ACOs to improve their performance.

For agreement periods beginning on July 1, 2019, and in subsequent years, we propose to modify the regulations at §§ 425.600 and 425.610 to designate Track 3 as the ENHANCED track. We propose that all references to the ENHANCED track in the program's regulations would be deemed to include Track 3. Within the preamble of this proposed rule, we intend references to the ENHANCED track to apply to Track 3 ACOs, unless otherwise noted.

As part of the redesign of the program's participation options, we believe it is timely to provide the program's tracks with more descriptive and meaningful names. We believe ''enhanced'' is indicative of the increased levels of risk and potential reward available to ACOs under the current design of Track 3, the new tools and flexibilities available to performance-based risk ACOs, and the relative incentives for ACOs under this financial model design to improve the quality of care for their assigned beneficiaries (for example, through the availability of the highest sharing rates based on quality performance under the program) and their potential to drive towards reduced costs for Medicare FFS beneficiaries and therefore increased savings for the Medicare Trust Funds. In contrast, ''basic'' suggests a foundational level, which is reflected in the opportunity under the BASIC track to provide a starting point for ACOs on a pathway to success from a one-sided shared savings model to two-sided risk.

We propose that for agreement periods beginning on July 1, 2019, the length of the agreement would be 5 years and 6 months (as discussed in section II.A.7 of this proposed rule). For agreement periods beginning on January 1, 2020, and in subsequent years, the length of the agreement would be 5 years.

Currently, under § 425.20, we define ''agreement period'' to mean the term of the participation agreement, which is 3 performance years unless otherwise specified in the participation agreement. We propose to revise this definition to more broadly mean the term of the participation agreement. Additionally, we propose to specify the term of participation agreements beginning on July 1, 2019 and in subsequent years in

revisions to § 425.200, which currently specifies the term of the participation agreement for each agreement start date since the beginning of the program. For consistency, we propose to revise the heading in § 425.200(b) from ''term of the participation agreement'' to ''agreement period,'' based on the modification to the definition of ''agreement period'' in § 425.20.

We also propose to revise § 425.502(e)(4)(v), specifying calculation of the quality improvement reward as part of determining the ACO's quality score, which includes language based on 3-year agreement periods. Through these revisions, we would specify that the comparison for performance in the first year of the new agreement period would be the last year in the previous agreement period, rather than the third year of the previous agreement period.

The regulation on renewal of participation agreements (§ 425.224(b)) includes criteria regarding an ACO's quality performance and repayment of shared losses that focus on specific years in the ACO's prior 3-year agreement period. In section II.A.5.c of this proposed rule, we discuss proposals to revise these evaluation criteria to be more relevant to assessing prior participation of ACOs under an agreement period of at least 5 years, among other factors.

For ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, we propose to allow ACOs annually to elect the beneficiary assignment methodology (preliminary prospective assignment with retrospective reconciliation, or prospective assignment) to apply for each remaining performance year within their agreement period. See discussion in section II.A.4.c of this proposed rule.

For ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, we propose to allow eligible ACOs in the BASIC track's glide path the option to elect entry into a higher level of risk and potential reward under the BASIC track for each performance year within their agreement period. See discussion in section II.A.4.b.

We propose to discontinue Track 1 as a participation option for the reasons described elsewhere in this section. We propose to amend § 425.600 to limit availability of Track 1 to agreement periods beginning before July 1, 2019.

We propose to discontinue Track 2 as a participation option. We propose to amend § 425.600 to limit availability of Track 2 to agreement periods beginning before July 1, 2019. We based these proposals on the following considerations.

For one, the proposal to allow ACOs to select their assignment methodology (section II.A.4.c) and the availability of the proposed BASIC track with relatively low levels of risk compared to the ENHANCED track would ensure the continued availability of a participation option with moderate levels of risk and potential reward in combination with the optional availability of the preliminary prospective beneficiary assignment in the absence of Track 2. We believe that maintaining Track 2 as a participation option between the lower risk of the proposed BASIC track and the higher risk of the ENHANCED track would create redundancy in participation options, while removing Track 2 would offer an opportunity to streamline the tracks offered.

Although Track 2 was the initial two-sided model of the Shared Savings Program, the statistics on Shared Savings Program participation by track (and in the Track 1+ Model) summarized in Table 1 show few ACOs entering and completing their risk bearing agreement period under Track 2 in recent years, and suggest that ACOs prefer either a lower level of risk and potential reward under the Track 1+ Model or a higher level of risk and potential reward under Track 3 than the Track 2 level of risk and potential reward.

Further, under the proposed modifications to the regulations (see section II.A.5.c of this proposed rule), Track 2 ACOs prepared to take on higher risk would have the option to elect to enter the ENHANCED track by completing their agreement period in Track 2 and applying to renew for a subsequent agreement period under the ENHANCED track or by voluntarily terminating their current 3-year agreement and entering a new agreement period under the ENHANCED track, without waiting until the expiration of their current 3-year agreement period. Certain Track 2 ACOs that may not be prepared for the higher level of risk under the ENHANCED track could instead elect to enter the proposed BASIC track at the highest level of risk and potential reward, under the same circumstances.

We propose to discontinue the policy that allows Track 1 ACOs in their first agreement period to defer renewal for a second agreement period in a two-sided model by 1 year, to remain in their current agreement period for a fourth performance year, and to also defer benchmark rebasing. We propose to amend § 425.200(e) to discontinue the deferred renewal option, so that it would be available to only those Track 1 ACOs that began a first agreement period in 2014 and 2015 and have already renewed their participation agreement under the deferred renewal option and therefore this option would not be available to Track 1 ACOs seeking to renew for a second agreement period beginning on July 1, 2019, or in subsequent years. We propose to amend § 425.200(b)(3) to specify that the extension of a first agreement period in Track 1 under the deferred renewal option is available only for ACOs that began a first agreement period in 2014 or 2015 and therefore deferred renewal in 2017 or 2018 (respectively). We considered the following issues in developing this proposal.

For one, continued availability of this option is inconsistent with our proposed redesign of the program, which encourages rapid transition to performance-based risk and requires ACOs on the BASIC track's glide path to enter performance-based risk within their first agreement period under the BASIC track.

Deferral of benchmark rebasing was likely a factor in some ACOs' decisions to defer renewal, particularly for ACOs concerned about the effects of the rebasing methodology on their benchmark. Under the proposal to extend the length of agreement periods from 3 years to not less than 5 years, benchmark rebasing would be delayed by 2 years (relative to a 3-year agreement), rather than 1 year, as provided under the current deferred renewal policy.

Eliminating the deferred renewal option would streamline the program's participation options and operations. Very few ACOs have elected the deferred renewal participation option, with only 8 ACOs that began participating in the program in either 2014 or 2015 renewing their Shared Savings Program agreement under this option to defer entry into a second agreement period under performance-based risk until 2018 or 2019, respectively. We believe the very low uptake of this option demonstrates that it is not effective at facilitating ACOs' transition to performance-based risk. The proposed timing of applicability would prevent ACOs from electing to defer renewal in 2019 for a second agreement period beginning in 2020.

Further, as discussed in section II.A.5.c of this proposed rule, we are proposing to discontinue the ''sit-out'' period under § 425.222(a), which is cross-referenced in the regulation at § 425.200(e) establishing the deferred renewal option. Under the proposed modifications to § 425.222(a), ACOs that have already been approved to defer renewal until 2019 under this

participation option (ACOs with 2015 start dates in the Shared Savings Program that deferred entering a second agreement period under two-sided risk until January 1, 2019), would have the option of terminating their participation agreement for their second agreement period under Track 2 or Track 3 and applying to enter the BASIC track at the highest level of risk and potential reward (Level E), or the ENHANCED track, for a new agreement period.

Modifying the participation options in the Shared Savings Program to offer a new performance-based risk track requires the use of our authority under section 1899(i)(3) of the Act. To add the BASIC track, we must determine that it will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. Consistent with our earlier discussions of the use of this authority to establish the current two-sided models in the Shared Savings Program (see 76 FR 67904 and 80 FR 32771), we believe that the BASIC track would provide an additional opportunity for organizations to enter a risk-sharing arrangement and accept greater responsibility for beneficiary care.

This proposed restructuring of participation options, more generally, would help ACOs transition to performance-based risk more quickly than under the program's current design. This proposed rule would eliminate Track 1 (under which a one-sided model currently is available for up to 6 years), offering instead a glide path with up to 2 performance years under a one-sided model (three, for ACOs that enter the glide path on July 1, 2019), followed by the incremental phase-in of risk and increasing potential for reward over the remaining 3 performance years of the agreement period. As described in section II.A.5.c. of this proposed rule, we propose that ACOs that previously participated in Track 1, or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO, entering the BASIC track's glide path would be eligible for a single performance year under a one-sided model (two, for ACOs that enter the glide path on July 1, 2019). As described in section II.A.7. of this proposed rule, we propose a one-time exception to be specified in revisions to § 425.600, under which the automatic advancement policy would not apply to the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019. For performance year 2020, the ACO may remain in the same level of the BASIC track's glide path that it entered for the performance year beginning on July 1, 2019 (6-month period). The ACO would be automatically advanced to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period, unless the ACO elects to advance to a higher level of risk and potential reward under the glide path more quickly, as proposed in section II.A.4.b of this proposed rule. The glide path concludes with the ACO entering a level of potential reward that is the same as is currently available under Track 1, with a level of risk that matches the lesser of either the revenue-based or benchmark-based loss sharing limit under the Track 1+ Model.

Further, we believe a significant incentive for ACOs to transition more quickly to the highest level of risk and reward under the BASIC track is the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program. Under the BASIC track's Level E, an ACO's eligible clinicians would have the opportunity to receive APM Incentive Payments and ultimately higher fee schedule updates starting in 2026, in the payment year corresponding to each performance year in which they attain QP status.

As noted in the Regulatory Impact Analysis (section IV. of this proposed rule), the proposed BASIC track is expected to increase participation in performance-based risk by ACOs that may not otherwise take on the higher exposure to risk required in the ENHANCED track (or in the current Track 2). Such added participation in performance-based risk is expected to include a significant number of low revenue ACOs, including physician-led ACOs. These ACOs have shown stronger performance in the first years of the program despite mainly opting to participate in Track 1. Furthermore, the option for BASIC track ACOs to progress gradually toward risk within a single agreement period or accelerate more quickly to the BASIC track's Level E is expected to further expand eventual participation in performance-based risk by ACOs that would otherwise hesitate to immediately transition to this level of risk because of uncertainty related to benchmark rebasing.

Therefore, we do not believe that adding the BASIC track as a participation option under the Shared Savings Program would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) (as discussed in the Regulatory Impact Analysis in section IV. of this proposed rule). Further, we believe that adding the BASIC track would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs would have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they must pay.

This proposed rule includes policy proposals that require that we reassess the policies adopted under the authority of section 1899(i)(3) of the Act to ensure that they comply with the requirements under section 1899(i)(3)(B) of the Act, as discussed in the Regulatory Impact Analysis (see section IV. of this proposed rule). As described in the Regulatory Impact Analysis, the elimination of Track 2 as an on-going participation option, the addition of the BASIC track, the benchmarking changes described in section II.D. of this proposed rule, and the proposal in section II.A.7. of this proposed rule to determine shared savings and shared losses for the 6-month performance years starting on January 1, 2019 and July 1, 2019, using expenditures for the entire calendar year 2019 and then pro-rating these amounts to reflect the shorter performance year, require the use of our authority under section 1899(i) of the Act. These proposed changes to our payment methodology are not expected to result in a situation in which all policies adopted under the authority of section 1899(i) of the Act, when taken together, result in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

3. Creating a BASIC Track With Glide Path to Performance-Based Risk

a. Overview

We propose that the BASIC track would be available as a participation option for agreement periods beginning on July 1, 2019 and in subsequent years.

Special considerations and proposals with respect to the midyear start of the first BASIC track performance year and the limitation of this first performance year to a 6-month period are discussed in section II.A.7. and, as needed, throughout this preamble.

In general, unless otherwise stated, we are proposing to model the BASIC track on the current provisions governing Shared Savings Program ACOs under 42 CFR part 425, including the general eligibility requirements (subpart B), application procedures (subpart C), program requirements and beneficiary protections (subpart D), beneficiary assignment methodology (subpart E), quality performance standards (subpart F), data sharing opportunities and requirements (subpart H), and benchmarking methodology (which as discussed in section II.D of this proposed rule, we propose to specify in a new section of the regulations at § 425.601). Further, we propose that the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations (§ 425.315), the preclusion of administrative and judicial review (§ 425.800), and the reconsideration process (subpart I) would apply to ACOs participating in the BASIC track in the same manner as for all other Shared Savings Program ACOs. Therefore, we propose to amend certain existing regulations to incorporate references to the BASIC track and the proposed new regulation at § 425.605. This includes amendments to §§ 425.100, 425.315, 425.600, and 425.800. As part of the revisions to § 425.800, we propose to clarify that the preclusion of administrative and judicial review with respect to certain financial calculations applies only to the extent that a specific calculation is performed in accordance with section 1899(d) of the Act.

As discussed in section II.A.4.c. of this proposed rule, we are proposing that ACOs in the BASIC track would have an opportunity to annually elect their choice of beneficiary assignment methodology. As discussed in section II.B. of this proposed rule, we propose to make the SNF 3-day rule waiver available to ACOs in the BASIC track under two-sided risk. If these ACOs select prospective beneficiary assignment, their physicians and practitioners billing under ACO participant TINs would also have the opportunity to provide telehealth services under section 1899(l) of the Act, starting in 2020. As described in section II.C. of this proposed rule, BASIC track ACOs under two-sided risk (Levels C, D, or E) would be allowed to apply for and, if approved, establish a CMS-approved beneficiary incentive program to provide incentive payments to eligible beneficiaries for qualifying services.

We propose that, unless otherwise indicated, all current policies that apply to ACOs under a two-sided model would apply also to ACOs participating under risk within the BASIC track. This includes the selection of a Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR) consistent with the options available under the ENHANCED track, as specified in § 425.610(b)(1) (with related proposals discussed in section II.A.6.b. of this proposed rule), and the requirement to establish and maintain an adequate repayment mechanism under § 425.204(f) (with related proposals discussed in section II.A.6.c. of this proposed rule). ACOs participating under the one-sided models of the BASIC track's glide path (Level A and Level B), would be required to select a MSR/MLR and establish an adequate repayment mechanism prior to their first performance year in performance-based risk. Additionally, the same policies regarding notification of savings and losses and the timing of repayment of any shared losses that apply to ACOs in the ENHANCED track (see § 425.610(h)) would apply to ACOs in two-sided risk models under the BASIC track, including the requirement that an ACO must make payment in full to CMS within 90 days of receipt of notification of shared losses.

As described in section II.E.4 of this proposed rule, we are proposing to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO quality and financial performance, as established for performance year 2017 to 2018 and subsequent years. We propose that these policies would also apply to BASIC track ACOs. Section 425.502(f) specifies the approach to calculating an ACO's quality performance score for all affected ACOs. Further, we propose that the policies regarding the calculation of shared losses for ACOs under a two-sided risk model that are affected by extreme and uncontrollable circumstances (see § 425.610(i)) would also apply to BASIC track ACOs under performance-based risk. We also propose to specify that policies to adjust shared losses for extreme and uncontrollable circumstances would also apply to BASIC track ACOs that are reconciled for a 6-month performance year under § 425.609 or a partial year of performance under § 425.221(b)(2) as a result of early termination as described in section II.E.4 and II.A.6.d of this proposed rule.

b. Proposals for Phase-in of Performance-Based Risk in the BASIC Track

(1) Background on Levels of Risk and Reward

To qualify for shared savings, an ACO must have savings equal to or above its MSR, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program (§§ 425.604(a)(7), (b) and (c), 425.606(a)(7), (b) and (c), 425.610(a)(7), (b) and (c)). If an ACO qualifies for savings by meeting or exceeding its MSR, then the final sharing rate (based on quality performance) is applied to the ACO's savings on a first dollar basis, to determine the amount of shared savings up to the performance payment limit (§§ 425.604(d) and (e), 425.606(d) and (e), 425.610(d) and (e)).

Under the current program regulations, an ACO that meets all of the requirements for receiving shared savings under the one-sided model can qualify to receive a shared savings payment of up to 50 percent of all savings under its updated benchmark, as determined on the basis of its quality performance, not to exceed 10 percent of its updated benchmark. A Track 2 ACO can potentially receive a shared savings payment of up to 60 percent of all savings under its updated benchmark, not to exceed 15 percent of its updated benchmark. A Track 3 ACO can potentially receive a shared savings payment of up to 75 percent of all savings under its updated benchmark, not to exceed 20 percent of its updated benchmark. The higher sharing rates and performance payment limits under Track 2 and Track 3 were established as incentives for ACOs to accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards. (See 76 FR 67929 through 67930, 67934 through 67936; 80 FR 32778 through 32779.)

Under the current two-sided models of the Shared Savings Program, an ACO is responsible for sharing losses with the Medicare program when the ACO's average per capita Medicare expenditures for the performance year are above its updated benchmark costs for the year by at least the MLR established for the ACO (§§ 425.606(b)(3), 425.610(b)(3)). For an ACO that is required to share losses with the Medicare program for expenditures over its updated benchmark, the shared loss rate (also

referred to as the loss sharing rate) is determined based on the inverse of its final sharing rate, but may not be less than 40 percent. The loss sharing rate is applied to an ACO's losses on a first dollar basis, to determine the amount of shared losses up to the loss recoupment limit (also referred to as the loss sharing limit) (§§ 425.606(f) and (g), 425.610(f) and (g)).

In earlier rulemaking, we discussed considerations related to establishing the loss sharing rate and loss sharing limit for Track 2 and Track 3. See 76 FR 67937 (discussing shared loss rate and loss sharing limit for Track 2) and 80 FR 32778 through 32779 (including discussion of shared loss rate and loss sharing limit for Track 3). Under Track 2 and Track 3, the loss sharing rate is determined as 1 minus the ACO's final sharing rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively (except that the loss sharing rate may not be less than 40 percent for Track 3). This creates symmetry between the sharing rates for savings and losses. The 40 percent floor on the loss sharing rate under both Track 2 and Track 3 ensures comparability in the minimum level of performance-based risk that ACOs accept under these tracks. The higher ceiling on the loss sharing rate under Track 3 reflects the greater risk Track 3 ACOs accept in exchange for the possibility of greater reward compared to Track 2.

Under Track 2, the limit on the amount of shared losses phases in over 3 years starting at 5 percent of the ACO's updated historical benchmark in the first performance year of participation in Track 2, 7.5 percent in year 2, and 10 percent in year 3 and any subsequent year. Under Track 3, the loss sharing limit is 15 percent of the ACO's updated historical benchmark, with no phase-in. Losses in excess of the annual limit would not be shared.

The level of risk under both Track 2 and Track 3 exceeds the Advanced APM generally applicable nominal amount standard under § 414.1415(c)(3)(i)(B) (set at 3 percent of the expected expenditures for which an APM Entity is responsible under the APM). CMS has determined that Track 2 and Track 3 meet the Advanced APM criteria under the Quality Payment Program, and are therefore Advanced APMs. Eligible clinicians that sufficiently participate in Advanced APMs such that they are QPs for a performance year receive APM Incentive Payments in the corresponding payment year between 2019 through 2024, and then higher fee schedule updates starting in 2026.

The Track 1+ Model is testing whether combining the upside sharing parameters of the popular Track 1 with limited downside risk sufficient for the model to qualify as an Advanced APM will encourage more ACOs to advance to performance-based risk. The Track 1+ Model has reduced risk in two main ways relative to Track 2 and Track 3. First, losses under the Track 1+ Model are shared at a flat 30 percent loss sharing rate, which is 10 percentage points lower than the minimum quality-adjusted loss sharing rate used in both Track 2 and Track 3. Second, a bifurcated approach is used to set the loss sharing limit for a Track 1+ Model ACO, depending on the ownership and operational interests of the ACO's ACO participants, as identified by TINs and CMS Certification Numbers (CCNs).

The applicable loss sharing limit under the Track 1+ Model is determined based on whether the ACO includes an ACO participant (TIN/CCN) that is an IPPS hospital, cancer center or a rural hospital with more than 100 beds, or that is owned or operated, in whole or in part, by such a hospital or by an organization that owns or operates such a hospital. If at least one of these criteria is met, then a potentially higher level of performance-based risk applies, and the loss sharing limit is set at 4 percent of the ACO's updated historical benchmark (described herein as the benchmark-based loss sharing limit). For the Track 1+ Model, this is a lower level of risk than is required under either Track 2 or Track 3, and greater than the Advanced APM generally applicable nominal amount standard under § 414.1415(c)(3)(i)(B) for 2018, 2019 and 2020. If none of these criteria is met, as may be the case with some ACOs composed of independent physician practices and/or ACOs that include small rural hospitals, then a potentially lower level of performance-based risk applies, and the loss sharing limit is determined as a percentage of the total Medicare Parts A and B FFS revenue of the ACO participants (described herein as the revenue-based loss sharing limit). For Track 1+ Model ACOs under a revenue-based loss sharing limit, in performance years 2018, 2019 and 2020, total liability for shared losses is limited to 8 percent of total Medicare Parts A and B FFS revenue of the ACO participants. If the loss sharing limit, as a percentage of the ACO participants' total Medicare Parts A and B FFS revenue, exceeds the amount that is 4 percent of the ACO's updated historical benchmark, then the loss sharing limit is capped and set at 4 percent of the updated historical benchmark. For performance years 2018 through 2020, this level of performance-based risk qualifies the Track 1+ Model as an Advanced APM under § 414.1415(c)(3)(i)(A). In subsequent years of the Track 1+ Model, if the relevant percentage specified in the Quality Payment Program regulations changes, the Track 1+ Model ACO would be required to take on a level of risk consistent with the percentage required in § 414.1415(c)(3)(i)(A) for an APM to qualify as an Advanced APM.

The loss sharing limit under this bifurcated structure is determined by CMS near the start of an ACO's agreement period under the Track 1+ Model (based on the ACO's application to the Track 1+ Model), and re-determined annually based on an annual certification process prior to the start of each performance year under the Track 1+ Model. The Track 1+ Model ACO's loss sharing limit could be adjusted up or down on this basis. See Track 1+ Model Fact Sheet for more detail.

Since the start of the Shared Savings Program, we have heard a variety of concerns and suggestions from ACOs and other program stakeholders about the transition from a one-sided model to performance-based risk (see discussion in section II.A.1.). Through rulemaking, we developed a one-sided shared savings only model and extended the allowable time in this track to support ACOs' readiness to take on performance-based risk. As a result, the vast majority of Shared Savings Program ACOs have chosen to enter and remain in the one-sided model. We believe that our early experience with the design of the Track 1+ Model demonstrates that the availability of a lower-risk, two-sided model is effective to encourage a large cohort of ACOs to rapidly progress to performance-based risk.

(2) Levels of Risk and Reward in the BASIC Track's Glide Path

In general, we propose the following participation options within the BASIC track.

First, we propose the BASIC track's glide path as an incremental approach to higher levels of risk and potential reward. The glide path includes 5 levels: a one-sided model available only for the first 2 consecutive performance years of a 5-year agreement period (Level A and B), each year of which is identified as a separate level; and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Level C, D, and E). ACOs would be automatically advanced at the start of each participation year along the

progression of risk/reward levels, over the course of a 5-year agreement period, until they reach the track's maximum level of risk/reward (designed to be the same as the level of risk and potential reward as under the Track 1+ Model). The automatic advancement policy would not apply to the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning July 1, 2019. Such an ACO would enter the BASIC track for its first performance year of July 1, 2019 through December 31, 2019, at its chosen level of the glide path. For performance year 2020, the ACO may remain in the same level of the BASIC track's glide path that it entered for the performance year beginning July 1, 2019 (6-month period). The ACO would be automatically advanced to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period (discussed in section II.A.7. of this proposed rule).

We propose that the participation options in the BASIC track's glide path would depend on an ACO's experience with the Shared Savings Program, as described in section II.A.5.c. of this proposed rule. ACOs eligible for the BASIC track's glide path that are new to the program would have the flexibility to enter the glide path at any one of the five levels. However, ACOs that previously participated in Track 1, or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO, would be ineligible to enter the glide path at Level A, thereby limiting their opportunity to participate in a one-sided model of the glide path. We also propose ACOs would be automatically transitioned to progressively higher levels of risk and potential reward (if higher levels are available) within the remaining years of the agreement period. We propose to allow ACOs in the BASIC track's glide path to more rapidly transition to higher levels of risk and potential reward within the glide path during the agreement period. As described in section II.A.4.b. of this proposed rule, ACOs in the BASIC track may annually elect to take on higher risk and potential reward within their current agreement period, to more rapidly progress along the glide path.

Second, we propose the BASIC track's highest level of risk and potential reward (Level E) may be elected for any performance year by ACOs that enter the BASIC track's glide path, but it will be required no later than the ACO's fifth performance year of the glide path (sixth performance year for eligible ACOs starting participation in Level A of the BASIC track on July 1, 2019, see section II.A.7.). ACOs in the BASIC track's glide path that previously participated in Track 1, or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO, would be eligible to begin in Level B, and therefore would be required to participate in Level E no later than the ACO's fourth performance year of the glide path (fifth performance year for ACOs starting participation in the BASIC track on July 1, 2019). The level of risk/reward under Level E of the BASIC track is also required for low revenue ACOs eligible to enter an agreement period under the BASIC track that are determined to be experienced with performance-based risk Medicare ACO initiatives (discussed in section II.A.5. of this proposed rule).

We believe that designing a glide path to performance-based risk that concludes with the level of risk and potential reward offered under the Track 1+ Model balances ACOs' interest in remaining under lower-risk options with our goal of more rapidly transitioning ACOs to performance-based risk. The BASIC track's glide path offers a pathway through which ACOs inexperienced with performance-based risk Medicare ACO initiatives can participate under a one-sided model before entering relatively low levels of risk and asymmetrical potential reward for several years, concluding with the lowest level of risk and potential reward available under a current Medicare ACO initiative. We believe the opportunity for eligible ACOs to participate in a one-sided model for up to 2 years (3 performance years, in the case of an ACO entering at Level A of the BASIC track's glide path on July 1, 2019) could offer new ACOs a chance to become experienced with the accountable care model and program requirements before taking on risk. The proposed approach also recognizes that ACOs that gained experience with the program's requirements during prior participation under Track 1, would need less additional time under a one-sided model before making the transition to performance-based risk. However, we also believe the glide path should provide strong incentives for ACOs to quickly move along the progression towards higher performance-based risk, and therefore prefer an approach that significantly limits the amount of potential shared savings in the one-sided model years of the BASIC track's glide path, while offering incrementally higher potential reward in relation to each level of higher risk. Under this approach ACOs would have reduced incentive to enter or remain in the one-sided model of the BASIC track's glide path if they are prepared to take on risk, and we would anticipate that these ACOs would seek to accept greater performance-based risk in exchange for the chance to earn greater reward.

As described in detail in this section, we are proposing a similar asymmetrical two-sided risk design for the BASIC track as is available under the Track 1+ Model, with key distinguishing features based on early lessons learned from the Track 1+ Model. Unless indicated otherwise, we propose that savings would be calculated based on the same methodology used to determine shared savings under the program's existing tracks (see § 425.604). The maximum amount of potential reward under the BASIC track would be the same as the upside of Track 1 and the Track 1+ Model. The methodology for determining shared losses would be a bifurcated approach similar to the approach used under the Track 1+ Model, as discussed in more detail elsewhere in this section. In all years under performance-based risk, we propose to apply asymmetrical levels of risk and reward, where the maximum potential reward would be greater than the maximum level of performance-based risk.

For the BASIC track's glide path, the phase-in schedule of levels of risk/reward by year would be as follows, and are summarized in comparison to the ENHANCED track in Table 2. This progression assumes an ACO enters the BASIC track's glide path under a one-sided model for 2 years and follows the automatic progression of the glide path through each of the 5 years of its agreement period.

- Level A and Level B: Eligible ACOs entering the BASIC track would have the option of being under a one-sided model for up to 2 consecutive performance years (3 consecutive performance years for ACOs that enter the BASIC track's glide path on July 1, 2019). As described elsewhere in this proposed rule, ACOs that previously participated in Track 1, or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO, would be ineligible to enter the glide path under Level A, although they could enter the under Level B. Under this proposed one-sided model, a final sharing rate not to exceed 25 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or

exceed their MSR. This sharing rate is one-half of the maximum sharing rate of 50 percent currently available under Track 1. Savings would be shared at this rate not to exceed 10 percent of the ACO's updated benchmark, consistent with the current policy for Track 1. For subsequent years, ACOs that wished to continue participating in the Shared Savings Program would be required to participate under performance-based risk.

- Level C risk/reward:

++ Shared Savings: a final sharing rate not to exceed 30 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark.

++ Shared Losses: a loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR, not to exceed 2 percent of total Medicare Parts A and B FFS revenue for ACO participants. If the loss sharing limit as a percentage of total Medicare Parts A and B FFS revenue for ACO participants exceeds the amount that is 1 percent of the ACO's updated historical benchmark, then the loss sharing limit would be capped and set at 1 percent of the ACO's updated historical benchmark for the applicable performance year. This level of risk is not sufficient to meet the generally applicable nominal amount standard for Advanced APMs under the Quality Payment Program specified in § 414.1415(c)(3)(i).

- Level D risk/reward:

++ Shared Savings: A final sharing rate not to exceed 40 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark.

++ Shared Losses: A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR, not to exceed 4 percent of total Medicare Parts A and B FFS revenue for ACO participants. If the loss sharing limit as a percentage of total Medicare Parts A and B FFS revenue for ACO participants exceeds the amount that is 2 percent of the ACO's updated historical benchmark, then the loss sharing limit would be capped and set at 2 percent of the ACO's updated historical benchmark for the applicable performance year. This level of risk is not sufficient to meet the generally applicable nominal amount standard for Advanced APMs under the Quality Payment Program specified in § 414.1415(c)(3)(i).

- Level E risk/reward: The ACO would be under the highest level of risk and potential reward for this track, which is the same level of risk and potential reward being tested in the Track 1+ Model. Further, ACOs that are eligible to enter the BASIC track, but that are ineligible to enter the glide path (as discussed in section II.A.5 of this proposed rule) would enter and remain under Level E risk/reward for the duration of their BASIC track agreement period.

++ Shared Savings: A final sharing rate not to exceed 50 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark. This is the same level of potential reward currently available under Track 1 and Track 1+ Model.

++ *Shared Losses:* A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR. The percentage of ACO participants' total Medicare Parts A and B FFS revenue used to determine the revenue-based loss sharing limit would be set for each performance year consistent with the generally applicable nominal amount standard for an Advanced APM under § 414.1415(c)(3)(i)(A) to allow eligible clinicians participating in a BASIC track ACO subject to this level of risk the opportunity to earn the APM incentive payment and ultimately higher fee schedule updates starting in 2026, in the payment year corresponding to each performance year in which they attain QP status. For example, for performance years 2019 and 2020, this would be 8 percent. However, if the loss sharing limit, as a percentage of the ACO participants' total Medicare Parts A and B FFS revenue exceeds the expenditure-based nominal amount standard, as a percentage of the ACO's updated historical benchmark, then the loss sharing limit would be capped at 1 percentage point higher than the expenditure-based nominal amount standard specified under § 414.1415(c)(3)(i)(B), which is calculated as a percentage of the ACO's updated historical benchmark. For example, for performance years 2019 and 2020, the expenditure-based nominal amount standard is 3 percent; therefore, the loss sharing limit for Level E of the BASIC track in these same years would be 4 percent of the ACO's updated historical benchmark. The proposed BASIC track at Level E risk/reward would meet all of the Advanced APM criteria and would be an Advanced APM. (See Table 2 and related notes for additional information and an overview of the Advanced APM criteria.)

This approach initially maintains consistency between the level of risk and potential reward offered under Level E of the BASIC track and the popular Track 1+ Model. We believe this approach to determining the maximum amount of shared losses under Level E of the BASIC track strikes a balance between (1) placing ACOs under a higher level of risk to recognize the greater potential reward under this financial model and the additional tools and flexibilities available to BASIC track ACOs under performance-based risk and (2) establishing an approach to help ensure the maximum level of risk under the BASIC track remains moderate. Specifically, this approach differentiates the level of risk and potential reward under Level E compared to Levels C and D of the BASIC track, by requiring greater risk in exchange for the greatest potential reward under the BASIC track, while still offering more manageable levels of benchmark-based risk than currently offered under Track 2 (in which the loss sharing limit phase-in begins at 5 percent of the ACO's updated benchmark) and Track 3 (15 percent of the ACO's updated benchmark). Further this approach recognizes that eligible ACOs in Level E have the opportunity to earn the greatest share of savings under the BASIC track, and should therefore be accountable for a higher level of losses, particularly in light of their access to tools for care coordination and beneficiary engagement, including furnishing telehealth services in accordance with 1899(l) of the Act, the SNF 3-day rule waiver (as discussed in section II.B of this proposed rule), and the opportunity to implement a CMS-approved beneficiary incentive program (as discussed in section II.C of this proposed rule).

We propose that ACOs entering the BASIC track's glide path would be automatically advanced along the progression of risk/reward levels, at the start of each performance year over the course of the agreement period (except at the start of performance year 2020 for ACOs that start in the BASIC track on July 1, 2019), until they reach the track's maximum level of risk and potential reward. As discussed in section II.A.4.b, BASIC track ACOs in the glide path would also be permitted to elect to advance more quickly to higher levels of

risk and potential reward within their agreement period. The longest possible glide path would be 5 performance years for eligible new ACOs entering the BASIC track (6 performance years for ACOs beginning their participation in the BASIC track on July 1, 2019). The maximum allowed time in Levels A, B, C and D of the glide path would be one performance year (with the exception that ACOs beginning their participation in the BASIC track on July 1, 2019, would have the option to remain at their chosen level of risk and potential reward for their first 2 performance years in the BASIC track). Once the highest level of risk and potential reward is reached on the glide path (Level E), ACOs would be required to remain under the maximum level of risk/reward for all subsequent years of participation in the BASIC track, which includes all years of a subsequent agreement period under the BASIC track for eligible ACOs. Further, an ACO within the BASIC track's glide path could not elect to return to lower levels of risk/reward or the one-sided model within an agreement period under the glide path.

To participate under performance-based risk in the BASIC track, an ACO would be required to establish a repayment mechanism and select a MSR/MLR to be applicable for the years of the agreement period under a two-sided model (as discussed in section II.A.6. of this proposed rule). We propose that an ACO that is unable to meet the program requirements for accepting performance-based risk would not be eligible to enter into a two-sided model under the BASIC track. If an ACO enters the BASIC track's glide path in a one-sided model and is unable to meet the requirements to participate under performance-based risk prior to being automatically transitioned to a performance year under risk, CMS would terminate the ACO's agreement under § 425.218. For example, if an ACO is participating in the glide path in Level B and is unable to establish an adequate repayment mechanism before the start of its performance year under Level C, the ACO would not be permitted to continue its participation in the program.

In section II.A.5.c of this proposed rule, we describe our proposed requirements for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track based on a combination of factors: ACO participants' Medicare FFS revenue (low revenue ACOs versus high revenue ACOs) and the experience of the ACO legal entity and its ACO participants with performance-based risk Medicare ACO initiatives. Tables 6 and 7 summarize the participation options available to ACOs under the BASIC track and ENHANCED track. As with current program policy, an ACO would apply to enter an agreement period under a specific track. If the ACO's application is accepted, the ACO would remain under that track for the duration of its agreement period.

TABLE 2—COMPARISON OF RISK AND REWARD UNDER BASIC TRACK AND ENHANCED TRACK

	BASIC Track's Glide Path				ENHANCED track (current track 3)
	Level A & Level B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
Shared Savings (once MSR met or exceeded).	1st dollar savings at a rate of up to 25% based on quality performance; not to exceed 10% of updated benchmark.	1st dollar savings at a rate of up to 30% based on quality performance, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of up to 40% based on quality performance, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark.	No change. 1st dollar savings at a rate of up to 75% based on quality performance, not to exceed 20% of updated benchmark.
Shared Losses (once MLR met or exceeded).	N/A	1st dollar losses at a rate of 30%, not to exceed 2% of ACO participant revenue capped at 1% of updated benchmark.	1st dollar losses at a rate of 30%, not to exceed 4% of ACO participant revenue capped at 2% of updated benchmark.	1st dollar losses at a rate of 30%, not to exceed the percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (for example, 8% of ACO participant revenue in 2019–2020), capped at a percentage of updated benchmark that is 1 percentage point higher than the expenditure-based nominal amount standard (for example, 4% of updated benchmark in 2019–2020).	No change. 1st dollar losses at a rate of 1 minus final sharing rate (between 40%–75%), not to exceed 15% of updated benchmark.
Annual choice of beneficiary assignment methodology? (see section II.A.4.c).	Yes	Yes	Yes	Yes	Yes.
Annual election to enter higher risk? (see section II.A.4.b).	Yes	Yes	No; ACO will automatically transition to Level E at the start of the next performance year.	No; maximum level of risk/reward under the BASIC track.	No; highest level of risk under Shared Savings Program.
Advanced APM status under the Quality Payment Program? [1] [2].	No	No	No	Yes	Yes.

Notes: [1] To be an Advanced APM, an APM must meet the following three criteria: 1. CEHRT criterion: Requires participants to use certified electronic health record technology (CEHRT); 2. Quality Measures criterion: Provides payment for covered professional services based on quality measures comparable to those used in the quality performance category of the Merit-based Incentive Payment System (MIPS); and 3. Financial Risk criterion: Either (1) be a Medical Home Model expanded under CMS Innovation Center authority; or (2) require participating APM Entities to bear more than a nominal amount of financial risk for monetary losses. See, for example Alternative Payment Models in the Quality Payment Program as of February 2018, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Comprehensive-List-of-APMs.pdf.*

[2] As proposed, BASIC track Levels A, B, C and D would not meet the Financial Risk criterion and therefore would not be Advanced APMs. BASIC track Level E and the ENHANCED track would meet all three Advanced APM criteria and thus would qualify as Advanced APMs. These preliminary assessments reflect the policies discussed in this proposed rule. CMS will make a final determination based on the policies adopted in the final rule.

We propose to codify these policies in a new section of the Shared Savings Program regulations governing the BASIC track, at § 425.605. We seek comment on these proposals.

(3) Calculation of Loss Sharing Limit

As we described earlier in this section, under the Track 1+ Model, either a revenue-based or a benchmark-based loss sharing limit is applied based on the Track 1+ Model ACO's self-reported composition of ACO participants as identified by TINs and CCNs, and the ownership of and operational interests in those ACO participants. We have concerns about use of self-reported information for purposes of determining the loss sharing limit in the context of the permanent, national program. The purpose of capturing information on the types of entities that are Track 1+ Model ACO participants and the ownership and operational interests of those ACO participants, as reported by ACOs applying to or participating in the Track 1+ Model, is to differentiate between those ACOs that are eligible for the lower level of risk potentially available under the revenue-based loss sharing limit and those that are subject to the benchmark-based loss sharing limit. For purposes of our proposal to establish the BASIC track in the permanent program, we reconsidered this method of identifying which ACOs are eligible for the revenue-based or benchmark-based loss sharing limits. One concern regarding the Track 1+ Model approach is the burden imposed on ACOs and CMS resulting from reliance on self-reported information. Under the Track 1+ Model, ACOs must collect information about their ACO participant composition and about ownership and operational interests from ACO participants, and potentially others in the TINs' and CCNs' ownership and operational chains, and assess this information to accurately answer questions as required by CMS.[14] These questions are complex and ACOs' ability to respond accurately could vary. Self-reported information is also more complex for CMS to audit. As a result, the use of ACOs' self-reported information in the permanent program could become burdensome for CMS to validate and monitor to ensure program integrity.

Based on CMS's experience with the initial application cycle for the Track 1+ Model, we believe a simpler approach that achieves similar results to the use of self-reported information would be to consider the total Medicare Parts A and B FFS revenue of ACO participants (TINs and CCNs) based on claims data, without directly considering their ownership and operational interests (or those of related entities). As part of the application cycle for the 2018 performance year under the Track 1+ Model, CMS gained experience with calculating estimates of ACO participant revenue to compare with estimates of ACO benchmark expenditures, for purposes of determining the repayment mechanism amounts for the Track 1+ Model (as described in section II.A.6.c of this proposed rule). The methodology for determining repayment mechanism amounts follows a similar bifurcated approach to the one used to determine the applicable loss sharing limit under the Track 1+ Model. Specifically, for ACOs eligible for a revenue-based loss sharing limit, when the specified percentage of estimated total Medicare Parts A and B FFS revenue for ACO participants exceeds a specified percentage of estimated historical benchmark expenditures, the benchmark-based methodology is applied to determine the ACO's loss sharing limit, which serves to cap the revenue-based amount (see Track 1+ Model Fact Sheet for a brief description of the repayment mechanism estimation methodology). Based on our calculations of repayment mechanism amounts for Track 1+ Model ACOs, we observed a high correlation between the loss sharing limits determined using an ACO's self-reported composition, and its ACO participants' total Medicare Parts A and B FFS revenue. For ACOs that reported including an ACO participant that was an IPPS hospital, cancer center or rural hospital with more than 100 beds, or that was owned or operated by, in whole or in part, such a hospital or by an organization that owns or operates such a hospital, the estimated total Medicare Parts A and B FFS revenue for the ACO participants tended to exceed an estimate of the ACO's historical benchmark expenditures for assigned beneficiaries. For ACOs that reported that they did not include an ACO participant that met these ownership and operational criteria, the estimated total Medicare Parts A and B FFS revenue for the ACO participants tended to be less than an estimate of the ACO's historical benchmark expenditures.

We recognize that this analysis was informed by the definitions for ownership and operational interests, and the definitions for IPPS hospital, cancer center and rural hospital with 100 or more beds, used in the Track 1+ Model. However, we believe these observations from the Track 1+ Model support a more generalizable principle about the extent to which ACOs can control total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and therefore their readiness to take on lower or higher levels of performance-based risk.

In this proposed rule, we use the phrases ''ACO participants' total Medicare Parts A and B FFS revenue'' and ''total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries'' in the discussion of certain proposed policies. For brevity, we sometimes use shorter phrases instead. For instance, we may refer to ACO participant Medicare FFS revenue, or expenditures for the ACO's assigned beneficiaries.

Based on our experience with the Track 1+ Model, we are proposing an approach under which the loss sharing limit for BASIC track ACOs would be determined as a percentage of ACO participants' total Medicare Parts A and B FFS revenue that is capped at a percentage of the ACO's updated historical benchmark expenditures when the amount that is a certain percentage of ACO participant FFS revenue (depending on the BASIC track risk/reward level) exceeds the specified percentage of the ACO's updated historical benchmark expenditures for the relevant BASIC track risk/reward level. Under our proposed approach, we would not directly consider the types of entities included as ACO participants or ownership and operational interests in ACO participants in determining the loss sharing limit that would apply to ACOs under Levels C, D, and E of the BASIC track. We believe that ACOs whose ACO participants have greater total Medicare Parts A and B FFS revenue relative to the ACO's benchmark are better financially prepared to move to greater levels of risk. Accordingly, this comparison of revenue to benchmark would provide a more accurate method for determining an ACO's preparedness to take on additional risk than an ACO's self-reported information regarding the composition of its ACO participants and any ownership and operational interests in those ACO participants.

[14] See Medicare Shared Savings Program, Medicare ACO Track 1+ Model, and SNF 3-Day Rule Waiver, 2018 Application Reference Manual, version #3, July 2017 (herein 2018 Application Reference Manual), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-Reference-Table.pdf* (see ''Appendix F. Application Reference Table—For Medicare ACO Track 1+ Model Applicants'', including definitions for institutional providers and ownership and operational interests for the purpose of the Track 1+ Model).

We also believe that ACOs that include a hospital billing through an ACO participant TIN are generally more capable of accepting higher risk given their control over a generally larger amount of their assigned beneficiaries' total Medicare Parts A and B FFS expenditures relative to their ACO participants' total Medicare Parts A and B FFS revenue. As a result, we believe that our proposed approach would tend to place ACOs that include hospitals under a benchmark-based loss sharing limit because their ACO participants typically have higher total Medicare Parts A and B FFS revenue compared to the ACO's benchmark. Less often, the ACO participants in an ACO that includes a hospital billing through an ACO participant TIN have low total Medicare Part A and B FFS revenue compared to the ACO's benchmark. Under a claims-based approach to determining the ACO's loss sharing limit, ACOs with hospitals billing through ACO participant TINs and relatively low ACO participant FFS revenue would be under a revenue-based loss sharing limit.

To illustrate, Table 3 compares two approaches to determining loss liability: a claims-based approach (proposed approach) and self-reported composition (approach used for the Track 1+ Model). The table summarizes information regarding ACO participant composition reported by the Track 1+ Model applicants for performance year 2018 and identifies the percentages of applicants whose self-reported composition would have placed the ACO under a revenue-based loss sharing limit or a benchmark-based loss sharing limit. The table then indicates the outcomes of a claims-based analysis applied to this same cohort of applicants. This analysis indicates the proposed claims-based method produces a comparable result to the self-reported composition method. Further, this analysis suggests that under a claims-based method, ACOs that include institutional providers with relatively low Medicare Parts A and B FFS revenue would be placed under a revenue-based loss sharing limit, which may be more consistent with their capacity to assume risk than an approach that considers only the inclusion of certain institutional providers among the ACO participants and their providers/suppliers (TINs and CCNs).

TABLE 3—DETERMINATION OF LOSS SHARING LIMIT BY SELF-REPORTED COMPOSITION VERSUS CLAIMS-BASED APPROACH FOR TRACK 1+ MODEL APPLICANTS

Approach to determining loss liability	Revenue-based loss sharing limit (%)	Benchmark-based loss sharing limit (%)
Use of applicants' self-reported composition (Track 1+ Model approach)	34	66
Use of claims: percentage of ACO participant revenue compared to percentage of ACO benchmark	38	62

We believe that using ACO participant Medicare FFS revenue to determine the ACO's loss sharing limit balances several concerns. For one, it allows CMS to make a claims-based determination about the ACO's loss limit instead of depending on self-reported information from ACOs. This approach would also alleviate the burden on ACOs of gathering information from ACO participants about their ownership and operational interests and reporting that information to CMS, and would address CMS's concerns about the complexity of auditing the information reported by ACOs.

We are proposing to establish the revenue-based loss sharing limit as the default for ACOs in the BASIC track and to phase-in the percentage of ACO participants' total Medicare Parts A and B FFS revenue as described in section II.A.3.b.2 of this proposed rule. However, if the amount that is the applicable percentage of ACO participants' total Medicare Parts A and B FFS revenue exceeds the amount that is the applicable percentage of the ACO's updated benchmark based on the previously described phase-in schedule, then the ACO's loss sharing limit would be capped and set at this percentage of the ACO's updated historical benchmark. We seek comment on this proposal.

We considered issues related to the generally applicable nominal amount standard for Advanced APMs in our development of the revenue-based loss sharing limit under Level E of the proposed BASIC track. Under § 414.1415(c)(3)(i)(A), the revenue-based nominal amount standard is set at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in a participating APM Entity for QP Performance Periods 2017, 2018, 2019, and 2020. We propose that, for the BASIC track, the percentage of ACO participants' FFS revenue used to determine the revenue-based loss sharing limit for the highest level of risk (Level E) would be set for each performance year consistent with the generally applicable nominal amount standard for an Advanced APM under § 414.1415(c)(3)(i)(A), to allow eligible clinicians participating in a BASIC track ACO subject to the revenue-based loss sharing limit the opportunity to earn the APM incentive payment when the ACO is participating under Level E. For example, for performance years 2019 and 2020, this would be 8 percent. As a result, the proposed BASIC track at Level E risk/reward would meet all of the criteria and be an Advanced APM.

Further, in the CY 2018 Quality Payment Program final rule with comment period, we revised § 414.1415(c)(3)(i)(A) to more clearly indicate that the revenue-based nominal amount standard is determined as a percentage of the revenue of all providers and suppliers in the participating APM Entity (see 82 FR 53836 through 53838). Under the Shared Savings Program, ACOs are composed of one or more ACO participant TINs, which include all providers and suppliers that bill Medicare for items and services that are participating in the ACO. See definitions at § 425.20. In accordance with § 425.116(a)(3), ACO participants must agree to ensure that each provider/supplier that bills through the TIN of the ACO participant agrees to participate in the Shared Savings Program and comply with all applicable requirements. Because all providers/suppliers billing through an ACO participant TIN must agree to participate in the program, for purposes of calculating ACO revenue under the nominal amount standard for Shared Savings Program ACOs, the FFS revenue of the ACO participant TINs is equivalent to the FFS revenue for all providers/suppliers participating in the ACO. Therefore, we intend to perform

these revenue calculations at the ACO participant level.

We propose to calculate the loss sharing limit for BASIC track ACOs in generally the same manner that is used under the Track 1+ Model. However, as discussed elsewhere in this section, we would not rely on an ACO's self-reported composition as used in the Track 1+ Model to determine if the ACO is subject to a revenue-based or benchmark-based loss sharing limit. Instead, we would calculate a revenue-based loss sharing limit for all BASIC track ACOs, and cap this amount as a percentage of the ACO's updated historical benchmark. Generally, calculation of the loss sharing limit would include the following steps:

- Determine ACO participants' total Medicare FFS revenue, which includes total Parts A and B FFS revenue for all providers and suppliers that bill for items and services through the TIN, or a CCN enrolled in Medicare under the TIN, of each ACO participant in the ACO for the applicable performance year.
- Apply the applicable percentage under the proposed phase-in schedule (described in section II.A.3.b.2. of this proposed rule) to this total Medicare Parts A and B FFS revenue for ACO participants to derive the revenue-based loss sharing limit.
- Use the applicable percentage of the ACO's updated benchmark, instead of the revenue-based loss sharing limit, if the loss sharing limit as a percentage of total Medicare Parts A and B FFS revenue for ACO participants exceeds the amount that is the specified percentage of the ACO's updated historical benchmark, based on the phase-in schedule. In that case, the loss sharing limit is capped and set at the applicable percentage of the ACO's updated historical benchmark for the applicable performance year.

To illustrate, Table 4 provides a hypothetical example of the calculation of the loss sharing limit for an ACO participating under Level E of the BASIC track. This example would be relevant, under the proposed policies, for an ACO participating in BASIC track Level E for the performance years beginning on July 1, 2019, and January 1, 2020, based on the percentages of revenue and ACO benchmark expenditures specified in generally applicable nominal amount standards in the Quality Payment Program regulations. In this scenario, the ACO's loss sharing limit would be set at $1,090,479 (8 percent of ACO participant revenue) because this amount is less than 4 percent of the ACO's updated historical benchmark expenditures.

TABLE 4—HYPOTHETICAL EXAMPLE OF LOSS SHARING LIMIT AMOUNTS FOR ACO IN BASIC TRACK LEVEL E

[A] ACO's Total updated benchmark expenditures	[B] ACO Participants' total medicare parts A and B FFS revenue	[C] 8 percent of ACO Participants' total medicare parts A and B FFS revenue ([B] x .08)	[D] 4 percent of ACO's updated benchmark expenditures ([A] x .04)
$93,411,313	$13,630,983	$1,090,479	$3,736,453

More specifically, ACO participants' total Medicare Parts A and B FFS revenue would be calculated as the sum of Medicare paid amounts on all non-denied claims associated with TINs on the ACO's certified ACO participant list, or the CCNs enrolled under an ACO participant TIN as identified in the Provider Enrollment, Chain, and Ownership System (PECOS), for all claim types used in program expenditure calculations that have dates of service during the performance year, using 3 months of claims run out. ACO participant Medicare FFS revenue would not be limited to claims associated with the ACO's assigned beneficiaries, and would instead be based on the claims for all Medicare FFS beneficiaries furnished services by the ACO participant. Further in calculating ACO participant Medicare FFS revenue, we would not truncate a beneficiary's total annual FFS expenditures or adjust to remove indirect medical education (IME), disproportionate share hospital (DSH), or uncompensated care payments or to add back in reductions made for sequestration. ACO participant Medicare FFS revenue would include any payment adjustments reflected in the claim payment amounts (for example, under MIPS or Hospital Value Based Purchasing Program) and would also include individually identifiable final payments made under a demonstration, pilot, or time-limited program, and would be determined using the same completion factor used for annual expenditure calculations.

This approach to calculating ACO participant Medicare FFS revenue is different from our approach to calculating benchmark and performance year expenditures for assigned beneficiaries, which we truncate at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries, and from which we exclude IME, DSH and uncompensated care payments (see subpart G of the program's regulations). We truncate expenditures to minimize variation from catastrophically large claims. We note that truncation occurs based on an assigned beneficiary's total annual Parts A and B FFS expenditures, and is not apportioned based on services furnished by ACO participant TINs. See Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (May 2018, version 6) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.html* (herein Shared Savings and Losses and Assignment Methodology Specifications, version 6). As discussed in earlier rulemaking, we exclude IME, DSH and uncompensated care payments from ACOs' assigned beneficiary expenditure calculations because we do not wish to incentivize ACOs to avoid the types of providers that receive these payments, and for other reasons described in earlier rulemaking (see 76 FR 67919 through 67922, and 80 FR 32796 through 32799). But to accurately determine ACO participants' revenue for purposes of determining a revenue-based loss sharing limit, we believe it is important to include total revenue uncapped by truncation and to include IME, DSH and uncompensated care payments. These payments represent resources available to ACO participants to support their operations and offset their costs and potential shared losses, thereby increasing the ACO's capacity to bear performance-based risk, which we believe should be reflected in the ACO's loss sharing limit. Excluding such payments could undercount revenue and also could be challenging to implement, particularly truncation, since it likely would require

apportioning responsibility for large claims among the ACO participants and non-ACO participants from which the beneficiary may have received the services resulting in the large claims.

Currently, for Track 2 and Track 3 ACOs, the loss sharing limit (as a percentage of the ACO's updated benchmark) is determined each performance year, at the time of financial reconciliation. Consistent with this approach, we would determine the loss sharing limit for BASIC track ACOs annually, at the time of financial reconciliation for each performance year. Further, under the existing policies for the Shared Savings Program, we adjust the historical benchmark annually for changes in the ACO's certified ACO participant list. See §§ 425.602(a)(8) and 425.603(b), (c)(8). See also the Shared Savings and Losses and Assignment Methodology Specifications, version 6. Similarly, the annual determination of a BASIC track ACO's loss sharing limit would reflect changes in ACO composition based on changes to the ACO's certified ACO participant list.

We propose to codify these policies in a new section of the Shared Savings Program regulations governing the BASIC track, at § 425.605. We seek comment on these proposals.

4. Permitting Annual Participation Elections

a. Overview

Background on our consideration of and stakeholders' interest in allowing ACOs the flexibility to elect different participation options within their current agreement period is described in section II.A.1 of this proposed rule. In this section, we propose policies to allow ACOs in the BASIC track's glide path to annually elect to take on higher risk and to allow ACOs in the BASIC track and ENHANCED track to annually elect their choice of beneficiary assignment methodology (either preliminary prospective assignment with retrospective reconciliation or prospective assignment).

b. Proposals for Permitting Election of Differing Levels of Risk Within the BASIC Track's Glide Path

We are proposing to incorporate additional flexibility in participation options by allowing ACOs that enter an agreement period under the BASIC track's glide path an annual opportunity to elect to enter higher levels of performance-based risk within the BASIC track within their agreement period. We believe this flexibility would be important for ACOs entering the glide path under either the one-sided model (Level A or Level B) or the lowest level of risk (Level C) that may seek to transition more quickly to higher levels of risk and potential reward. (We note that an ACO entering the glide path at Level D would be automatically transitioned to Level E in the following year, and an ACO that enters the glide path at Level E must remain at this level for the duration of its agreement period.)

In developing this proposal, we considered that an ACO under performance-based risk has the potential to induce more meaningful systematic change in providers' and suppliers' behavior. We also considered that an ACO's readiness for greater performance-based risk may vary depending on a variety of factors, including the ACO's experience with the program (for example, in relation to its elected beneficiary assignment methodology, composition of ACO participants, and benchmark value) and its ability to coordinate care and carry out other interventions to improve quality and financial performance. Lastly, we considered that an ACO may seek to more quickly take advantage of the features of higher levels of risk and potential reward within the BASIC track's glide path, including: Potential for greater shared savings; increased ability to use telehealth services as provided under section 1899(l) of the Act, use of a SNF 3-day rule waiver, and the opportunity to establish a CMS-approved beneficiary incentive program (described in sections II.B and II.C of this proposed rule); and the opportunity to participate in an Advanced APM under the Quality Payment Program after progressing to Level E of the BASIC track's glide path.

We believe it would be protective of the Trust Funds to restrict ACOs from moving from the BASIC track to the ENHANCED track within their current agreement period. This would guard against selective participation in a financial model with the highest potential level of reward while the ACO remains subject to a benchmark against which it is very confident of its ability to generate shared savings. However, under the proposal to eliminate the sit-out period for re-entry into the program after termination (see discussion in section II.A.5.c of this proposed rule), an ACO (such as a BASIC track ACO) may terminate its participation agreement and quickly enter a new agreement period under a different track (such as the ENHANCED track).

We propose to add a new section of the Shared Savings Program regulations at § 425.226 to govern annual participation elections. Specifically, we propose to allow an ACO in the BASIC track's glide path to annually elect to accept higher levels of performance-based risk, available within the glide path, within its current agreement period. We propose that the annual election for a change in the ACO's level of risk and potential reward must be made in the form and manner, and according to the timeframe, established by CMS. We also propose that an ACO executive who has the authority to legally bind the ACO must certify the election to enter a higher level of risk and potential reward within the agreement period. We propose that the ACO must meet all applicable requirements for the newly selected level of risk, which in the case of ACOs transitioning from a one-sided model to a two-sided model include establishing an adequate repayment mechanism and electing the MSR/MLR that will apply for the remainder of their agreement period under performance-based risk. (See section II.A.6 for a detailed discussion of these requirements.) We propose that the ACO must elect to change its participation option before the start of the performance year in which the ACO wishes to begin participating under a higher level of risk and potential reward. We envision that the timing of an ACO's election would generally follow the timing of the Shared Savings Program's application cycle.

The ACO's participation in the newly selected level of risk and potential reward, if approved, would be effective at the start of the next performance year. In subsequent years, the ACO may again choose to elect a still higher level of risk and potential reward (if a higher risk/reward option is available within the glide path). Otherwise, the automatic transition to higher levels of risk and potential reward in subsequent years would continue to apply to the remaining years of the ACO's agreement period in the glide path. We also propose related changes to § 425.600 to reflect the opportunity for ACOs in the BASIC track's glide path to transition to higher risk and potential reward during an agreement period.

For example, if an eligible ACO enters the glide path in year 1 at Level A (one-sided model) and elects to enter Level D (two-sided model) for year 2, the ACO would automatically transition to Level E (highest level of risk/reward under the BASIC track) for year 3, and would remain in Level E for year 4 and year 5 of the agreement period. We note that ACOs starting in the BASIC track's glide path for an agreement period beginning July 1, 2019 could elect to enter a higher level of risk/reward within the BASIC

track in advance of the performance year beginning January 1, 2020.

In general, we wish to clarify that the proposal to allow ACOs to elect to transition to higher levels risk and potential reward within an agreement period in the BASIC track's glide path does not alter the timing of benchmark rebasing under the proposed new section of the regulations at § 425.601. For example, if an ACO participating in the BASIC track's glide path transitions to a higher level of risk and potential reward during its agreement period, the ACO's historical benchmark would not be rebased as a result of this change. We would continue to assess the ACO's financial performance using the historical benchmark established at the start of the ACO's current agreement period, as adjusted and updated consistent with the benchmarking methodology under the proposed new provision at § 425.601.

c. Proposals for Permitting Annual Election of Beneficiary Assignment Methodology

Section 1899(c)(1) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on utilization of primary care services furnished by physicians in the ACO and, in the case of performance years beginning on or after January 1, 2019, services provided by a FQHC or RHC. The provisions of section 1899(c) govern beneficiary assignment under all tracks of the Shared Savings Program. Although, to date, we have designated which beneficiary assignment methodology will apply for each track of the Shared Savings Program, section 1899(c) of the Act (including as amended by the Bipartisan Budget Act) does not expressly require that the beneficiary assignment methodology be determined by track.

Under the Shared Savings Program regulations, we have established two claims-based beneficiary assignment methods (prospective assignment and preliminary prospective assignment with retrospective reconciliation) that currently apply to different program tracks, as well as a non-claims based process for voluntary alignment (discussed in section II.E.2 of this proposed rule) that applies to all program tracks and is used to supplement claims-based assignment. The regulations governing the assignment methodology under the Shared Savings Program are in 42 CFR part 425, subpart E. In the November 2011 final rule, we adopted a claims-based hybrid approach (called preliminary prospective assignment with retrospective reconciliation) for assigning beneficiaries to an ACO (76 FR 67851 through 67870), which is currently applicable to ACOs participating under Track 1 or Track 2 of the Shared Savings Program (except for Track 1 ACOs that are also participating in the Track 1+ Model for which we use a prospective assignment methodology in accordance with our authority under section 1115A of the Act). Under this approach, beneficiaries are preliminarily assigned to an ACO, based on a two-step assignment methodology, at the beginning of a performance year and quarterly thereafter during the performance year, but final beneficiary assignment is determined after the performance year based on where beneficiaries chose to receive the plurality of their primary care services during the performance year. Subsequently, in the June 2015 final rule, we implemented an option for ACOs to participate in a new performance-based risk track, Track 3 (80 FR 32771 through 32781). Under Track 3, beneficiaries are prospectively assigned to an ACO at the beginning of the performance year using the same two-step methodology used in the preliminary prospective assignment approach, based on where the beneficiaries have chosen to receive the plurality of their primary care services during a 12-month assignment window offset from the calendar year that reflects the most recent 12 months for which data are available prior to the start of the performance year. The ACO is held accountable for beneficiaries who are prospectively assigned to it for the performance year. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list, such as if the beneficiary enrolls in MA during the performance year or no longer lives in the United States or U.S. territories and possessions (as determined based on the most recent available data in our beneficiary records regarding residency at the end of the performance year).

Finally, in the CY 2017 PFS final rule (81 FR 80501 through 80510), we augmented the claims-based beneficiary assignment methodology by finalizing a policy under which beneficiaries, beginning in 2017 for assignment for performance year 2018, may voluntarily align with an ACO by designating a ''primary clinician'' (referred to as a ''main doctor'' in the prior rulemaking) they believe is responsible for coordinating their overall care using MyMedicare.gov, a secure, online, patient portal. Notwithstanding the assignment methodology in § 425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at § 425.401(a) and is not excluded from assignment by the criteria in § 425.401(b), and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician or a physician with one of the primary specialty designations included in § 425.402(c). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year. See section II.E.2 of this proposed rule for a discussion of the new provisions regarding voluntary alignment added to section 1899(c) of the Act by section 50331 of the Bipartisan Budget Act, and our related proposed regulatory changes.

Section 50331 of the Bipartisan Budget Act specifies that, for agreement periods entered into or renewed on or after January 1, 2020, ACOs in a track that provides for retrospective beneficiary assignment will have the opportunity to choose a prospective assignment methodology, rather than the retrospective assignment methodology, for the applicable agreement period. The Bipartisan Budget Act incorporates this requirement as a new provision at section 1899(c)(2)(A) of the Act.

In this proposed rule, we are proposing to implement this provision of the Bipartisan Budget Act to provide all ACOs with a choice of prospective assignment for agreement periods beginning July 1, 2019 and in subsequent years. We are also proposing to incorporate additional flexibility into the beneficiary assignment methodology consistent with the Secretary's authority under section 1899(c)(1) of the Act to determine an appropriate beneficiary assignment methodology. We do not believe that section 1899(c) of the Act, as amended by the Bipartisan Budget Act, requires that we must continue to specify the applicable beneficiary assignment methodology for each track of the Shared Savings Program. Although section 1899(c)(2)(A) of the Act now provides that ACOs must be permitted to choose prospective assignment for each agreement period, we do not believe this requirement limits our discretion to allow ACOs the

additional flexibility to change beneficiary assignment methodologies more frequently during an agreement period. As summarized in section II.A.1 of this proposed rule and as described in detail in earlier rulemaking, commenters have urged us to allow greater flexibility for ACOs to select their assignment methodology. Accordingly, we are proposing an approach that separates the choice of beneficiary assignment methodology from the choice of participation track (financial model), and that allows ACOs to make an annual election of assignment methodology. Such an approach would afford greater flexibility for ACOs to choose between assignment methodologies for each year of the agreement period, without regard to their participation track. We believe we are able to begin offering all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning July 1, 2019, while meeting the requirements of the Bipartisan Budget Act.

As an approach to meeting the requirements of the Bipartisan Budget Act while building on them to offer greater flexibility, we propose to offer ACOs entering agreement periods in the BASIC track or ENHANCED track, beginning July 1, 2019 and in subsequent years, the option to choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation, prior to the start of their agreement period (at the time of application). We also propose to provide an opportunity for ACOs to switch their selection of beneficiary assignment methodology on an annual basis. Under this approach, in addition to the requirement under the Bipartisan Budget Act that ACOs be permitted to change from retrospective assignment to prospective assignment, an ACO would have the added flexibility to change from prospective assignment to preliminary prospective assignment with retrospective reconciliation. As an additional flexibility that further builds on the Bipartisan Budget Act, ACOs would be allowed to retain the same beneficiary assignment methodology for an entire agreement period or to change the methodology annually. An individual ACO's preferred choice of beneficiary assignment methodology may vary depending on the ACO's experience with the two assignment methodologies used under the Shared Savings Program. Therefore, we believe this proposed approach implements the requirements of the Bipartisan Budget Act and will also be responsive to stakeholders' suggestions that we allow additional flexibility around choice of beneficiary assignment methodology to facilitate ACOs' transition to performance-based risk (as discussed earlier in this section). Further, allowing this additional flexibility for choice of beneficiary assignment methodology within the proposed BASIC track and ENHANCED track would enable ACOs to select a combination of participation options that would overlap with certain features of Track 2, and thus lessen the need to maintain Track 2 as a separate participation option. Accordingly, as discussed in section II.A.2 of this proposed rule, we are proposing to discontinue Track 2. Finally, we believe it is appropriate and reasonable to start offering the choice of beneficiary assignment to ACOs in the BASIC track or ENHANCED track for agreement periods beginning July 1, 2019, in order to align with the availability of these two tracks under the proposed redesign of the Shared Savings Program.

We propose that, in addition to choosing the track to which it is applying, an ACO would choose the beneficiary assignment methodology at the time of application to enter or re-enter the Shared Savings Program or to renew its participation for another agreement period. If the ACO's application is accepted, the ACO would remain under that beneficiary assignment methodology for the duration of its agreement period, unless the ACO chooses to change the beneficiary assignment methodology through the annual election process. We also propose that the ACO must indicate its desire to change assignment methodology before the start of the performance year in which it wishes to begin participating under the alternative assignment methodology. The ACO's selection of a different assignment methodology would be effective at the start of the next performance year, and for the remaining years of the agreement period, unless the ACO again chooses to change the beneficiary assignment methodology. For example, if an ACO selects preliminary prospective assignment with retrospective reconciliation at the time of its application to the program for an agreement period beginning July 1, 2019, this methodology would apply in the ACO's first performance year (6-month performance year from July 2019–December 2019) and all subsequent performance years of its agreement period, unless the ACO selects prospective assignment in advance of the start of performance year 2020, 2021, 2022, 2023, or 2024. To continue this example, during its first performance year, the ACO would have the option to select prospective assignment to be applicable beginning with performance year 2020. If selected, this assignment methodology would continue to apply unless the ACO again selects a different methodology.

We propose to incorporate the requirements governing the ACO's initial selection of beneficiary assignment methodology and the annual opportunity for an ACO to notify CMS that it wishes to change its beneficiary assignment methodology within its current agreement period, in a new section of the Shared Savings Program regulations at § 425.226 along with the other annual elections described elsewhere in this proposed rule. We propose that the initial selection of, and any annual selection for a change in, beneficiary assignment methodology must be made in the form and manner, and according to the timeframe, established by CMS. We also propose that an ACO executive who has the authority to legally bind the ACO must certify the selection of beneficiary assignment methodology for the ACO. We envision that the timing of this opportunity for an ACO to change assignment methodology would generally follow the Shared Savings Program's application cycle. For consistency, we also propose to make conforming changes to regulations that currently identify assignment methodologies according to program track. Specifically, we propose to revise §§ 425.400 and 425.401 (assignment of beneficiaries), § 425.702 (aggregate reports) and § 425.704 (beneficiary-identifiable claims data) to reference either preliminary prospective assignment with retrospective reconciliation or prospective assignment instead of referencing the track to which a particular assignment methodology applies (currently Track 1 and Track 2, or Track 3, respectively).

We wish to clarify that this proposal would have no effect on the voluntary alignment process under § 425.402(e). Because beneficiaries may voluntarily align with an ACO through their designation of a ''primary clinician,'' and eligible beneficiaries will be prospectively assigned to that ACO regardless of the ACO's track or claims-based beneficiary assignment methodology, an ACO's choice of claims-based assignment methodology under this proposal would not alter the voluntary alignment process.

As part of the proposed approach to allow ACOs to elect to change their assignment methodology within their

agreement period, we also propose to adjust the ACO's historical benchmark to reflect the ACO's election of a different assignment methodology. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate.

As we explained in earlier rulemaking, we currently use differing assignment windows to determine beneficiary assignment for the benchmark years and performance years, according to the ACO's track and the beneficiary assignment methodology used under that track. The assignment window for ACOs under prospective assignment is a 12-month period off-set from the calendar year, while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year (see 80 FR 32699, and 80 FR 32775 through 32776). However, for all ACOs, the claims used to determine the per capita expenditures for a benchmark or performance year are the claims for services furnished to assigned beneficiaries from January 1 through December 31 of the calendar year that corresponds to the applicable benchmark or performance year (see for example, 79 FR 72812 through 72813, see also 80 FR 32776 through 32777). We explained that this approach removes actuarial bias between the benchmarking and performance years for assignment and financial calculations, since the same method would be used to determine assignment and the financial calculations for each benchmark and performance year. Further, basing the financial calculations on the calendar year is necessary to align with actuarial analyses with respect to risk score calculations and other data inputs based on national FFS expenditures used in program financial calculations, which are determined on a calendar year basis (79 FR 72813). We continue to believe it is important to maintain symmetry between the benchmark and performance year calculations, and therefore believe it is necessary to adjust the benchmark for ACOs that change beneficiary assignment methodology within their current agreement period to reflect changes in beneficiary characteristics due to the change in beneficiary assignment methodology, as provided in section 1899(d)(1)(B)(ii) of the Act. For example, if an ACO were to elect to change its applicable beneficiary assignment methodology during its initial agreement period from preliminary prospective assignment with retrospective reconciliation to prospective assignment, we would adjust the ACO's historical benchmark for the current agreement period to reflect the expenditures of beneficiaries that would have been assigned to the ACO during the benchmark period using the prospective assignment methodology, instead of the expenditures of the beneficiaries assigned under the preliminary prospective assignment methodology that were used to establish the benchmark at the start of the agreement period. Therefore, we propose to specify in the proposed new section of the regulations at § 425.601 that would govern establishing, adjusting, and updating the benchmark for all agreement periods beginning July 1, 2019 and in subsequent years that we will adjust an ACO's historical benchmark to reflect a change in the ACO's beneficiary assignment methodology within an agreement period. However, any adjustment to the benchmark to account for a change in the ACO's beneficiary assignment methodology would not alter the timing of benchmark rebasing under § 425.601; the historical benchmark would not be rebased as a result of a change in the ACO's beneficiary assignment methodology.

We seek comment on these proposals.

5. Determining Participation Options Based on Medicare FFS Revenue and Prior Participation

a. Overview

In this section, we describe considerations related to, and proposed policies for, distinguishing among ACOs based on their degree of control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries by identifying low revenue versus high revenue ACOs, experience of the ACO's legal entity and ACO participants with the Shared Savings Program and performance-based risk Medicare ACO initiatives, and prior performance in the Shared Savings Program. Based on operational experience and considerations related to our proposal to extend the length of an agreement period under the program from 3 to not less than 5 years for agreement periods beginning on July 1, 2019 and in subsequent years, we aim to strengthen the following programmatic areas by further policy development.

First, we believe that differentiating between ACOs based on their degree of control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries would allow us to transition high revenue ACOs more quickly to higher levels of performance-based risk under the ENHANCED track, rather than remaining in a lower level of risk under the BASIC track. We aim to drive more meaningful systematic change in high revenue ACOs which have greater potential to control total Medicare Parts A and B FFS expenditures for their assigned beneficiaries and in turn the potential to drive significant change in spending and coordination of care for assigned beneficiaries across care settings. We also aim to encourage continued participation by low revenue ACOs, which control a smaller proportion of total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and thus may be encouraged to continue participation in the program by having additional time under the BASIC track's revenue-based loss sharing limits before transitioning to the ENHANCED track.

Second, we believe that differentiating between ACOs that are experienced and inexperienced with performance-based risk Medicare ACO initiatives to determine their eligibility for participation options would allow us to prevent experienced ACOs from taking advantage of options designed for inexperienced ACOs, namely lower levels of performance-based risk.

Third, we believe it is timely to clarify the differences between ACOs applying to renew their participation agreements and ACOs applying to re-enter the program after a break in participation, and to identify new ACOs as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACOs accountable for their ACO participants' experience with the program. We aim to provide a more consistent evaluation of these ACOs' prior performance in the Shared Savings Program at the time of re-application. We also aim to update policies to identify the agreement period an ACO is entering into for purposes of benchmark calculations and quality performance requirements that phase-in as the ACO gains experience in the program, as appropriate for renewing ACOs, re-entering ACOs, and new program entrants.

Fourth, and lastly, we believe it is appropriate to modify the evaluation criteria for prior quality performance to be relevant to ACOs' participation in longer agreement periods and introduce a monitoring approach for and evaluation criterion related to financial performance to prevent underperforming ACOs from remaining in the program.

b. Differentiating Between Low Revenue ACOs and High Revenue ACOs

In this section, we propose to differentiate between the participation options available to low revenue ACOs and high revenue ACOs, through the following: (1) Proposals for defining ''low revenue ACO'' and ''high revenue ACO'' relative to a threshold of ACO participants' total Medicare Parts A and B FFS revenue compared to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the same 12 month period; (2) proposals for establishing distinct participation options for low revenue ACOs and high revenue ACOs, with the availability of multiple agreement periods under the BASIC track as the primary distinction; and (3) consideration of approaches to allow greater potential for reward for low revenue ACOs, such as by reducing the MSR ACOs must meet to share in savings during one-sided model years of the BASIC track's glide path, or allowing higher sharing rates based on quality performance during the first 4 years in the glide path.

(1) Identifying Low Revenue ACOs and High Revenue ACOs

To define low revenue ACOs and high revenue ACOs for purposes of determining ACO participation options, we believe it is important to consider the relationship between an ACO's degree of control over the Medicare Parts A and B FFS expenditures for its assigned beneficiaries and its readiness to accept higher or lower degrees of performance-based risk. Elsewhere in this proposed rule, we explain that an ACO's ability to control the expenditures of its assigned beneficiary population can be gauged by comparing the total Medicare Parts A and B FFS revenue of its ACO participants to total Medicare Parts A and B FFS expenditures of its assigned beneficiary population. Thus, high revenue ACOs, which typically include a hospital billing through an ACO participant TIN, are generally more capable of accepting higher risk, given their control over a generally larger amount of their assigned beneficiaries' total Medicare Parts A and B FFS expenditures. In contrast, lower risk options could be more suitable for low revenue ACOs, which have control over a smaller amount of their assigned beneficiaries' total Medicare Parts A and B FFS expenditures.

In the Regulatory Impact Analysis (section IV. of this proposed rule), we describe an approach for differentiating low revenue versus high revenue ACOs that reflects the amount of control ACOs have over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries. Under this analysis, an ACO was identified as low revenue if its ACO participants' total Medicare Parts A and B FFS revenue for assigned beneficiaries was less than 10 percent of the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures. In contrast, an ACO was identified as high revenue if its ACO participants' total Medicare Parts A and B FFS revenue for assigned beneficiaries was at least 10 percent of the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures. As further explained in section IV, nationally, evaluation and management spending accounts for about 10 percent of total Parts A and B per capita spending. Because beneficiary assignment principally is based on allowed charges for primary care services, which are highly correlated with evaluation and management spending, we concluded that identifying low revenue ACOs by applying a 10 percent limit on the ACO participants' Medicare FFS revenue for assigned beneficiaries in relation to total Medicare Parts A and B expenditures for these beneficiaries would be likely to capture all ACOs that were solely comprised of ACO providers/suppliers billing for Medicare PFS services, and generally exclude ACOs with ACO providers/suppliers that bill for inpatient or other institutional services for their assigned beneficiaries. We considered this approach as an option for distinguishing between low revenue and high revenue ACOs.

However, we are concerned that this approach does not sufficiently account for ACO participants' total Medicare Parts A and B FFS revenue (as opposed to their revenue for assigned beneficiaries), and therefore could misrepresent the ACO's overall risk bearing potential, which would diverge from other aspects of the proposed design of the BASIC track. We believe it is important to consider ACO participants' total Medicare Parts A and B FFS revenue for all FFS beneficiaries, not just assigned beneficiaries, as a factor in assessing an ACO's readiness to accept performance-based risk. The total Medicare Parts A and B FFS revenue of the ACO participants could be indicative of whether the ACO participants, and therefore potentially the ACO, are more or less capitalized. For example, ACO participants with high levels of total Medicare Parts A and B FFS revenue are presumed to be better capitalized, and may be better positioned to contribute to repayment of any shared losses owed by the ACO. Further, the proposed methodologies for determining the loss sharing limit under the BASIC track (see section II.A.3 of this proposed rule) and the estimated repayment mechanism values for BASIC track ACOs (see section II.A.6.c of this proposed rule), include a comparison of a specified percentage of ACO participants' total Medicare Parts A and B FFS revenue for all Medicare FFS beneficiaries to a percentage of the ACO's updated historical benchmark expenditures for its assigned beneficiary population.

Accordingly, we propose that if ACO participants' total Medicare Parts A and B FFS revenue exceeds a specified threshold of total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO would be considered high revenue, while ACOs with a percentage less than the threshold amount would be considered low revenue. In determining the appropriate threshold, we considered our claims-based analysis comparing estimated revenue and benchmark values for Track 1+ Model applicants, as described in section II.A.3. of this proposed rule. We believe setting the threshold at 25 percent would tend to categorize ACOs that include institutional providers as ACO participants or as ACO providers/suppliers billing through the TIN of an ACO participant, as high revenue because their ACO participants' total Medicare Parts A and B FFS revenue would likely significantly exceed 25 percent of total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. Among Track 1+ Model ACOs that self-reported as eligible for the Model's benchmark-based loss sharing limit because of the presence of an ownership or operational interest by an IPPS hospital, cancer center or rural hospital with more than 100 beds among their ACO participants, we compared estimated total Medicare Parts A and B FFS revenue for ACO participants to estimated total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. We found that self-reported composition and high-revenue determinations made using the 25 percent threshold were in agreement

for 96 percent of ACOs. For two ACOs, the proposed approach would have categorized the ACOs as low revenue ACOs and therefore allowed for a potentially lower loss sharing limit than the self-reported method.

We believe small, physician-only and rural ACOs would tend to be categorized as low revenue ACOs because their ACO participants' total Medicare Parts A and B FFS revenue would likely be significantly less than total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. Among Track 1+ Model ACOs that self-reported to be eligible for the Model's revenue-based loss sharing limit because of the absence of an ownership or operational interest by the previously described institutional providers among their ACO participants, we compared estimated total Medicare Parts A and B FFS revenue for ACO participants to estimated total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. We found the self-reported composition and low-revenue determinations made using the 25 percent threshold were in agreement for 88 percent of ACOs. The proposed approach would move ACOs with higher revenue to a higher loss sharing limit, while continuing to categorize low revenue ACOs, which are often composed of small physician practices, rural providers, and those serving underserved areas, as eligible for potentially lower loss sharing limits. Further, based on initial modeling with performance year 2016 program data, ACOs for which the total Medicare Parts A and B FFS revenue of their ACO participants was less than 25 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries tended to have either no or almost no inpatient revenue and generally showed stronger than average financial results compared to higher revenue ACOs.

We believe these observations are generalizable and suggest our proposal to use ACO participants' total Medicare Parts A and B FFS revenue to classify ACOs would serve as a proxy for ACO participant composition. The proposed approach generally would categorize ACOs that include hospitals, health systems or other providers and suppliers that furnish Part A services as ACO participants or ACO providers/suppliers as high revenue ACOs, while categorizing ACOs with ACO participants and ACO providers/suppliers that mostly furnish Part B services as low revenue ACOs. Accordingly, we propose to use a 25 percent threshold to determine low revenue versus high revenue ACOs by comparing total Medicare Parts A and B FFS revenue of ACO participants to the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. Consistent with this proposal, we also propose to add new definitions at § 425.20 for ''low revenue ACO,'' and ''high revenue ACO.''

We propose to define ''high revenue ACO'' to mean an ACO whose total Medicare Parts A and B FFS revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is at least 25 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

We propose to define ''low revenue ACO'' to mean an ACO whose total Medicare Parts A and B FFS revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 25 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

We also considered using a lower or higher percentage as the threshold for determining low revenue ACOs and high revenue ACOs. Specifically, we considered instead setting the threshold for ACO participant revenue lower, for example at 15 percent or 20 percent of total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. However, we are concerned a lower threshold could categorize ACOs with more moderate revenue as high revenue, for example because of the presence of multi-specialty physician practices or certain rural or safety net providers/suppliers (such as CAHs, FQHCs and RHCs). Categorizing these moderate revenue ACOs as high revenue, could require ACOs that have a smaller degree of control over the expenditures of their assigned beneficiaries, and ACOs that are not as adequately capitalized, to participate in a level of performance-based risk that the ACO would not be prepared to manage. We also considered setting the threshold higher, for example at 30 percent. We are concerned a higher threshold could inappropriately categorize ACOs as low revenue when their ACO participants have substantial total Medicare Parts A and B FFS revenue and therefore an increased ability to influence expenditures for their assigned beneficiaries and also greater access to capital to support participation under higher levels of performance-based risk. We seek comment on these alternative thresholds for defining ''low revenue ACO'' and ''high revenue ACO.''

The proposed 12 month comparison period for determining whether an ACO is low revenue or high revenue is consistent with the proposed 12 month period for determining repayment mechanism amounts (as described in section II.A.6.c of this proposed rule). Such an approach could allow us to use the same sources of revenue and expenditure data during the program's annual application cycle to estimate the ACO's repayment mechanism amount and to determine the ACO's participation options according to whether the ACO is categorized as a low revenue or high revenue ACO. Additionally, for ACOs with a participant agreement start date of July 1, 2019, we also propose to determine whether the ACO is low revenue or high revenue using expenditure data from the most recent calendar year for which 12 months of data are available.

We note that under this proposed approach to using claims data to determine participation options, it would be difficult for ACOs to determine at the time of application submission whether they would be identified as a low revenue or high revenue ACO. However, after an ACO's application is submitted and before the ACO would be required to execute a participation agreement, we would determine how the ACO participants' total Medicare Parts A and B FFS revenue for the applicable calendar year compare to total Medicare Parts A and B FFS expenditures for the ACO's assigned Medicare beneficiaries in the same calendar year, provide feedback and then notify the applicant of our determination of its status as a low revenue ACO or high revenue ACO.

We also considered using a longer look back period, for example, using multiple years of revenue and expenditure data to identify low revenue ACOs and high revenue ACOs. For example, instead of using a single year of data, we considered instead using 2 years of data (such as the 2 most recent calendar years for which 12 months of data are available). In evaluating ACOs applying to enter a new agreement period in the Shared Savings Program, the 2 most recent calendar years for which 12 months of data are available would align with the ACOs' first and second benchmark years. While this approach could allow us to take into account changes in the ACO's composition over multiple years, it could also make the policy more

complex because it could require determinations for each of the 2 calendar years and procedures to decide how to categorize ACOs if there were different determinations for each year, for example, as a result of changes in ACO participants. We seek comment on the alternative of using multiple years of data in determining whether an ACO is a low revenue ACO or a high revenue ACO.

ACO participant list changes during the agreement period could affect the categorization of ACOs, particularly for ACOs close to the threshold percentage. We considered that an ACO may change its composition of ACO participants each performance year, as well as experience changes in the providers/suppliers billing through ACO participants, during the course of its agreement period. Any approach under which we would apply different policies to ACOs based on a determination of ACO participant revenue would need to recognize the potential for an ACO to add or remove ACO participants, and for the providers/suppliers billing through ACO participants to change, which could affect whether an ACO meets the definition of a low revenue ACO or high revenue ACO. We are especially concerned about the possibility that an ACO may be eligible to continue for a second agreement period in the BASIC track because of a determination that it is a low revenue ACO at the time of application, and then quickly thereafter seek to add higher-revenue ACO participants, thereby avoiding the requirement under our proposed participation options to participate under the ENHANCED track.

To protect against these circumstances, we propose to monitor low revenue ACOs experienced with performance-based risk Medicare ACO initiatives participating in the BASIC track, to determine if they continue to meet the definition of low revenue ACO. This is because high revenue ACOs experienced with performance-based risk Medicare ACO initiatives are restricted to participation in the ENHANCED track only. We propose to monitor these low revenue ACOs for changes in the revenue of ACO participants and assigned beneficiary expenditures that would cause an ACO to be considered a high revenue ACO and ineligible for participation in the BASIC track. We are less concerned about the circumstance where an ACO inexperienced with performance-based risk Medicare ACO initiatives enters an agreement period under the BASIC track and becomes a high revenue ACO during the course of its agreement because inexperienced, high revenue ACOs are also eligible for a single agreement period of participation in the BASIC track.

We propose the following approach to ensuring continued compliance of ACOs with the proposed eligibility requirements for participation in the BASIC track, for an ACO that was accepted into the BASIC track's Level E because the ACO was experienced with performance-based risk Medicare ACO initiatives and determined to be low revenue at the time of application. If, during the agreement period, the ACO meets the definition of a high revenue ACO, we propose that the ACO would be permitted to complete the remainder of its current performance year under the BASIC track, but would be ineligible to continue participation in the BASIC track after the end of that performance year unless it takes corrective action, for example by changing its ACO participant list. We propose to take compliance action, up to and including termination of the participation agreement, as specified in §§ 425.216 and 425.218, to ensure the ACO does not continue in the BASIC track for subsequent performance years of the agreement period. For example, we may take pre-termination actions as specified in § 425.216, such as issuing a warning notice or requesting a corrective action plan. To remain in the BASIC track, the ACO would be required to remedy the issue. For example, if the ACO participants' total Medicare Parts A and B FFS revenue has increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO could remove an ACO participant from its ACO participant list, so that the ACO can meet the definition of low revenue ACO. If corrective action is not taken, CMS would terminate the ACO's participation under § 425.218. We propose to revise § 425.600 to include these requirements to account for changes in ACO participant revenue during an agreement period.

We also considered two alternatives to the proposed claims-based approach to differentiating low revenue versus high revenue ACOs, which, as discussed, can also serve as a proxy for ACO participant composition. One alternative would be to differentiate ACOs based directly on ACO participant composition using Medicare provider enrollment data and certain other data. Under this option we could define ''physician-led ACO'' and ''hospital-based ACO'' based on an ACO's composition of ACO participant TINs, including any CCNs identified as billing through an ACO participant TIN, as determined using Medicare enrollment data and cost report data for rural hospitals. A second alternative to the claims-based approach to distinguishing between ACOs based on their revenue would be to differentiate between ACOs based on the size of their assigned population (that is, small versus large ACOs).

First, we considered differentiating between physician-led and hospital-based ACOs by ACO composition, determined based on the presence or absence of certain institutional providers as ACO participants. This approach deviates from the Track 1+ Model design to determining ACO composition for the purposes of identifying whether the ACO is eligible to participate under a benchmark-based or a revenue-based loss sharing limit (described elsewhere in this proposed rule) by using Medicare enrollment data and certain other data to determine ACO composition rather than relying on ACOs' self-reported information, and by using a different approach to identifying institutional providers than applies under the Track 1+ Model.

Under this alternative approach, we could define a hospital-based ACO as an ACO that includes a hospital or cancer center, but excluding an ACO whose only hospital ACO participants are rural hospitals. As used in this definition, a hospital could be defined according to § 425.20. As defined under § 425.20, ''hospital'' means a hospital as defined in section 1886(d)(1)(B) of the Act. A cancer center could be defined as a prospective payment system-exempt cancer hospital as defined under section 1886(d)(1)(B)(v) of the Act (see CMS website on PPS-exempt cancer hospitals, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html*). Rural hospital could be a hospital defined according to § 425.20 that meets both of the following requirements: (1) The hospital is classified as being in a rural area for purposes of the CMS area wage index (as determined in accordance with section 1886(d)(2)(d) or section 1886(d)(8)(E) of the Act); and (2) The hospital reports total revenue of less than $30 million a year. We could determine total revenue based on the most recently available hospital 2552–10 cost report form or any successor form. In contrast, we could define physician-led ACO as an ACO that does not include a hospital or cancer center, except for a hospital that is a rural hospital (as we previously described). Physician-led ACOs therefore could also

include certain hospitals that are not cancer centers, such as CAHs.

Under this alternative approach to differentiating between ACOs we would identify hospitals and cancer centers in our Medicare provider enrollment files based on their Medicare enrolled TINs and/or CCNs. We would include any CCNs identified as billing through an ACO participant TIN, as determined using PECOS enrollment data and claims data. We believe this alternative approach would provide increased transparency to ACOs because ACOs could work with their ACO participants to identify all facilities enrolled under their TINs to tentatively determine the composition of their ACO, and thus, the available participation options under the Shared Savings Program. However, this alternative approach to categorizing ACOs deviates from the proposed claims-based approaches to determining loss sharing limits and the repayment mechanism estimate amounts for ACOs in the BASIC track using ACO participant Medicare FFS revenue and expenditures for the ACO's assigned beneficiaries.

Second, we also considered differentiating between ACOs based on the size of their assigned beneficiary population, as small versus large ACOs. Under this approach, we could determine an ACO's participation options based on the size of its assigned population. We recognize that an approach that distinguishes between ACOs based on population size would require that we set a threshold for determining small versus large ACOs as well as to determine the assignment data to use in making this determination (such as the assignment data used in determining an ACO's eligibility to participate in the program under the requirement that the ACO have at least 5,000 assigned beneficiaries under § 425.110). For instance, we considered whether an ACO with fewer than 10,000 assigned beneficiaries could be defined as a small ACO whereas an ACO with 10,000 or more assigned beneficiaries could be defined as a large ACO. However, we currently have low revenue ACOs participating in the program that have well over 10,000 assigned beneficiaries, as well as high revenue ACOs that have fewer than 10,000 assigned beneficiaries. As described in detail throughout this section of this proposed rule, we believe a revenue-based approach is a more accurate means to measure the degree of control that ACOs have over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries compared to an approach that only considers the size of the ACO's assigned population.

We seek comment on the proposed definitions of ''low revenue ACO'' and ''high revenue ACO''. We also seek comment on the alternatives considered. Specifically, we seek comment on the alternative of defining hospital-based ACO and physician-led ACO based on an ACO's composition of ACO participant TINs, including any CCNs identified as billing through an ACO participant TIN, as determined using Medicare enrollment data and cost report data for rural hospitals. In addition, we seek comment on the second alternative of differentiating between ACOs based on the size of their assigned population (that is, small versus large ACOs).

(2) Restricting ACOs' Participation in the BASIC Track Prior to Transitioning to Participation in the ENHANCED Track

As discussed in section II.A.5.c of this proposed rule, we propose to use factors based on ACOs' experience with performance-based risk to determine their eligibility for the BASIC track's glide path, or to limit their participation options to either the highest level of risk and potential reward under the BASIC track (Level E) or the ENHANCED track. We also propose to differentiate between low revenue ACOs and high revenue ACOs with respect to the continued availability of the BASIC track as a participation option. This approach would allow low revenue ACOs, new to performance-based risk arrangements, additional time under the BASIC track's revenue-based loss sharing limits, while requiring high revenue ACOs to more rapidly transition to the ENHANCED track under which they would assume relatively higher, benchmark-based risk. We believe that all ACOs should ultimately transition to the ENHANCED track, the highest level of risk and potential reward under the program, which could drive ACOs to more aggressively pursue the program's goals of improving quality of care and lowering growth in FFS expenditures for their assigned beneficiary populations.

We considered that some low revenue ACOs may need additional time to prepare to take on the higher levels of performance-based risk required under the ENHANCED track. Low revenue ACOs, which could include small, physician-only and rural ACOs, may be encouraged to enter and remain in the program based on the availability of lower-risk options. For example, small, physician-only and rural ACOs may have limited experience submitting quality measures or managing patient care under two-sided risk arrangements, which could deter their participation in higher-risk options. ACOs and other program stakeholders have suggested that the relatively lower levels of risk available under the Track 1+ Model (an equivalent level of risk and potential reward to the payment model available under Level E of the BASIC track) encourages transition to risk by providing a more manageable level of two-sided risk for small, physician-only, and rural ACOs, compared to the levels of risk and potential reward currently available under Track 2 and Track 3, and that would be offered under the proposed ENHANCED track.

We also considered that, without limiting high revenue ACOs to a single agreement period under the BASIC track, they could seek to remain under a relatively low level of performance-based risk for a longer period of time, and thereby curtail their incentive to drive more meaningful and systematic changes to improve quality of care and lower growth in FFS expenditures for their assigned beneficiary populations. Further, high revenue ACOs, whose composition likely includes institutional providers, particularly hospitals and health systems, are expected generally to have greater opportunity to coordinate care for assigned beneficiaries across care settings among their ACO participants than low revenue ACOs. One approach to ensure high revenue ACOs accept a level of risk commensurate with their degree of control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and to further encourage these ACOs to more aggressively pursue the program's goals, is to require these ACOs to transition to higher levels of risk and potential reward.

We propose to limit high revenue ACOs to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. We believe an approach that allows high revenue ACOs that are inexperienced with the accountable care model the opportunity to become experienced with program participation within the BASIC track's glide path prior to undertaking the higher levels of risk and potential reward in the ENHANCED track offers an appropriate balance between allowing ACOs time to become experienced with performance-based risk and protecting the Medicare Trust Funds. This approach recognizes that high revenue ACOs control a relatively large share of assigned beneficiaries'

total Medicare Parts A and B FFS expenditures and generally are positioned to coordinate care for beneficiaries across care settings, and is protective of the Medicare Trust Funds by requiring high revenue ACOs to more quickly transition to higher levels of performance-based risk.

In contrast, we propose to limit low revenue ACOs to, at most, two agreement periods under the BASIC track. These agreement periods would not be required to be sequential, which would allow low revenue ACOs that transition to the ENHANCED track after a single agreement period under the BASIC track the opportunity to return to the BASIC track if the ENHANCED track initially proves too high of risk. An experienced ACO may also seek to participate in a lower level of risk if, for example, it makes changes to its composition to include providers/suppliers that are less experienced with the accountable care model and the program's requirements. Once an ACO has participated under the BASIC track's glide path (if eligible), a subsequent agreement period under the BASIC track would be required to be at the highest level of risk and potential reward (Level E), according to the proposed approach to identifying ACOs experienced with performance-based Medicare ACO initiatives as described in section II.A.5.c of this proposed rule.

Therefore, we propose that in order for an ACO to be eligible to participate in the BASIC track for a second agreement period, the ACO must meet the requirements for participation in the BASIC track as described in this proposed rule (as determined based on whether an ACO is low revenue versus high revenue and inexperienced versus experienced with performance-based risk Medicare ACO initiatives) and either of the following: (1) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track only one time; or (2) for a new ACO identified as a re-entering ACO because at least 50 percent of its ACO participants have recent prior participation in the same ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track only one time.

Several examples illustrate this proposed approach. First, for an ACO legal entity with previous participation in the program, we would consider the ACO's current and prior participation in the program. For example, if a low revenue ACO enters the program in the BASIC track's glide path, and remains an eligible, low revenue ACO, it would be permitted to renew in Level E of the BASIC track for a second agreement period. Continuing this example, for the ACO to continue its participation in the program for a third or subsequent agreement period, it would need to renew its participation agreement under the ENHANCED track. As another example, a low revenue ACO that enters the program in the BASIC track's glide path could participate for a second agreement under the ENHANCED track, and enter a third agreement period under the Level E of the BASIC track before being required to participate in the ENHANCED track for its fourth and any subsequent agreement period.

Second, for ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO, we would determine the eligibility of the ACO to participate in the BASIC track based on the prior participation of this other entity. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO B during the relevant look back period, we would consider ACO B's prior participation in the BASIC track in determining the eligibility of ACO A to enter a new participation agreement in the program under the BASIC track. For example, if ACO B had previously participated in two different agreement periods under the BASIC track, regardless of whether ACO B completed these agreement periods, ACO A would be ineligible to enter the program for a new agreement period under the BASIC track and would be limited to participating in the ENHANCED track. Changing the circumstances of this example, if ACO B had previously participated under the BASIC track during a single agreement period, ACO A may be eligible to participate in the BASIC track under Level E, the track's highest level of risk and potential reward, but would be ineligible to enter the BASIC track's glide path because ACO A would have been identified as experienced with performance-based risk Medicare ACO initiatives as described in section II.A.5.c of this proposed rule.

We recognize that the difference in the level of risk and potential reward under the BASIC track, Level E compared to the payment model under the ENHANCED track could be substantial for low revenue ACOs. Therefore, we also considered and seek comment on an approach that would allow low revenue ACOs to gradually transition from the BASIC track's Level E up to the level of risk and potential reward under the ENHANCED track. For example, we seek comment on whether it would be helpful to devise a glide path that would be available to low revenue ACOs entering the ENHANCED track. We also considered, and seek comment on, whether such a glide path under the ENHANCED track should be available to all ACOs. As another alternative, we considered allowing low revenue ACOs to continue to participate in the BASIC track under Level E for longer periods of time, such as a third or subsequent agreement period. However, we believe that without a time limitation on participation in the BASIC track, ACOs may not prepare to take on the highest level of risk that could drive the most meaningful change in providers'/suppliers' behavior toward achieving the program's goals.

As an alternative to the proposed approach for allowing low revenue ACOs to participate in the BASIC track in any two agreement periods (non-sequentially), we seek comment on an approach that would require participation in the BASIC track to occur over two consecutive agreement periods before the ACO enters the ENHANCED track. This approach would prevent low revenue ACOs that entered the ENHANCED track from participating in a subsequent agreement period under the BASIC track. That is, it would prevent an ACO from moving from a higher level of risk to a lower level of risk. However, given changes in ACO composition, among other potential factors, we believe it is important to offer low revenue ACOs some flexibility in their choice of level of risk from one agreement period to the next.

We propose to specify these proposed requirements for low revenue ACOs and high revenue ACOs in revisions to § 425.600, along with other requirements for determining participation options based on the experience of the ACO and its ACO participants, as discussed in section II.A.5.c of this proposed rule. We propose to use our determination of whether an ACO is a low revenue ACO or high revenue ACO in combination with our determination of whether the ACO is experienced or inexperienced with performance-based risk (which we propose to determine based on the experience of both the ACO legal entity and the ACO participant TINs with performance-based risk), in determining the participation options available to the ACO. We seek comment on these proposals.

More generally, we note that the proposed approach to redesigning the

program's participation options maintains flexibility for ACOs to elect to enter higher levels of risk and potential reward more quickly than is required under the proposed participation options. Any ACO may choose to apply to enter the program under or renew its participation in the ENHANCED track. Further, ACOs eligible to enter the BASIC track's glide path may choose to enter at the highest level of risk and potential reward under the BASIC track (Level E), or advance to that level more quickly than is provided for under the automatic advancement along the glide path.

(3) Allowing Greater Potential for Reward for Low Revenue ACOs

In this section, we describe and seek comment on several approaches to allowing for potentially greater access to shared savings for low revenue ACOs compared to high revenue ACOs, but do not make any specific proposals at this time. The approaches to rewarding low revenue ACOs discussed in this section recognize the performance trends of low revenue ACOs based on program results and the potential that low revenue ACOs would need additional capital, as a means of encouraging their continued participation in the program.

Although low revenue ACOs generally have control over a smaller share of the total Medicare Parts A and B FFS expenditures for their assigned beneficiaries compared to high revenue ACOs, they have tended to perform better financially than high revenue ACOs, demonstrating their ability to more quickly meet the program's aim of lowering growth in expenditures. High revenue ACOs, in comparison, despite having the advantage of generally controlling a greater share of total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and having more institutional capacity to affect care processes and better manage care across settings, have demonstrated comparatively poor financial performance.

As previously described in section I of this proposed rule, using the methodology for identifying low revenue and high revenue ACOs described in the Regulatory Impact Analysis (section IV. of this proposed rule), program results for performance year 2016 show that low revenue ACOs outperformed high revenue ACOs, as 41 percent of low revenue ACOs shared savings compared to 23 percent of high revenue ACOs. Among ACOs with four performance years of program results, low revenue ACOs in Track 1 outperformed high revenue ACOs, generating average gross savings of 2.9 percent compared to 0.5 percent for high revenue ACOs. Low revenue ACOs in Track 2 and Track 3 also outperformed high revenue ACOs. The four Track 3 ACOs that owed losses in performance year 2016 were all high revenue. These results suggest high revenue ACOs may be underperforming in containing growth in expenditures, while taking advantage of other aspects of program participation.

We believe low revenue ACOs, identified as proposed previously in this section (that is, using a threshold of 25 percent of Medicare Parts A and B FFS expenditures for assigned beneficiaries), which may tend to be small, physician-only and rural ACOs, are likely less capitalized organizations and may be relatively risk-averse. These ACOs may be encouraged to participate and remain in the program under performance-based risk based on the availability of additional incentives, such as the opportunity to earn a greater share of savings.

We believe that offering increased potential for low revenue ACOs to earn shared savings would support their success in meeting the program's goals by allowing these organizations to maximize their return on investment, which may be needed to support start-up and operational expenses, and to facilitate their participation in performance-based risk. For example, shared savings payments received by low revenue ACOs could be used to support funding of a repayment mechanism required for their participation in performance-based risk, support meeting the program's quality reporting requirements, or support, when eligible, implementation of an approved beneficiary incentive program as discussed in section II.C.2 of this proposed rule. Any additional incentive would complement previously described proposals that would provide low revenue ACOs a longer pathway to participation under the highest level of risk and potential reward in the ENHANCED track.

One approach we considered would be to allow for a lower MSR for low revenue ACOs in the BASIC track. In section II.A.6.b of this proposed rule, we propose that under Level A and Level B of the BASIC track, under a one-sided model, ACOs with at least 5,000 assigned beneficiaries will have a MSR that varies between 2 percent and 3.9 percent based on the size of the ACO's assigned beneficiary population (which is the same MSR methodology currently used in Track 1). In performance years under a two-sided model of either the BASIC track or the ENHANCED track, we propose to apply a symmetrical MSR/MLR, as chosen by the ACO prior to entering into performance-based risk. As an alternative, to provide a greater incentive for low revenue ACOs, we considered applying a lower MSR during the one-sided model years (Level A and B) for low revenue ACOs that have at least 5,000 assigned beneficiaries for the performance year. For example, we considered a policy under which we would apply a MSR that is a fixed 1 percent. We also considered setting the MSR at a fixed 2 percent, or effectively removing the threshold by setting the MSR at zero percent. However, we would apply a variable MSR based on the ACO's number of assigned beneficiaries in the event the ACO's population falls below 5,000 assigned beneficiaries for the performance year, consistent with our proposal in section II.A.6.b of this proposed rule.

A lower MSR (such as a fixed 1 percent) would reduce the threshold level of savings the ACO must generate to be eligible to share in savings. This would give low revenue ACOs greater confidence that they would be eligible to share in savings, once generated. This may be especially important for small ACOs, which would otherwise have MSRs towards the higher end of the range (closer to 3.9 percent, for an ACO with at least 5,000 assigned beneficiaries) for years in which the ACO participates under a one-sided model. However, we do not believe a lower MSR would be needed to encourage participation by high revenue ACOs. For one, high revenue ACOs are likely to have larger numbers of assigned beneficiaries and therefore more likely to have lower MSRs (ranging from 3 percent to 2 percent, for ACOs with 10,000 or more assigned beneficiaries). Further, their control over a significant percentage of the total Medicare Parts A and B FFS expenditures for their assigned beneficiaries may provide a sufficient incentive for participation as they would have an opportunity to generate significant savings.

Another approach we considered is to allow for a relatively higher final sharing rate under the first four levels of the BASIC track's glide path for low revenue ACOs. For example, rather than the proposed approach under which the final sharing rate would phase in from a maximum of 25 percent in Level A to a maximum of 50 percent in Level E, we could allow a maximum 50 percent sharing rate based on quality performance to be available at all levels within the BASIC track's glide path for low revenue ACOs.

For any policies that would apply differing levels of potential reward to ACOs based on factors such as ACO participants' revenue and expenditures for the ACO's assigned beneficiaries, we prefer an approach under which we would annually re-evaluate whether an ACO is low revenue or high revenue, taking into consideration any changes to the ACO's list of ACO participants or to the providers/suppliers billing through the TINs of the ACO participants that are made during the agreement period. This approach would help ensure, for example, that ACOs do not omit certain institutional providers or other high revenue providers/suppliers from their initial ACO participant list for the purpose of securing their participation in a more favorable financial model, only to subsequently add these organizations to their ACO in subsequent years of the same agreement period.

We seek comment on these considerations. We will carefully consider the comments received regarding these options during the development of the final rule, and may consider adopting one or more of these options in the final rule.

c. Determining Participation Options Based on Prior Participation of ACO Legal Entity and ACO Participants

(1) Overview

In this section of the proposed rule we describe proposed modifications to the regulations to address the following:

- Allowing flexibility for ACOs currently within a 3-year agreement period under the Shared Savings Program to transition quickly to a new agreement period that is not less than 5 years under the BASIC track or ENHANCED track.
- Establishing definitions to more clearly differentiate ACOs applying to renew for a second or subsequent agreement period and ACOs applying to re-enter the program after their previous Shared Savings Program participation agreement expired or was terminated resulting in a break in participation, and to identify new ACOs as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACO accountable for their ACO participants' experience with the program.
- Revising the criteria for evaluating an ACO's prior participation in the Shared Savings Program to determine the eligibility of ACOs seeking to renew their participation in the program for a subsequent agreement period, ACOs applying to re-enter the program after termination or expiration, and ACOs that are identified as re-entering ACOs based on their ACO participants' recent experience with the program.
- Establishing criteria for determining the participation options available to an ACO based on its experience with performance-based risk Medicare ACO initiatives and on whether the ACO is low revenue or high revenue.
- Establishing policies that more clearly differentiate the participation options, and the applicability of program requirements that phase-in over time based on the ACO's and ACO participants' prior experience in the Shared Savings Program or with other Medicare ACO initiatives.

The regulatory background for the proposed policies in this section of the proposed rule includes multiple sections of the program's regulations, as developed over several rulemaking cycles.

(2) Background on Re-Entry Into the Program After Termination

In the initial rulemaking for the program, we specified criteria for terminated ACOs that are re-entering the program in § 425.222 (see 76 FR 67960 through 67961). In the June 2015 final rule, we revised this section to address eligibility for continued participation in Track 1 by previously terminated ACOs (80 FR 32767 through 32769). Currently, this section prohibits ACOs re-entering the program after termination from participating in the one-sided model beyond a second agreement period and from moving back to the one-sided model after participating in a two-sided model. This section also specifies that terminated ACOs may not re-enter the program until after the date on which their original agreement period would have ended if the ACO had not been terminated (the ''sit-out'' period). This policy was designed to restrict re-entry into the program by ACOs that voluntarily terminate their participation agreement, or have been terminated for failing to meet program integrity or other requirements (see 76 FR 67960 and 67961). Under the current regulations, we only consider whether an ACO applying to the program is the same legal entity as a previously terminated ACO, as identified by TIN (see definition of ACO under § 425.20), for purposes of determining whether the appropriate ''sit-out'' period of § 425.222(a) has been observed and the ACO's eligibility to participate under the one-sided model. Section 425.222 also provides criteria to determine the applicable agreement period when a previously terminated ACO re-enters the program. We explained the rationale for these policies in prior rulemaking and refer readers to the November 2011 and June 2015 final rules for more detailed discussions.

Additionally, under § 425.204(b), the ACO must disclose to CMS whether the ACO or any of its ACO participants or ACO providers/suppliers have participated in the Shared Savings Program under the same or a different name, or are related to or have an affiliation with another Shared Savings Program ACO. The ACO must specify whether the related participation agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary. If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the participation agreement (§ 425.204(b)(3)).

The agreement period in which an ACO is placed upon re-entry into the program has ramifications not only for its risk track participation options, but also for the benchmarking methodology that is applied and the quality performance standard against which the ACO will be assessed. ACOs in a second or subsequent agreement period receive a rebased benchmark as currently specified under § 425.603. For ACOs that renew for a second or subsequent agreement period beginning in 2017 and subsequent years, the rebased benchmark incorporates regional expenditure factors, including a regional adjustment. The weight applied in calculating the regional adjustment depends in part on the agreement period for which the benchmark is being determined (see § 425.603(c)), with relatively higher weights applied over time. Further, for an ACO's first agreement period, the benchmark expenditures are weighted 10 percent in benchmark year 1, 30 percent in benchmark year 2, and 60 percent in benchmark year 3 (see § 425.602(a)(7)). In contrast, for an ACO's second or subsequent agreement period we equally weight each year of the benchmark (§ 425.603). With respect to quality performance, the quality performance standard for ACOs in the first performance year of their first agreement period is set at the level of complete and accurate reporting of all quality measures. Pay-for-performance is phased in over the remaining years of the first agreement period, and

continues to apply in all subsequent performance years (see § 425.502(a)).

We believe the regulations as currently written create flexibilities that allow more experienced ACOs to take advantage of the opportunity to re-form and re-enter the program under Track 1 or to re-enter the program sooner or in a different agreement period than otherwise permissible. In particular, terminated ACOs may re-form as a different legal entity and apply to enter the program as a new organization to extend their time in Track 1 or enter Track 1 after participating in a two-sided model. These ACOs would effectively circumvent the requisite ''sit-out'' period (the remainder of the term of an ACO's previous agreement period), benchmark rebasing, including the application of equal weights to the benchmark years and the higher weighted regional adjustment that applies in later agreement periods, or the pay-for-performance quality performance standard that is phased in over an ACO's first agreement period in the program.

(3) Background on Renewal for Uninterrupted Program Participation

In the June 2015 final rule, we established criteria in § 425.224 applicable to ACOs seeking to renew their agreements, including requirements for renewal application procedures and factors CMS uses to determine whether to renew a participation agreement (see 80 FR 32729 through 32730). Under our current policies, we consider a renewing ACO to be an organization that continues its participation in the program for a consecutive agreement period, without interruption resulting from termination of the participation agreement by CMS or by the ACO (see §§ 425.218 and 425.220). Therefore, to be considered for timely renewal, an ACO within its third performance year of an agreement period is required to meet the application requirements, including submission of a renewal application, by the deadline specified by CMS, during the program's typical annual application process. If the ACO's renewal application is approved by CMS, the ACO would have the opportunity to enter into a new participation agreement with CMS for the agreement period beginning on the first day of the next performance year (typically January 1 of the following year), and thereby to continue its participation in the program without interruption.

In evaluating the application of a renewing ACO, CMS considers the ACO's history of compliance with program requirements generally, whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program, including the ability to repay shared losses, if applicable, and whether it has a history of meeting the quality performance standard in its previous agreement period, as well as whether the ACO satisfies the criteria for operating under the selected risk track, including whether the ACO has repaid shared losses generated during the prior agreement period.

Under § 425.600(c), an ACO experiencing a net loss during a previous agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. In the initial rulemaking establishing the Shared Savings Program, we proposed, but did not finalize, a requirement that would prevent an ACO from reapplying to participate in the Shared Savings Program if it previously experienced a net loss during its first agreement period. We explained that this proposed policy would ensure that under-performing organizations would not get a second chance (see 76 FR 19562, 19623). However, we were persuaded by commenters' suggestions that barring ACOs that demonstrate a net loss from continuing in the program could serve as a disincentive for ACO formation, given the anticipated high startup and operational costs of ACOs (see 76 FR 67908 and 67909). We finalized the provision at § 425.600(c) that would allow for continued participation by ACOs despite their experience of a net loss.

(4) Proposals for Streamlining Regulations

We seek to modify the requirements for ACOs applying to renew their participation in the program (§ 425.224) and re-enter the program after termination (§ 425.222) or expiration of their participation agreement by both eliminating regulations that would restrict our ability to ensure that ACOs quickly migrate to the redesigned tracks of the program and strengthening our policies for determining the eligibility of ACOs to renew their participation in the program (to promote consecutive and uninterrupted participation in the program) or to re-enter the program after a break in participation. We also seek to establish criteria to identify as re-entering ACOs new ACOs for which greater than 50 percent of ACO participants have recent prior participation in the same ACO, and to hold these ACO accountable for their ACO participants' experience in the program.

(a) Defining Renewing and Re-Entering ACOs

We propose to define a renewing ACO and an ACO re-entering after termination or expiration of their participation agreement. Under the program's regulations, there is currently no definition of a renewing ACO, and based on our operational experience, this has caused some confusion among applicants. For example, there is confusion as to whether an ACO that has terminated from the program would be considered a first time applicant into the program or a renewing ACO. The definition of these terms is also important for identifying the agreement period that an ACO is applying to enter, which is relevant to determining the applicability of certain factors used in calculating the ACO's benchmark that phase-in over the span of multiple agreement periods as well as the phase-in of pay-for-performance under the program's quality performance standards. We believe having definitions that clearly distinguish renewing ACOs from ACOs that are applying to re-enter the program after a termination, or other break in participation will help us more easily differentiate between these organizations in our regulations and other programmatic material. We propose to define renewing ACO and re-entering ACO in new definitions in § 425.20.

We propose to define renewing ACO to mean an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either: (1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or (2) an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program. This proposed definition is consistent with current program policies for ACOs applying to timely renew their agreement under § 425.224 to continue participation following the expiration of their participation agreement. This proposed definition would include a new policy that would consider an ACO to be renewing in the circumstance where the ACO voluntarily terminates its current participation agreement and enters a new agreement period under

the BASIC track or ENHANCED track, beginning immediately after the termination date of its previous agreement period thereby avoiding an interruption in participation. We would consider these ACOs to have effectively renewed their participation early. This part of the definition is consistent with the proposal to discontinue use of the ''sit out'' period after termination under § 425.222(a).

We considered two possible scenarios in which an ACO might seek to re-enter the program. In one case, a re-entering ACO would be a previously participating ACO, identified by a TIN (see definition of ACO under § 425.20), that applies to re-enter the program after its prior participation agreement expired without having been renewed, or after the ACO was terminated under § 425.218 or § 425.220 and did not immediately enter a new agreement period (that is, an ACO with prior participation in the program that does not meet the proposed definition of renewing ACO). In this case, it is clear that the ACO is a previous participant in the program. In the other scenario, an entity applies under a TIN that is not previously associated with a Shared Savings Program ACO, but the entity is composed of ACO participants that previously participated together in the same Shared Savings Program ACO in a previous performance year. Under the current regulations, there is no mechanism in place to prevent a terminated ACO from re-forming under a different TIN and applying to re-enter the program, or for a new legal entity to be formed from ACO participants in a currently participating ACO. Doing so could allow an ACO to avoid accountability for the experience and prior participation of its ACO participants, and to avoid the application of policies that phase-in over time (the application of equal weights to the benchmark years and the higher weighted regional adjustment that applies in later agreement periods, or the pay-for-performance quality performance standard that is phased in over an ACO's first agreement period in the program). We are also concerned that, under the current regulations, Track 1 ACOs would be able to re-form to take advantage of the BASIC track's glide path, which allows for 2 years under a one-sided model for new ACOs only. We are therefore interested in adopting an approach to better identify prior participation and to specify participation options and program requirements applicable to re-entering ACOs.

We propose to define ''re-entering ACO'' to mean an ACO that does not meet the definition of a ''renewing ACO'' and meets either of the following conditions:

(1) Is the same legal entity as an ACO, identified by TIN according to the definition of ACO in § 425.20, that previously participated in the program and is applying to participate in the program after a break in participation, because it is either: (a) An ACO whose participation agreement expired without having been renewed; or (b) an ACO whose participation agreement was terminated under § 425.218 or § 425.220.

(2) Is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

We note that a number of proposed policies depend on the prior participation of an ACO or the experience of its ACO participants. As discussed elsewhere in section II.A of this proposed rule, these include: (1) Using the ACO's and its ACO participants' experience or inexperience with performance-based risk Medicare ACO initiatives to determine the participation options available to the ACO (proposed in § 425.600(d)); (2) identifying ACOs experienced with Track 1 to determine the amount of time an ACO may participate under a one-sided model of the BASIC track's glide path (proposed in § 425.600(d)); (3) determining how many agreement periods an ACO has participated under the BASIC track as eligible ACOs are allowed a maximum of two agreement periods under the BASIC track (proposed in § 425.600(d)); (4) assessing the eligibility of the ACO to participate in the program (proposed revisions to § 425.224); and (5) determining the applicability of program requirements that phase-in over multiple agreement periods (proposed in § 425.600(f)). The proposed revisions to the regulations to establish these requirements would apply directly to an ACO that is the same legal entity as a previously participating ACO. We also discuss throughout the preamble how these requirements would apply to new ACOs that are identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO.

Several examples illustrate the application of the proposed definition of re-entering ACO. For example, if ACO A is applying to the program for an agreement period beginning on July 1, 2019, and ACO A is the same legal entity as an ACO whose previous participation agreement expired without having been renewed (that is, ACO A has the same TIN as the previously participating ACO) we would treat ACO A as the previously participating ACO, regardless of what share of ACO A's ACO participants previously participated in the ACO. As another example, if ACO A were a different legal entity (identified by a different TIN) from any ACO that previously participated in the Shared Savings Program, we would also treat ACO A as if it were an ACO that previously participated in the program (ACO B) if more than 50 percent of ACO A's ACO participants participated in ACO B in any of the 5 most recent performance years (that is, performance year 2015, 2016, 2017, 2018, or the 6-month performance year from January 1, 2019 through June 30, 2019), even though ACO A and ACO B are not the same legal entity.

We believe that looking at the experience of the ACO participants, in addition to the ACO legal entity, would be a more robust check on prior participation. It would also help to ensure that ACOs re-entering the program are treated comparably regardless of whether they are returning as the same legal entity or have re-formed as a new entity. With ACOs allowed to make changes to their certified ACO participant list for each performance year, we have observed that many ACOs make changes to their ACO participants over time. For example, among ACOs that participated in the Shared Savings Program as the same legal entity in both PY 2014 and PY 2017, only around 60 percent of PY 2017 ACO participants had also participated in the same ACO in PY 2014, on average. For this reason, we believe that the ACO legal entity alone does not always capture the ACO's experience in the program and therefore it is also important to look at the experience of ACO participants.

We chose to propose a 5 performance year look back period for determining prior participation by ACO participants as it would align with the look back period for determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives as discussed elsewhere in this section of this proposed rule. We wish to clarify that the threshold for prior participation by ACO participants is not cumulative when determining whether an ACO is a re-entering ACO. For example, assume 22 percent of applicant ACO A's ACO participants participated in ACO C in the prior 5

performance years, 30 percent participated in ACO D, and the remaining 48 percent did not participate in any ACO during this period. ACO A would not be considered a re-entering ACO (assuming that ACO A is a new legal entity), because more than 50 percent of its ACO participants did not participate in the same ACO during the 5-year look back period. Although unlikely, we recognize the possibility that an ACO could quickly re-form multiple times and therefore more than 50 percent of its ACO participants may have been included on the ACO participant list of more than one ACO in the 5 performance year look back period. In these cases we believe the most recent experience of the ACO participants in the new ACO is most relevant to determining the applicability of policies to the re-entering ACO. We therefore propose that the ACO in which more than 50 percent of the ACO participants most recently participated would be used in identifying the participation options available to the new ACO.

We opted to propose a threshold of greater than 50 percent because we believe that it will identify ACOs with significant participant overlap and would allow us to more clearly identify a single, Shared Savings Program ACO in which at least the majority of ACO participants recently participated. We also considered whether to use a higher or lower threshold percentage threshold. A lower threshold, such as 20, 30 or 40 percent, would further complicate the analysis for identifying the ACO or ACOs in which the ACO participants previously participated, and the ACO whose prior performance should be evaluated in determining the eligibility of the applicant ACO. On the other hand, using a higher percentage for the threshold would identify fewer ACOs that significantly resemble ACOs with experience participating in the Shared Savings Program.

We considered alternate approaches to identifying prior participation other than the overall percentage of ACO participants that previously participated in the same ACO, including using the percentage of ACO participants weighted by the paid claim amounts, the percentage of individual practitioners (NPIs) that had reassigned their billing rights to ACO participants, or the percentage of assigned beneficiaries the new legal entity has in common with the assigned beneficiaries of a previously participating ACO. While we believe that these alternative approaches have merit, we concluded that they would be less transparent to ACOs than using a straight percentage of TINs, as well as more operationally complex to compute.

We seek comment on these proposed definitions and on the alternatives considered.

(b) Eligibility Requirements and Application Procedures for Renewing and Re-Entering ACOs

We believe it would be useful to revise our regulations to clearly set forth the eligibility requirements and application procedures for renewing ACOs and re-entering ACOs. Therefore, we propose to revise § 425.222 to address limitations on the ability of re-entering ACOs to participate in the Shared Savings Program for agreement periods beginning before July 1, 2019. In addition, we propose to revise § 425.224 to address general application requirements and procedures for all re-entering ACOs and all renewing ACOs.

In revising § 425.222 (which consists of paragraphs (a) through (c)), we considered that removing the required ''sit-out'' period for terminated ACOs under § 425.222(a) would facilitate transition of ACOs within current 3-year agreement periods to new agreements under the participation options proposed in this rule. As discussed elsewhere in this section, we propose to retain policies similar to those under § 425.222(b) for evaluating the eligibility of ACOs to participate in the program after termination. Further, instead of the approach used for determining participation options for ACOs that re-enter the program after termination described in § 425.222(c), our proposed approach to making these determinations is described in detail in section II.A.5.c.5 of this proposed rule.

The ''sit-out'' period policy restricts the ability of ACOs in current agreement periods to transition to the proposed participation options under new agreements. For example, if left unchanged, the ''sit-out'' period would prevent existing, eligible Track 1 ACOs from quickly entering an agreement period under the proposed BASIC track and existing Track 2 ACOs from quickly entering a new agreement period under either the BASIC track at the highest level of risk (Level E), if available to the ACO, or the ENHANCED track. Participating under Levels C, D, or E of the BASIC track or under the ENHANCED track could allow eligible physicians and practitioners billing under ACO participant TINs in these ACOs to provide telehealth services under section 1899(l) of the Act (discussed in section II.B.2.b. of this proposed rule), the ACO could apply for a SNF 3-day rule waiver (as proposed in section II.B.2.a. of this proposed rule), and the ACO could elect to offer incentive payments to beneficiaries under a CMS-approved beneficiary incentive program (as proposed in section II.C.2. of this proposed rule).

The ''sit-out'' period also applies to ACOs that deferred renewal in a second agreement period under performance-based risk as specified in § 425.200(e)(2)(ii), a participation option we propose to discontinue (as described in section II.A.2 of this proposed rule). Therefore, by eliminating the ''sit-out'' period, ACOs that deferred renewal may more quickly transition to the BASIC track (Level E), if available to the ACO, or the ENHANCED track. An ACO that deferred renewal and is currently participating in Track 2 or Track 3 may terminate its current agreement to enter a new agreement period under the BASIC track (Level E), if eligible, or the ENHANCED track. Similarly, an ACO that deferred renewal and is currently participating in Track 1 for a fourth performance year may terminate its current agreement and the participation agreement for its second agreement period under Track 2 or Track 3 that it deferred for 1 year. In either case, the ACO may immediately apply to re-enter the BASIC track (Level E), if eligible, or the ENHANCED track without having to wait until the date on which the term of its second agreement would have expired if the ACO had not terminated.

We note that, to avoid interruption in program participation, an ACO that seeks to terminate its current agreement and enter a new agreement in the BASIC track or ENHANCED track beginning the next performance year should ensure that there is no gap in time between when it concludes its current agreement period and when it begins the new agreement period so that all related program requirements and policies would continue to apply. For an ACO that is completing a 12 month performance year and is applying to enter a new agreement period beginning January 1 of the following year, the effective termination date of its current agreement should be the last calendar day of its current performance year, to avoid an interruption in the ACO's program participation. For instance, for a 2018 starter ACO applying to enter a new agreement beginning on January 1, 2020, the effective termination date of its current agreement should be December 31, 2019. For an ACO that starts a 12-month performance year on January 1, 2019, that is applying to enter a new agreement period beginning on July 1, 2019 (as discussed in section II.A.7 of this proposed rule), the effective termination date of its current agreement should be June 30, 2019.

We propose to amend § 425.224 to make certain policies applicable to both renewing ACOs and re-entering ACOs and to incorporate certain other technical changes, as follows:

(1) Revisions to refer to the ACO's ''application'' more generally, instead of specifically referring to a ''renewal request,'' so that the requirements would apply to both renewing ACOs and re-entering ACOs.

(2) Addition of a requirement, consistent with the current provision at § 425.222(c)(3), for ACOs previously in a two-sided model to reapply to participate in a two-sided model. We further propose that a renewing or re-entering ACO that was previously under a one-sided model of the BASIC track's glide path may only reapply for participation in a two-sided model for consistency with our proposal to include the BASIC track within the definition of a performance-based risk Medicare ACO initiative. This includes a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO that was previously under a two-sided model or a one-sided model of the BASIC track's glide path (Level A or Level B).

(3) Revision to § 425.224(b)(1)(iv) (as redesignated from § 425.224(b)(1)(iii)) to cross reference the requirement that an ACO establish an adequate repayment mechanism under § 425.204(f), to clarify our intended meaning with respect to the current requirement that an ACO demonstrate its ability to repay losses.

(4) Modifications to the evaluation criteria specified in § 425.224(b) for determining whether an ACO is eligible for continued participation in the program in order to permit them to be used in evaluating both renewing ACOs and re-entering ACOs, to adapt some of these requirements to longer agreement periods (under the proposed approach allowing for agreement periods of at least 5 years rather than 3-year agreements), and to prevent ACOs with a history of poor performance from participating in the program. As described in detail, as follows, we address: (1) Whether the ACO has a history of compliance with the program's quality performance standard; (2) whether an ACO under a two-sided model repaid shared losses owed to the program; (3) the ACO's history of financial performance; and (4) whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it perform poorly or to be terminated.

First, we propose modifications to the criterion governing our evaluation of whether the ACO has a history of compliance with the program's quality performance standard. We propose to revise the existing provision at § 425.224(b)(1)(iv), which specifies that we evaluate whether the ACO met the quality performance standard during at least 1 of the first 2 years of the previous agreement period, to clarify that this criterion is used in evaluating ACOs that entered into a participation agreement for a 3-year period. We propose to add criteria for evaluating ACOs that entered into a participation agreement for a period longer than 3 years by considering whether the ACO was terminated under § 425.316(c)(2) for failing to meet the quality performance standard or whether the ACO failed to meet the quality performance standard for 2 or more performance years of the previous agreement period, regardless of whether the years were consecutive.

In proposing this approach, we considered that the current policy is specified for ACOs with 3-year agreements. With the proposal to shift to agreement periods of not less than 5 years, additional years of performance data would be available at the time of an ACO's application to renew its agreement, and may also be available for evaluating ACOs re-entering after termination (depending on the timing of their termination) or the expiration of their prior agreement, as well as being available to evaluate new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO.

Further, under the program's monitoring requirements at § 425.316(c), ACOs with 2 consecutive years of failure to meet the program's quality performance standard will be terminated. However, we are concerned about a circumstance where an ACO that fails to meet the quality performance standard for multiple, non-consecutive years may remain in the program by seeking to renew its participation for a subsequent agreement period, seeking to re-enter the program after termination or expiration of its prior agreement, or by re-forming to enter under a new legal entity (identified as a re-entering ACO based on the experience of its ACO participants).

Second, we propose to revise the criterion governing the evaluation of whether an ACO under a two-sided model repaid shared losses owed to the program that were generated during the first 2 years of the previous agreement period (§ 425.224(b)(1)(v)), to instead consider whether the ACO failed to repay shared losses in full within 90 days in accordance with subpart G of the regulations for any performance year of the ACO's previous agreement period. In section II.A.7 we propose a 6-month performance year for ACOs that started a first or second agreement period on January 1, 2016, that elect an extension of their agreement period by 6 months from January 1, 2019 through June 30, 2019, and a 6-month first performance year for ACOs entering agreement periods beginning on July 1, 2019. We have also proposed to reconcile these ACOs, and ACOs that start a 12-month performance year on January 1, 2019, and terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019, separately for the 6-month periods from January 1, 2019, to June 30, 2019, and from July 1, 2019, to December 31, 2019, as described in section II.A.7 of this proposed rule. In evaluating this proposed criterion on repayment of losses, we would consider whether the ACO timely repaid any shared losses for these 6-month performance years, or the 6-month performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, which we propose would be determined according to the methodology specified under a new section of the regulations at § 425.609.

The current policy regarding repayment of shared losses is specified for ACOs with 3-year agreements. With the proposal to shift to agreement periods of at least 5 years, we believe it is appropriate to broaden our evaluation of the ACO's timely repayment of shared losses beyond the first 2 years of the ACO's prior agreement period. For instance, without modification, this criterion could have little relevance when evaluating the eligibility of ACOs in the BASIC track's glide path that elect to participate under a one-sided model for their first 2 performance years (or 3 performance years for ACOs that start an agreement period in the BASIC track's glide path on July 1, 2019).

We note that timely repayment of shared losses is required under subpart G of the regulations (§§ 425.606(h)(3) and 425.610(h)(3)), and non-compliance with this requirement may be the basis for pre-termination actions or termination under §§ 425.216 and 425.218. A provision that permits us to consider more broadly whether an ACO failed to timely repay shared losses for any performance year in the previous agreement period would be relevant to all renewing and re-entering ACOs that may have unpaid shared losses, as well

as all re-entering ACOs that may have been terminated for non-compliance with the repayment requirement. This includes ACOs that have participated under Track 2, Track 3, and ACOs that would participate under the BASIC track or ENHANCED track for a new agreement period. For ACOs that have participated in two-sided models authorized under section 1115A of the Act, including the Track 1+ Model, we also propose to consider whether an ACO failed to repay shared losses for any performance year under the terms of the ACO's participation agreement for such model.

Third, we propose to add a financial performance review criterion to § 425.224(b) to allow us to evaluate whether the ACO generated losses that were negative outside corridor for 2 performance years of the ACO's previous agreement period. We propose to use this criterion to evaluate the eligibility of ACOs to enter agreement periods beginning on July 1, 2019 and in subsequent years. For purposes of this proposal, an ACO is negative outside corridor when its benchmark minus performance year expenditures are less than or equal to the negative MSR for ACOs in a one-sided model, or the MLR for ACOs in a two-sided model. This proposed approach relates to our proposal to monitor for financial performance as described in section II.A.5.d of this proposed rule.

Lastly, we propose to add a review criterion to § 425.224(b), which would allow us to consider whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to fail to meet the quality performance standard for 2 or more years, fail to timely repay shared losses, or to generate losses outside its negative corridor for 2 years, or any other factors that may have caused the ACO to be terminated from the Shared Savings Program. We propose to require that the ACO also demonstrate it has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.

We propose to discontinue use of the requirement at § 425.600(c), under which an ACO with net losses during a previous agreement period must identify in its application the causes for the net loss and specify what safeguards are in place to enable it to potentially achieve savings in its next agreement period. We believe the proposed financial performance review criterion (discussed in this section of this proposed rule) would be more effective in identifying ACOs with a pattern of poor financial performance. An approach that accounts for financial performance year after year allows ACOs to understand if their performance is triggering a compliance concern and take action to remedy their performance during the remainder of their agreement period. Further, an approach that only considers net losses across performance years may not identify as problematic an ACO that generates losses in multiple years which in aggregate are canceled out by a single year with large savings. Although uncommon, such a pattern of performance, where an ACO's results change rapidly and dramatically, is concerning and warrants consideration in evaluating the ACO's suitability to continue its participation in the program.

This proposed requirement is similar to the current provision at § 425.222(b), which specifies that a previously terminated ACO must demonstrate that it has corrected deficiencies that caused it to be terminated from the program and has processes in place to ensure that it will remain in compliance with the terms of its new participation agreement. As we discussed previously, we propose to discontinue use of § 425.222. We believe adding a similar requirement to § 425.224 would allow us to more consistently apply policies to renewing and re-entering ACOs. Further, we believe applying this requirement to both re-entering and renewing ACOs would safeguard the program against organizations that have not met the program's goals or complied with program requirements and that may not be qualified to participate in the program, and therefore we believe this approach would be protective of the program, the Trust Funds, and Medicare FFS beneficiaries.

For ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO, we would determine the eligibility of the ACO to participate in the program based on the past performance of this other entity. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO B during the relevant look back period, we would consider ACO B's financial performance, quality performance, and compliance with other program requirements (as discussed in this section of this proposed rule) in determining the eligibility of ACO A to enter a new participation agreement in the program.

(5) Proposed Evaluation Criteria for Determining Participation Options

We have a number of concerns about the vulnerability of certain program policies to gaming by ACOs seeking to continue in the program under the BASIC track's glide path, as well as the need to ensure that an ACO's participation options are commensurate with the experience of the organization and its ACO participants with the Shared Savings Program and other performance-based risk Medicare ACO initiatives.

First, as the program matures and ACOs become more prevalent throughout the country, and as an increasing number of ACO participants become experienced in different Medicare ACO initiatives with differing levels of risk, we believe the regulations as currently written create flexibilities that would allow more experienced ACOs to take advantage of the opportunity to participate under the proposed BASIC track's glide path.

There are many Medicare ACO initiatives in which organizations may gain experience, specifically: Shared Savings Program Track 1, Track 2 and Track 3, as well as the proposed BASIC track and ENHANCED track, and the Track 1+ Model, Pioneer ACO Model, Next Generation ACO Model, and the Comprehensive End-Stage Renal Disease (ESRD) Care (CEC) Model. All but Shared Savings Program Track 1 ACOs and non-Large Dialysis Organization (LDO) End-Stage Renal Disease Care Organizations (ESCOs) participating in the one-sided risk track of the CEC Model participate in a degree of performance-based risk within an ACO's agreement period in the applicable program or model.

As discussed elsewhere in this section (II.A.5.c of this proposed rule), we are proposing to discontinue application of the policies in § 425.222(a). As a result of this change, we will allow ACOs currently participating in Track 1, Track 2, Track 3, or the Track 1+ Model, to choose whether to finish their current agreement or to terminate and apply to immediately enter a new agreement period through an early renewal. We are concerned that removing the existing safeguard under § 425.222(a) without putting in place other policies that assess an ACO's experience with performance-based risk would enable ACOs to participate in the BASIC track's glide path in Level A and Level B, under a one-sided model, terminate, and enter a one-sided model of the glide path again.

We are also concerned that existing and former Track 1 ACOs would have

the opportunity to gain additional time under a one-sided model of the BASIC track's glide path before accepting performance-based risk. Under the current regulations, Track 1 ACOs are limited to two agreement periods under a one-sided model before transitioning to a two-sided model beginning with their third agreement period (see § 425.600(b)). Without some restriction, Track 1 ACOs that would otherwise be required to assume performance-based risk at the start of their third agreement period in the program could end up continuing to participate under a one-sided model (BASIC track's Levels A and B) for 2 additional performance years, or 3 additional performance years in the case of ACOs that enter the BASIC track's glide path for an agreement period of 5 years and 6 months beginning July 1, 2019. We believe the performance-based risk models within the BASIC track's glide path would offer former Track 1 ACOs an opportunity to continue participation within the program under relatively low levels of two-sided risk and that these ACOs have sufficient experience with the program to begin the gradual transition to performance-based risk. Therefore we believe some restriction is needed to prevent all current and previously participating Track 1 ACOs from taking advantage of additional time under a one-sided model in the BASIC track's glide path and instead to encourage their more rapid progression to performance-based risk. For similar reasons we also believe it is important to prevent new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in a Track 1 ACO from also taking advantage of additional time under a one-sided model in the BASIC track's glide path. This restriction would help to ensure that ACOs do not re-form as new legal entities to maximize the time allowed under a one-sided model.

We also considered that currently § 425.202(b) of the program's regulations addresses application requirements for organizations that were previous participants in the Physician Group Practice (PGP) demonstration, which concluded in December 2012 with the completion of the PGP Transition Demonstration, and the Pioneer ACO Model, which concluded in December 2016, as described elsewhere in this section. We believe it is appropriate to propose to eliminate these provisions, while at the same time proposing criteria for identifying ACOs and ACO participants with previous experience in Medicare ACO initiatives as part of a broader approach to determining available participation options for applicants.

Second, we believe that using prior participation by ACO participant TINs in Medicare ACO initiatives along with the prior participation of the ACO legal entity is important when gauging the ACO's experience, given the observed churn in ACO participants over time and our experience with determining eligibility to participate in the Track 1+ Model. ACOs are allowed to make changes to their certified ACO participant list for each performance year, and we have observed that, each year, about 80 percent of ACOs make ACO participant list changes. We also considered CMS's recent experience with determining the eligibility of ACOs to participate in the Track 1+ Model. The Track 1+ Model is designed to encourage more group practices, especially small practices, to advance to performance-based risk. As such, it does not allow participation by current or former Shared Savings Program Track 2 or Track 3 ACOs, Pioneer ACOs, or Next Generation ACOs. As outlined in the Track 1+ Model Fact Sheet, the same legal entity that participated in any of these performance-based risk ACO initiatives cannot participate in the Track 1+ Model. Furthermore, an ACO would not be eligible to participate in the Track 1+ Model if 40 percent or more of its ACO participants had participation agreements with an ACO that was participating in one of these performance-based risk ACO initiatives in the most recent prior performance year.

Third, any approach to determining participation options relative to the experience of ACOs and ACO participants must also factor in our proposals to differentiate between low revenue and high revenue ACOs, as previously discussed in this section.

Fourth, and lastly, we believe the experience of ACOs and their ACO participants in Medicare ACO initiatives should be considered in determining which track (BASIC track or ENHANCED track) the ACO is eligible to enter as well as the applicability of policies that phase-in over time, namely the equal weighting of benchmark year expenditures, the policy of adjusting the benchmark based on regional FFS expenditures (which, for example, applies different weights in calculating the regional adjustment depending upon the ACO's agreement period in the program) and the phase-in of pay-for-performance under the program's quality performance standards.

Although § 425.222(c) specifies whether a former one-sided model ACO can be considered to be entering its first or second agreement period under Track 1 if it is re-entering the program after termination, the current regulations do not otherwise address how we should determine the applicable agreement period for a previously participating ACO after termination or expiration of its previous participation agreement.

We prefer an approach that would help to ensure that ACOs, whether they are initial applicants to the program, renewing ACOs or re-entering ACOs, would be treated comparably. Any approach should also ensure eligibility for participation options reflects the ACO's and ACO participants' experience with the program and other Medicare ACO initiatives and be transparent. Therefore, we propose to identify the available participation options for an ACO (regardless of whether it is applying to enter, re-enter, or renew its participation in the program) by considering all of the following factors: (1) Whether the ACO is a low revenue ACO or a high revenue ACO; and (2) the level of risk with which the ACO or its ACO participants has experience based on participation in Medicare ACO initiatives in recent years.

As a factor in determining an ACO's participation options, we propose to establish requirements for evaluating whether an ACO is inexperienced with performance-based risk Medicare ACO initiatives such that the ACO would be eligible to enter into an agreement period under the BASIC track's glide path or whether the ACO is experienced with performance-based risk Medicare ACO initiatives and therefore limited to participating under the higher-risk tracks of the Shared Savings Program (either an agreement period under the maximum level of risk and potential reward for the BASIC track (Level E), or the ENHANCED track).

To determine whether an ACO is inexperienced with performance-based risk Medicare ACO initiatives, we propose that both of the following requirements would need to be met: (1) The ACO legal entity has not participated in any performance-based risk Medicare ACO initiative (for example, the ACO is a new legal entity identified as an initial applicant or the same legal entity as a current or previously participating Track 1 ACO); and (2) CMS determines that less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative in each of the 5 most recent performance years prior to the agreement start date.

We propose that CMS would determine that an ACO is experienced with performance-based risk Medicare ACO initiatives if either of the following criteria are met: (1) The ACO is the same legal entity as a current or previous participant in a performance-based risk Medicare ACO initiative; or (2) CMS determines that 40 percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years prior to the agreement start date.

We propose to specify these requirements in a new provision at § 425.600(d). This provision would be used to evaluate eligibility for specific participation options for any ACO that is applying to enter the Shared Savings Program for the first time or to re-enter after termination or expiration of its previous participation agreement, or any ACO that is renewing its participation. As specified in the proposed definition of re-entering ACO, we also propose to apply the provisions at § 425.600(d) to new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO. Thus, the proposed provision at § 425.600(d) would also apply in determining eligibility for these ACOs to enter the BASIC track's glide path for agreement periods beginning on July 1, 2019, and in subsequent years. Because the 40 percent threshold that we are proposing to use to identify ACOs as experienced or inexperienced with performance-based risk on the basis of their ACO participants' prior participation in certain Medicare ACO initiatives is lower than the 50 percent threshold that would be used to identify new legal entities as re-entering ACOs based on the prior participation of their ACO participants in the same ACO, this proposed policy would automatically capture new legal entities identified as re-entering ACOs that have experience with performance-based risk based on the experience of their ACO participants.

We also propose to add new definitions at § 425.20 for ''Experienced with performance-based risk Medicare ACO initiatives'', ''Inexperienced with performance-based risk Medicare ACO initiatives'' and ''Performance-based risk Medicare ACO initiative''.

We propose to define ''performance-based risk Medicare ACO initiative'' to mean an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period. We propose this would include Track 2, Track 3 or the ENHANCED track, and the proposed BASIC track (including Level A through Level E) of the Shared Savings Program. We also propose this would include the following Innovation Center ACO Models involving two-sided risk: The Pioneer ACO Model, Next Generation ACO Model, the performance-based risk tracks of the CEC Model (including the two-sided risk tracks for LDO ESCOs and non-LDO ESCOs), and the Track 1+ Model. The proposed definition also includes such other Medicare ACO initiatives involving two-sided risk as may be specified by CMS.

We propose to define ''experienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets either of the following criteria:

(1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative as defined under § 425.20, or that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e).

(2) 40 percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative as defined under § 425.20, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e), in any of the 5 most recent performance years prior to the agreement start date.

As we previously discussed, we are proposing to discontinue use of the ''sit-out'' period under § 425.222(a) as well as the related ''sit-out'' period for ACOs that deferred renewal under § 425.200(e). Thus, we propose to identify all Track 1 ACOs that deferred renewal as being experienced with performance-based risk Medicare ACO initiatives. This includes ACOs that are within a fourth and final year of their first agreement period under Track 1 because they were approved to defer entry into a second agreement period under Track 2 or Track 3, and ACOs that have already entered their second agreement period under a two-sided model after a one year deferral. Under § 425.200(e)(2), in the event that a Track 1 ACO that has deferred its renewal terminates its participation agreement before the start of the first performance year of its second agreement period under a two-sided model, the ACO is considered to have terminated its participation agreement for its second agreement period under § 425.220. In this case, when the ACO seeks to re-enter the program after termination, it would need to apply for a two-sided model. We believe our proposal to consider ACOs that deferred renewal to be experienced with performance-based risk Medicare ACO initiatives and therefore eligible for either the BASIC track's Level E (if a low revenue ACO and certain other requirements are met) or the ENHANCED track, is necessary to ensure that ACOs that deferred renewal continue to be required to participate under a two-sided model in all future agreement periods under the program consistent with our current policy under § 425.200(e)(2).

We propose to define ''inexperienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets all of the following requirements:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under § 425.20, and has not deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e); and

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative as defined under § 425.20, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e), in each of the 5 most recent performance years prior to the agreement start date.

Under our proposed approach, for an ACO to be eligible to enter an agreement period under the BASIC track's glide path, less than 40 percent of its ACO participants can have participated in a performance-based risk Medicare ACO initiative in each of the five prior performance years. This proposed requirement is modeled after the threshold currently used in the Track 1+ Model (see Track 1+ Model Fact Sheet), although with a longer look back period. Based on experience with the Track 1+ Model during the 2018 application cycle, we do not believe that the proposed parameters are excessively restrictive. We considered the following issues in developing our proposed approach: (1) Whether to consider participation of ACO participants in a particular ACO, or cumulatively across multiple ACOs, during the 5-year look back period; (2) whether to use a shorter or longer look back period; and (3) whether to use a threshold amount lower than 40 percent.

We propose that in applying this threshold, we would not limit our consideration to ACO participants that participated in the same ACO or the same performance-based risk Medicare ACO initiative during the look back

period. Rather, we would determine, cumulatively, what percentage of ACO participants were in any performance-based risk Medicare ACO initiative in each of the 5 most recent performance years prior to the agreement start date. We believe the following illustrations help to clarify the use of the proposed threshold for determining ACO participants' experience with performance-based risk Medicare ACO initiatives.

For applicants applying to enter the BASIC track for an agreement period beginning on July 1, 2019, for example, we would consider what percentage of the ACO participants participated in any of the following during 2019 (January—June), 2018, 2017, 2016, and 2015: Track 2 or Track 3 of the Shared Savings Program, the Track 1+ Model, the Pioneer ACO Model, the Next Generation ACO Model, or the performance-based risk tracks of the CEC Model. In future years (in determining eligibility for participation options for agreement periods starting in 2020 and subsequent years), we would also consider prior participation in the BASIC track and ENHANCED track (which are proposed to become available for agreement periods beginning on July 1, 2019 and in subsequent years).

An ACO would be ineligible for the BASIC track's glide path if, for example, in the performance year prior to the start of the agreement period, 20 percent of its ACO participants participated in a Track 3 ACO and 20 percent of its ACO participants participated in a Next Generation ACO, even if the ACO did not meet or exceed the 40 percent threshold in any of the remaining 4 performance years of the 5-year look back period.

We considered a number of alternatives for the length of the look back period for determining an ACO's experience or inexperience with performance-based risk Medicare ACO initiatives. For example, we considered using a single performance year look back period, as used under the Track 1+ Model. We also considered using a longer look back period, for example of greater than 5 performance years, or a shorter look back period that would be greater than 1 performance year, but less than 5 performance years, such as a 3 performance year look back period.

A number of considerations informed our proposal to use a 5 performance year look back period. For one, we believe a longer look back period would help to guard against a circumstance where an ACO enters the BASIC track's glide path, terminates its agreement after one or 2 performance years under a one-sided model and seeks to enter the program under the one-sided model of the glide path. Whether or not the ACO applies to enter the program as the same legal entity or a new legal entity, the proposed eligibility criteria would identify this ACO as experienced with performance-based risk Medicare ACO initiatives if the ACO's ACO participant list remains relatively unchanged. Second, we believe a longer look back period may reduce the incentive for organizations to wait out the period in an effort to re-form as a new legal entity with the same or very similar composition of ACO participants for purposes of gaming program policies. Third, we believe a longer look back period also recognizes that new ACOs composed of ACO participants that were in performance-based risk Medicare ACO initiatives many years ago (for instance more than 5 performance years prior to the ACO's agreement start date) may benefit from gaining experience with the program's current requirements under the glide path (if our proposal is finalized), prior to transitioning to higher levels of risk and reward. Fourth, and lastly, in using the 5 most recent performance years prior to the start date of an ACO's agreement period, for ACOs applying to enter an agreement period beginning on July 1, 2019, we would consider the participation of ACO participants during the first 6 months of 2019. This would allow us to capture the ACO participants' most recent prior participation in considering an ACO's eligibility for participation options for an agreement period beginning July 1, 2019. An alternative approach that bases the look back period on prior calendar years would overlook this partial year of participation in 2019.

We also considered using a threshold amount lower than 40 percent. Based on checks performed during the 2018 application cycle, for the average Track 1+ Model applicant, less than 2 percent of ACO participants had participated under performance-based risk in the prior year. The maximum percentage observed was 30 percent. In light of these findings, we considered whether to propose a lower threshold for eligibility to participate in the BASIC track's glide path. However, our goal is not to be overly restrictive, but rather to ensure that ACOs with significant experience with performance-based risk are appropriately placed. While we favor 40 percent for its consistency with the Track 1+ Model requirement, we also seek comment on other numeric thresholds.

As previously discussed in this section, we believe some restriction is needed to prevent all current and previously participating Track 1 ACOs, and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO, from taking advantage of additional time under a one-sided model in the BASIC track's glide path. We believe an approach that restricts the amount of time a former Track 1 ACO or a new ACO, identified as a re-entering ACO because of its ACO participants' prior participation in a Track 1 ACO, may participate in the one-sided models of the BASIC track's glide path (Level A and Level B) would balance several concerns. Allowing Track 1 ACOs and eligible re-entering ACOs some opportunity to continue participation in a one-sided model within the BASIC track's glide path could smooth their transition to performance-based risk. For example, it would provide these ACOs a limited time under a one-sided model in a new agreement period under the BASIC track, during which they could gain experience with their rebased historical benchmark, and prepare for the requirements of participation in a two-sided model (such as establishing a repayment mechanism arrangement). Limiting time in the one-sided models of the BASIC track's glide path for former Track 1 ACOs and new ACOs that are identified as re-entering ACOs because of their ACO participants' recent prior participation in the same Track 1 ACO would also allow these ACOs to progress more rapidly to performance-based risk, and therefore further encourage accomplishment of the program's goals.

After weighing these considerations, we propose that ACOs that previously participated in Track 1 of the Shared Savings Program or new ACOs, for which the majority of their ACO participants previously participated in the same Track 1 ACO, that are eligible to enter the BASIC track's glide path, may enter a new agreement period under either Level B, C, D or E. Former Track 1 ACOs and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO would not be eligible to participate under Level A of the glide path. Therefore, if an ACO enters the glide path at Level B and is automatically transitioned through the levels of the glide path, the ACO would participate in Level E for the final 2 performance years of its agreement period. For a former Track 1 ACO or a new ACO identified as a re-entering ACO because of its ACO participants' prior participation in a Track 1 ACO that enters an agreement period in the

BASIC track's glide path beginning on July 1, 2019, the ACO could participate under Level B for a 6-month performance year from July 1, 2019 through December 31, 2019 and the 12 month performance year 2020 (as discussed in section II.A.7.c of this proposed rule). A former Track 1 ACO or a new ACO identified as a re-entering ACO because of its ACO participants' prior participation in a Track 1 ACO that begins an agreement period in the BASIC track's glide path in any subsequent year (2020 and onward) could participate in Level B for 1 performance year before advancing to a two-sided model within the glide path.

We also considered a more aggressive approach to transitioning ACOs with experience in Track 1 to performance-based risk. Specifically, we considered whether the one-sided models of the BASIC track's glide path should be unavailable to current or previously participating Track 1 ACOs and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO. Under this alternative, ACOs that are experienced with Track 1, would be required to enter the BASIC track's glide path under performance-based risk at Level C, D or E. This alternative would more aggressively transition ACOs along the glide path. This approach would recognize that some of these ACOs may have already had the opportunity to participate under a one-sided model for 6 performance years (or 7 performance years for ACOs that elect to extend their agreement period for the 6-month performance year from January 1, 2019 through June 30, 2019), and should already have been taking steps to prepare to enter performance-based risk to continue their participation in the program under the current requirements, and therefore should not be allowed to take advantage of additional time under a one-sided model. For ACOs that have participated in a single agreement period in Track 1, an approach that requires transition to performance-based risk at the start of their next agreement period would be more consistent with the proposed redesign of participation options, under which ACOs would be allowed only 2 years, or 2 years and 6 months in the case of July 1, 2019 starters, under the one-sided models of the BASIC track's glide path. We seek comment on this alternative approach.

In summary, in combination with determining an whether ACOs are low revenue versus high revenue, we propose to add a new paragraph (d) under § 425.600, to provide that CMS will identify ACOs as inexperienced or experienced with performance-based risk Medicare ACO initiatives for purposes of determining an ACO's eligibility for certain participation options, as follows:

- If an ACO is identified as high revenue, the following options would apply:

++ If we determine the ACO is inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter the BASIC track's glide path, or the ENHANCED track. With the exception of ACOs that previously participated in Track 1 and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO, an ACO may enter the BASIC track's glide path at any level (Level A through Level E). Therefore, eligible ACOs that are new to the program, identified as initial applicants and not as re-entering ACOs, would have the flexibility to enter the glide path at any one of the five levels. An ACO that previously participated in Track 1 or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in the same Track 1 ACO may enter the glide path under either Level B, C, D or E.

++ If we determine the ACO is experienced with performance-based risk Medicare ACO initiatives, the ACO may only enter the ENHANCED track.

- If an ACO is identified as low revenue, the following options would apply:

++ If we determine the ACO is inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter the BASIC track's glide path, or the ENHANCED track. With the exception of ACOs that previously participated in Track 1 and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO, an ACO may enter the BASIC track's glide path at any level (Level A through Level E). Therefore, eligible ACOs that are new to the program, identified as initial applicants and not re-entering ACOs, would have the flexibility to enter the glide path at any one of the five levels. An ACO that previously participated in Track 1 or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in the same Track 1 ACO may enter the glide path under either Level B, C, D or E.

++ If we determine the ACO is experienced with performance-based risk Medicare ACO initiatives, the ACO may enter the BASIC track Level E (highest level of risk and potential reward) or the ENHANCED track. As discussed in section II.A.3.b of this proposed rule, low revenue ACOs are limited to two agreement periods of participation under the BASIC track.

We propose to specify these requirements in revisions to the regulations under § 425.600, which would be applicable for determining participation options for agreement periods beginning on July 1, 2019, and in subsequent years. We seek comment on these proposals for determining an ACO's participation options by evaluating the ACO legal entity's and ACO participants' experience or inexperience with performance-based risk Medicare ACO initiatives. In particular, we welcome commenters' input on our proposal to assess ACO participants' experience with performance-based risk Medicare ACOs using a 40 percent threshold, and the alternative of employing a threshold other than 40 percent, for example, 30 percent. We welcome comments on the proposed 5 performance year look back period for determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives, and our consideration of a shorter look back period, such as 3 performance years. We also welcome comments on our proposal to limit former Track 1 ACOs and new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO to a single performance year under the one-sided models of the BASIC track's glide path (two performance years, in the case of an ACO starting its agreement period under the BASIC track on July 1, 2019), and the alternative approach that would preclude such ACOs from participating in one-sided models of the BASIC track's glide path.

We also believe it is appropriate to consider an ACO's experience with the program or other performance-based risk Medicare ACO initiatives in determining which agreement period an ACO should be considered to be entering for purposes of applying policies that phase-in over the course of the ACO's first agreement period and subsequent agreement periods: (1) The weights applied to benchmark year expenditures (equal weighting in second or subsequent agreement periods instead of weighting the 3 benchmark years (BYs) at 10 percent (BY1), 30 percent (BY2), and 60 percent (BY3)); (2) the weights used in calculating the regional adjustment to an ACO's historical benchmark, which phase in over multiple agreement periods; and (3) the quality performance standard, which phases in from complete and

accurate reporting of all quality measures in the first performance year of an ACO's first agreement period to pay-for-performance over the remaining years of the ACO's first agreement period, and ACOs continue to be assessed on performance in all subsequent performance years under the program (including subsequent agreement periods). We note that for purposes of this discussion, we consider agreement periods to be sequential and consecutive. For instance, after an ACO participates in its first agreement period, the ACO would enter a second agreement period, followed by a third agreement period, and so on.

We propose to specify under § 425.600(f)(1) that an ACO entering the program for the first time (an initial entrant) would be considered to be entering a first agreement period in the Shared Savings Program for purposes of applying program requirements that phase-in over time, regardless of its experience with performance-based risk Medicare ACO initiatives. Under this approach, in determining the ACO's historical benchmark, we would weight the benchmark year expenditures as follows: 10 percent (BY1), 30 percent (BY2), and 60 percent (BY3). We would apply a weight of either 25 percent or 35 percent in determining the regional adjustment amount (depending on whether the ACO is higher or lower spending compared to its regional service area) under the proposed approach to applying factors based on regional FFS expenditures beginning with the ACO's first agreement period (see section II.D of this proposed rule). Further, under § 425.502, an initial entrant would be required to completely and accurately report all quality measures to meet the quality performance standard (referred to as pay-for-reporting) in the first performance year of its first agreement period, and for subsequent years of the ACO's first agreement period the pay-for-performance quality performance standard would phase-in.

We propose to divide re-entering ACOs into three categories in order to determine which agreement period an ACO will be considered to be entering for purposes of applying program requirements that phase-in over time, and to specify this policy at § 425.600(f)(2). For an ACO whose participation agreement expired without having been renewed, we propose the ACO would re-enter the program under the next consecutive agreement period. For example, if an ACO completed its first agreement period and did not renew, upon re-entering the program, the ACO would participate in its second agreement period.

For an ACO whose participation agreement was terminated under § 425.218 or § 425.220, we propose the ACO re-entering the program would be treated as if it is starting over in the same agreement period in which it was participating at the time of termination, beginning with the first performance year of the new agreement period. For instance, if an ACO terminated at any time during its second agreement period, the ACO would be considered participating in a second agreement period upon re-entering the program, beginning with the first performance year of their new agreement period. Alternatively, we considered determining which performance year a terminated ACO should re-enter within the new agreement period, in relation to the amount of time the ACO participated during its most recent prior agreement period. For example, under this approach, an ACO that terminated its participation in the program in the third performance year of an agreement period would be treated as re-entering the program in performance year three of the new agreement period. However, we believe this alternative approach could be complicated given the proposed transition from 3-year agreements to agreement periods of at least 5 years.

For a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO, we would consider the prior participation of the ACO in which the majority of the ACO participants in the new ACO were participating in order to determine the agreement period in which the new ACO would be considered to be entering the program. That is, we would determine the applicability of program policies to the new ACO based on the number of agreement periods the other entity participated in the program. If the participation agreement of the other ACO was terminated or expired, the previously described rules for re-entering ACOs would also apply. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO B during the relevant look back period, we would consider ACO B's prior participation in the program. For instance, if ACO B terminated during its second agreement period in the program, we would consider ACO A to be entering a second agreement period in the program, beginning with the first performance year of that agreement period. However, if the other ACO is currently participating in the program, the new ACO would be considered to be entering into the same agreement period in which this other ACO is currently participating, beginning with the first performance year of that agreement period. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO C during the relevant look back period, and ACO C is actively participating in its third agreement period in the program, ACO A would be considered to be participating in a third agreement period, beginning with the first performance year of that agreement period.

We propose to specify at § 425.600(f)(3) that renewing ACOs would be considered to be entering the next consecutive agreement period for purposes of applying program requirements that phase-in over time. This proposed approach is consistent with current program policies for ACOs whose participation agreements expire and that immediately enter a new agreement period to continue their participation in the program. For example, an ACO that entered its first participation agreement on January 1, 2017, and concludes this participation agreement on December 31, 2019, would renew to enter its second agreement period beginning on January 1, 2020. Further, under the proposed definition of ''Renewing ACO'', an ACO that terminates its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program would also be considered to be entering the next consecutive agreement period. For example, an ACO that entered its first participation agreement on January 1, 2018, and terminates its agreement effective June 30, 2019, to enter a new participation agreement beginning on July 1, 2019, would be considered to be a renewing ACO that is renewing early to enter its second agreement period beginning on July 1, 2019. This approach would ensure that an ACO that terminates from a first agreement period and immediately enters a new agreement period in the program could not take advantage of program flexibilities aimed at ACOs that are completely new to the Shared Savings Program, such as the pay-for-reporting quality performance standard available to ACOs in their first performance year of their first agreement period under the program. We would therefore apply a consistent approach among renewing ACOs by

placing these ACOs in the next agreement period in sequential order.

This proposed approach would replace the current approach to determining which agreement period an ACO is considered to be entering into, for a subset of ACOs, as specified in the provision at § 425.222(c), which we are proposing to discontinue using. We believe this proposed approach ensures that ACOs that are experienced with the program or with performance-based risk Medicare ACO initiatives are not participating under policies designed for ACOs inexperienced with the program's requirements or similar requirements under other Medicare ACO initiatives, and also helps to preserve the intended phase-in of requirements over time by taking into account ACOs' prior participation in the program.

The proposed approach would help to ensure that ACOs that are new to the program are distinguished from renewing ACOs and ACOs that are re-entering the program, and would also ensure that program requirements are applied in a manner that reflects ACOs' prior participation in the program, which we believe would limit the opportunity for more experienced ACOs to seek to take advantage of program policies. These policies protect against ACOs terminating or discontinuing their participation, and potentially re-forming as a new legal entity, simply to be able to apply to re-enter the program in a way that could allow for the applicability of lower weights used in calculating the regional adjustment to the benchmark or to avoid moving to performance-based risk more quickly on the BASIC track's glide path or under the ENHANCED track.

We believe the proposed approach to determining ACO participation options and the proposal to limit access the BASIC track's glide path to ACOs that are inexperienced with performance-based risk, in combination with the rebasing of ACO benchmarks at the start of each new agreement period, mitigate our concerns regarding ACO gaming. We believe that the requirement that ACOs' benchmarks are rebased at the start of each new agreement period, in combination with the proposed new requirements governing ACO participation options, would be sufficiently protective of the Trust Funds to guard against undesirable ACO gaming behavior. Under the policies discussed elsewhere in this section of the proposed rule for identifying ACOs that are experienced with performance-based risk Medicare ACOs initiatives, ACOs that terminate from the BASIC track's glide path (for example) and seek to re-enter the program, and renewing ACOs (including ACOs renewing early for a new agreement period beginning July 1, 2019) that are identified as experienced with performance-based risk Medicare ACO initiatives could only renew under the BASIC track Level E (if an otherwise eligible low revenue ACO) or the ENHANCED track. This mitigates our concerns about ACOs re-forming and re-entering the program, or serially terminating and immediately participating again as a renewing ACO, since there would be consequences for the ACO's ability to continue participation under lower-risk options that may help to deter these practices.

We acknowledge that under our proposals regarding early renewals (that is, our proposal that ACOs that terminate their current agreement period and immediately enter a new agreement period without interruption qualify as renewing ACOs), it is possible for ACOs to serially enter a participation agreement, terminate from it and enter a new agreement period, to be considered entering the next consecutive agreement period in order to more quickly take advantage of the higher weights used in calculating the regional adjustment to the benchmark. However, we note that these ACOs' benchmarks would be rebased, which we believe would help to mitigate this concern. We seek comment on possible approaches that would prevent ACOs from taking advantage of participation options to delay or hasten the phase-in of higher weights used in calculating the regional adjustment to the historical benchmark, while still maintaining the flexibility for existing ACOs to quickly move from a current 3-year agreement period to a new agreement period under either the BASIC track or ENHANCED track.

In the June 2016 final rule, we established the phase-in of the weights used in calculating the regional adjustment to the ACO's historical benchmark, for second or subsequent agreement periods beginning in 2017 and subsequent years. As discussed in section II.D of this proposed rule, we propose to use factors based on regional FFS expenditures in calculating an ACO's historical benchmark beginning with an ACO's first agreement period for agreement periods beginning on July 1, 2019, and in subsequent years. We would maintain the phase-in for the regional adjustment weights for ACOs with start dates in the program before July 1, 2019, according to the structure established in the earlier rulemaking (such as using these factors for the first time in resetting benchmarks for the third agreement period for 2012 and 2013 starters). Table 5 includes examples of the phase-in of the proposed regional adjustment weights based on agreement start date and applicant type (initial entrant, renewing ACO, or re-entering ACO). This table illustrates the weights that would be used in determining the regional adjustment to the ACO's historical benchmark under this proposed approach to differentiating initial entrants, renewing ACOs (including ACOs that renew early), and re-entering ACOs for purposes of policies that phase-in over time.

TABLE 5—EXAMPLES OF PHASE-IN OF PROPOSED REGIONAL ADJUSTMENT WEIGHTS BASED ON AGREEMENT START DATE AND APPLICANT TYPE

Applicant type	First time regional adjustment used: 35 percent or 25 percent (if spending above region)	Second time regional adjustment used: 50 percent or 35 percent (if spending above region)	Third and subsequent time regional adjustment used: 50 percent weight
New entrant with start date on July 1, 2019.	Applicable to first agreement period starting on July 1, 2019.	Applicable to second agreement period starting in 2025.	Applicable to third agreement period starting in 2030 and all subsequent agreement periods.
Renewing ACO for agreement period starting on July 1, 2019, with initial start date in 2012, 2013, or 2016.	Applicable to third (2012/2013) or second (2016) agreement period starting on July 1, 2019.	Applicable to fourth (2012/2013) or third (2016) agreement period starting in 2025.	Applicable to fifth (2012/2013) or fourth (2016) agreement period starting in 2030 and all subsequent agreement periods.

TABLE 5—EXAMPLES OF PHASE-IN OF PROPOSED REGIONAL ADJUSTMENT WEIGHTS BASED ON AGREEMENT START DATE AND APPLICANT TYPE—Continued

Applicant type	First time regional adjustment used: 35 percent or 25 percent (if spending above region)	Second time regional adjustment used: 50 percent or 35 percent (if spending above region)	Third and subsequent time regional adjustment used: 50 percent weight
Early renewal for agreement period starting on July 1, 2019, ACO with initial start date in 2014 that terminates effective June 30, 2019.	Currently applies to second agreement period starting in 2017.	Applicable to third agreement period starting on July 1, 2019.	Applicable to fourth agreement period starting in 2025 and all subsequent agreement periods.
Re-entering ACO with initial start date in 2014 whose agreement expired December 31, 2016 (did not renew) and *re-enters* second agreement period starting on July 1, 2019.	Applicable to second agreement period starting on July 1, 2019 (ACO considered to be re-entering a second agreement period).	Applicable to third agreement period starting in 2025.	Applicable to fourth agreement period starting in 2030 and all subsequent agreement periods.
Re-entering ACO with second agreement period start date in 2017 terminated during performance year 2 (2018) and *re-enters* second agreement period starting on July 1, 2019.	Applicable to second agreement period starting on July 1, 2019 (ACO considered to be re-entering a second agreement period).	Applicable to third agreement period starting in 2025.	Applicable to fourth agreement period starting in 2030 and all subsequent agreement periods.

As part of the development of these proposals, we also revisited our current policy that allows certain organizations with experience in Medicare ACO initiatives to use a condensed application form to apply to the Shared Savings Program. Under § 425.202(b), we allow for use of a condensed Shared Savings Program application form by organizations that participated in the PGP demonstration. Former Pioneer Model ACOs may also use a condensed application form if specified criteria are met (including that the applicant is the same legal entity as the Pioneer ACO and the ACO is not applying to participate in the one-sided model). For the background on this policy, we refer readers to discussions in earlier rulemaking. (See 76 FR 67833 through 67834, and 80 FR 32725 through 32728.)

The PGP demonstration ran for 5 years from April 2005 through March 2010, and the PGP transition demonstration began in January 2011 and concluded in December 2012.[15] The Pioneer ACO Model began in 2012 and concluded in December 2016.[16] Many former PGP demonstration sites and Pioneer ACOs have already transitioned to other Medicare ACO initiatives including the Shared Savings Program and the Next Generation ACO Model. Accordingly, we believe it is no longer necessary to maintain the provision permitting these entities to use condensed application forms. First, since establishing this policy, we have modified the program's application to reduce burden on all applicants. See 82 FR 53217 through 53222. Second, our proposed approach for identifying ACOs experienced with performance-based risk Medicare ACO initiatives for purposes of determining an ACO's participation options would require former Pioneer Model ACOs to participate under the higher levels of risk: Either the highest level of risk and potential reward in the BASIC track (Level E), or the ENHANCED track. This includes, for example, a former Pioneer ACO that applies to the Shared Savings Program using the same legal entity, or if 40 percent or more of the ACO's ACO participants are determined to be experienced with the Pioneer ACO Model or other two-sided model Medicare ACO initiatives within the 5 performance year look back period prior to the start date of the ACO's agreement period in the Shared Savings Program.

Under the proposed approach described in this section, we would identify these experienced, former Pioneer Model ACOs entering the program for the first time as participating in a first agreement period for purposes of the applicability of the program policies that phase-in over time. On the other hand, if an ACO terminated its participation in the Shared Savings Program, entered the Next Generation ACO Model, and then re-enters the Shared Savings Program, under the proposed approach we would consider the ACO to be entering either: (1) Its next consecutive agreement period in the Shared Savings Program, if the ACO had completed an agreement period in the program before terminating its prior participation; or (2) the same agreement period in which it was participating at the time of program termination. We note that commenters in earlier rulemaking suggested we apply the benchmark rebasing methodology that incorporates factors based on regional FFS expenditures to former Pioneer ACOs and Next Generation ACOs entering their first agreement period under the Shared Savings Program (see 81 FR 37990). We believe that our proposal, as discussed in section II.D of this proposed rule, to apply factors based on regional FFS expenditures to ACOs' benchmarks in their first agreement periods addresses these stakeholder concerns.

However, we also considered an alternative approach that would allow ACOs formerly participating in these Medicare ACO models to be considered to be entering a second agreement period for the purpose of applying policies that phase-in over time. We decline to propose this approach at this time, because ACOs entering the Shared Savings Program after participation in another Medicare ACO initiative may need time to gain experience with program's policies. Therefore, we prefer the proposed approach that would allow ACOs new to the Shared Savings Program to gain experience with the program's requirements, by entering the program in a first agreement period.

Therefore, we propose to amend § 425.202(b) to discontinue the option for certain applicants to use a condensed application when applying to participate in the Shared Savings Program for agreement periods beginning on July 1, 2019 and in subsequent years.

[15] See Fact Sheet on Physician Group Practice Transition Demonstration (August 2012), available at *https://innovation.cms.gov/Files/Migrated-Medicare-Demonstration-x/PGP_TD_Fact_Sheet.pdf.*

[16] See Pioneer ACO Model web page, available at *https://innovation.cms.gov/initiatives/Pioneer-aco-model/.*

We seek comment on the proposals described in this section and the alternatives considered. The participation options available to ACOs based on the policies proposed in this section are summarized in Table 6 (low revenue ACOs) and Table 7 (high revenue ACOs).

TABLE 6—PARTICIPATION OPTIONS FOR LOW REVENUE ACOS BASED ON APPLICANT TYPE AND EXPERIENCE WITH RISK

Applicant type	ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives	Participation options [1]			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		BASIC track's glide path (option for incremental transition from one-sided to two-sided models during agreement period)	BASIC track's Level E (track's highest level of risk/reward applies to all performance years during agreement period)	ENHANCED track (program's highest level of risk/reward applies to all performance years during agreement period)	
New legal entity	Inexperienced	Yes—glide path Levels A through E.	Yes	Yes	First agreement period.
New legal entity	Experienced	No	Yes	Yes	First agreement period.
Re-entering ACO ..	Inexperienced—former Track 1 ACOs or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO.	Yes—glide path Levels B through E.	Yes	Yes	Either: (1) The next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for new ACO identified as re-entering because of ACO participants' experience in the same ACO.
Re-entering ACO ..	Experienced—including former Track 1 ACOs that deferred renewal under a two-sided model.	No	Yes	Yes	Either: (1) The next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for new ACO identified as re-entering because of ACO participants' experience in the same ACO.
Renewing ACO	Inexperienced—former Track 1 ACOs.	Yes—glide path Levels B through E.	Yes	Yes	Subsequent consecutive agreement period.
Renewing ACO	Experienced—including former Track 1 ACOs that deferred renewal under a two-sided model.	No	Yes	Yes	Subsequent consecutive agreement period.

Notes: [1] Low revenue ACOs may operate under the BASIC track for a maximum of two agreement periods.

TABLE 7—PARTICIPATION OPTIONS FOR HIGH REVENUE ACOS BASED ON APPLICANT TYPE AND EXPERIENCE WITH RISK

Applicant type	ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives	Participation Options [1]			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		BASIC track's glide path (option for incremental transition from one-sided to two-sided models during agreement period)	BASIC track's Level E (track's highest level of risk/reward applies to all performance years during agreement period)	ENHANCED track (program's highest level of risk/reward applies to all performance years during agreement period)	
New legal entity	Inexperienced	Yes—glide path Levels A through E.	Yes	Yes	First agreement period.
New legal entity	Experienced	No	No	Yes	First agreement period.

TABLE 7—PARTICIPATION OPTIONS FOR HIGH REVENUE ACOS BASED ON APPLICANT TYPE AND EXPERIENCE WITH RISK—Continued

Applicant type	ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives	Participation Options [1]			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		BASIC track's glide path (option for incremental transition from one-sided to two-sided models during agreement period)	BASIC track's Level E (track's highest level of risk/reward applies to all performance years during agreement period)	ENHANCED track (program's highest level of risk/reward applies to all performance years during agreement period)	
Re-entering ACO ..	Inexperienced—former Track 1 ACOs or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO.	Yes—glide path Levels B through E.	Yes	Yes	Either: (1) The next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for new ACO identified as re-entering because of ACO participants' experience in the same ACO.
Re-entering ACO ..	Experienced—including former Track 1 ACOs that deferred renewal under a two-sided model.	No	No	Yes	Either: (1) The next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for new ACO identified as re-entering because of ACO participants' experience in the same ACO.
Renewing ACO	Inexperienced—former Track 1 ACOs.	Yes—glide path Levels B through E.	Yes	Yes	Subsequent consecutive agreement period.
Renewing ACO	Experienced—including former Track 1 ACOs that deferred renewal under a two-sided model.	No	No	Yes	Subsequent consecutive agreement period.

Notes: [1] High revenue ACOs that have participated in the BASIC track are considered experienced with performance-based risk Medicare ACO initiatives and are limited to participating under the ENHANCED track for subsequent agreement periods.

d. Monitoring for Financial Performance

(1) Background

The program regulations at § 425.316 enable us to monitor the performance of ACOs. In particular, § 425.316 authorizes monitoring for performance related to two statutory provisions regarding ACO performance: Avoidance of at-risk beneficiaries (section 1899(d)(3) of the Act) and failure to meet the quality performance standard (section 1899(d)(4) of the Act). If we discover that an ACO has engaged in the avoidance of at-risk beneficiaries or has failed to meet the quality performance standard, we can impose remedial action or terminate the ACO (see § 425.316(b), (c)).

In monitoring the performance of ACOs, we can analyze certain financial data (see § 425.316(a)(2)(i)), but the regulations do not specifically authorize termination or remedial action for poor financial performance. Similarly, there are no provisions that specifically authorize non-renewal of a participation agreement for poor financial performance, although we had proposed issuing such provisions in prior rules.

In the December 2014 proposed rule (79 FR 72802 through 72806), we proposed to allow Track 1 ACOs to renew their participation in the program for a second agreement period in Track 1 if in at least one of the first 2 performance years of the previous agreement period they did not generate losses in excess of their negative MSR, among other criteria. We refer readers to the June 2015 final rule for a detailed discussion of the proposal and related comments (80 FR 32764 through 32767). Ultimately, we did not adopt a financial performance criterion to determine the eligibility of ACOs to continue in Track 1 in the June 2015 final rule. Although some commenters supported an approach for evaluating an ACO's financial performance for determining its eligibility to remain in a one-sided model, many commenters expressed opposition, citing concerns that this approach could be premature and could disadvantage ACOs that need more time to implement their care management strategies, and could discourage participation. At the time of the June 2015 final rule, we were persuaded by commenters' concerns that application of the additional proposed financial performance criterion for continued participation in Track 1 was premature for ACOs that initially struggled to demonstrate cost savings in their first years in the program. Instead, we

explained our belief that our authority to monitor ACOs (§ 425.316) allows us to take action to address ACOs that are outliers on financial performance by placing poorly performing ACOs on a special monitoring plan. Furthermore, if our monitoring reveals that an ACO is out of compliance with any of the requirements of the Shared Savings Program, we may request a corrective action plan and, if the required corrective action plan is not submitted or is not satisfactorily implemented, we may terminate the ACO's participation in the program (80 FR 32765).

Now that we have additional experience with monitoring ACO financial performance, we believe that the current regulations are insufficient to address recurrent poor financial performance, particularly for ACOs that may be otherwise in compliance with program requirements. Consequently, some ACOs may not have sufficient incentive to remain accountable for the expenditures of their assigned beneficiaries. This may leave the program, the Trust Funds, and Medicare FFS beneficiaries vulnerable to organizations that may be participating in the program for reasons other than meeting the program's goals.

We believe that a financial performance requirement is necessary to ensure that the program promotes accountability for the cost of the care furnished to an ACO's assigned patient population, as contemplated by section 1899(b)(2)(A) of the Act. We believe there is an inherent financial performance requirement that is embedded within the third component of the program's three-part aim: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in Medicare Parts A and B expenditures. Therefore, just as poor quality performance can subject an ACO to remedial action or termination, an ACO's failure to lower growth in Medicare FFS expenditures should be the basis for CMS to take pre-termination actions under § 425.216, including a request for corrective action by the ACO, or termination of the ACO's participation agreement under § 425.218.

(2) Proposed Revisions

We propose to modify § 425.316 to add a provision for monitoring ACO financial performance. Specifically, we propose to monitor for whether the expenditures for the ACO's assigned beneficiary population are ''negative outside corridor,'' meaning that the expenditures for assigned beneficiaries exceed the ACO's updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model, or the ACO's MLR under a two-sided model.[17] If the ACO is negative outside corridor for a performance year, we propose that we may take any of the pre-termination actions set forth in § 425.216. If the ACO is negative outside corridor for another performance year of the ACO's agreement period, we propose that we may immediately or with advance notice terminate the ACO's participation agreement under § 425.218.

We propose that financial performance monitoring would be applicable for performance years beginning in 2019 and subsequent years. Specifically, we would apply this proposed approach for monitoring financial performance results for performance years beginning on January 1, 2019, and July 1, 2019, and for subsequent performance years. Financial and quality performance results are typically made available to ACOs in the summer following the conclusion of the calendar year performance year. For example, we anticipate that the financial performance results for performance years beginning on January 1, 2019 and July 1, 2019, will be available for CMS review in the summer of 2020 and will be made available to ACOs when that review is complete. The one-sided model monitoring (relative to the ACO's negative MSR) would apply to ACOs in Track 1 or the first 2 years of the BASIC track's glide path, and the two-sided model monitoring (relative to the ACO's MLR) would apply to ACOs under performance-based risk in the BASIC track (including the glide path) and the ENHANCED track, as well as Track 2.

Generally, based on our experience, ACOs in two-sided models tend to terminate their participation after sharing in losses for a single year in Track 2 or Track 3. We have observed that a small, but not insignificant, number of Track 1 ACOs are negative outside corridor in their first 2 performance years in the program. Among 194 Track 1 ACOs that renewed for a second agreement period under Track 1, 19 were negative outside corridor in their first 2 performance years in their first agreement period. This includes 14 of 127 Track 1 ACOs that started their first agreement period in either 2012 or 2013 and renewed for a second agreement period in Track 1 beginning January 1, 2016, as well as 5 of 67 Track 1 ACOs that started their first agreement period in 2014 and renewed for a second agreement period in Track 1 beginning January 1, 2017. Moreover, the majority of these organizations have thus far failed to achieve shared savings in subsequent performance years. For example, of the 14 2012/2013 starters in Track 1 that were negative outside corridor for the first 2 consecutive performance years in their first agreement period, only 2 ACOs achieved shared savings in their third performance year, while 10 were still negative outside corridor and 2 were negative within corridor. All 14 ACOs entered a second agreement period in Track 1 starting on January 1, 2016: In performance year 2016, 5 shared savings, 4 were positive within corridor, 4 were negative within corridor, and 1 was negative outside corridor. While some of these ACOs appeared to show improvement, the 2016 results do not take into account ACO participant list changes for these ACOs or rebasing of the ACOs' historical benchmarks for their second agreement period. Because the benchmark years for the second agreement period correspond to the performance years of the first agreement period, ACOs that had losses in their initial years are likely to receive a higher rebased benchmark than those that shared savings. We observed similar trends following the first 2 performance years for ACOs that started their first agreement period in 2014 and 2015. Therefore, while experience does not suggest that a large share of ACOs would be affected, we believe that the proposed policy, if adopted, will help to ensure that ACOs are not allowed multiple years of losses without being held accountable for their performance.

Alternatively, we considered an approach under which we would monitor ACOs for generating any losses, beginning with first dollar losses, including monitoring for ACOs that are negative inside corridor and negative outside corridor. However, we prefer the proposed approach previously described, because the corridor (MLR threshold above the benchmark) is established to protect ACOs against sharing losses that result from random variation.

As described briefly in section II.A.2 of this proposed rule, ACOs that

[17] For purposes of this proposed rule, an ACO is considered to have shared savings when its benchmark minus performance year expenditures are greater than or equal to the MSR. An ACO is ''positive within corridor'' when its benchmark minus performance year expenditures are greater than zero, but less than the MSR. An ACO is ''negative within corridor'' when its benchmark minus performance year expenditures are less than zero, but greater than the negative MSR for ACOs in a one-sided model or the MLR for ACOs in a two-sided model. An ACO is ''negative outside corridor'' when its benchmark minus performance year expenditures are less than or equal to the negative MSR for ACOs in a one-sided model or the MLR for ACOs in a two-sided model.

continue in the program despite poor financial performance may provide little benefit to the Medicare program while taking advantage of the potential benefits of program participation, such as receipt of program data and the opportunity to enter into certain contracting arrangements with ACO participants and ACO providers/suppliers. The redesign of the program includes a number of features that may encourage continued participation by poor performing ACOs under performance-based risk: The relatively lower levels of risk under the BASIC track, the additional features available to eligible ACOs under performance-based risk (the opportunity for physicians and other practitioners participating in eligible two-sided model ACOs to furnish telehealth services under section 1899(l) of the Act, availability of a SNF 3-day rule waiver, and the ability to offer incentive payments to beneficiaries under a CMS-approved beneficiary incentive program), and the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program. We are concerned that ACOs may seek to obtain reinsurance to help offset their liability for shared losses as a way of enabling their continued program participation while undermining the program's goals. Although we considered prohibiting ACOs from obtaining reinsurance to mitigate their performance-based risk, we believe that such a requirement could be overly restrictive and that the proposed financial monitoring approach would be effective in removing from the program ACOs with a history of poor financial performance. We seek comment on this issue, and on ACOs' use of reinsurance, including their ability to obtain viable reinsurance products covering a Medicare FFS population.

We seek comment on these proposals and related considerations.

6. Requirements for ACO Participation in Two-Sided Models

a. Overview

In this section, we address requirements related to an ACO's participation in performance-based risk. We propose technical changes to the program's policies on election of the MSR/MLR for ACOs in the BASIC track's glide path, and to address the circumstance of ACOs in two-sided models that elected a fixed MSR/MLR that have fewer than 5,000 assigned beneficiaries for a performance year. We propose changes to the repayment mechanism requirement to update these policies to address the new participation options included in this proposed rule, including the BASIC track's glide path under which participating ACOs must transition from a one-sided model to performance-based risk within a single agreement period. We propose to add a provision that could lower the required repayment mechanism amount for BASIC track ACOs in Levels C, D, or E. In addition, we propose to add provisions to permit recalculation of the estimated amount of the repayment mechanism each performance year to account for changes in ACO participant composition, to codify requirements on the duration of repayment mechanism arrangements, to grant a renewing ACO (as defined in proposed § 425.20) the flexibility to maintain a single, existing repayment mechanism arrangement to support its ability to repay shared losses in the new agreement period so long as it is sufficient to cover an increased repayment mechanism amount during the new agreement period (if applicable), and to establish requirements regarding the issuing institutions for a repayment mechanism arrangement. In this section, we also propose new policies to hold ACOs participating in two-sided models accountable for sharing in losses when they terminate, or CMS terminates, their agreement before the end of a performance year, while also reducing the amount of advance notice required for early termination.

b. Election of MSR/MLR by ACOs

(1) Background

As discussed in earlier rulemaking, the MSR and MLR protect against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than an actual change in performance (see 76 FR 67927 through 67929; and 76 FR 67936 through 67937). The MSR and MLR are calculated as a percentage of the ACO's updated historical benchmark (see §§ 425.604(b) and (c), 425.606(b), 425.610(b)).

In the June 2015 final rule, we finalized an approach to offer Track 2 and Track 3 ACOs the opportunity to select the MSR/MLR that will apply for the duration of the ACO's 3-year agreement period from several symmetrical MSR/MLR options (see 80 FR 32769 through 32771, and 80 FR 32779 through 32780; §§ 425.606(b)(1)(ii) and 425.610(b)(1)). We explained our belief that offering ACOs a choice of MSR/MLR will encourage ACOs to move to two-sided risk, and that ACOs are best positioned to determine the level of risk they are prepared to accept. For instance, ACOs that are more hesitant to enter a performance-based risk arrangement may choose a higher MSR/MLR, to have the protection of a higher threshold before the ACO would become liable to repay shared losses, thus mitigating downside risk, although the ACO would in turn have a higher threshold to meet before being eligible to receive shared savings. ACOs that are comfortable with a lower threshold of protection from risk of shared losses may select a lower MSR/MLR to benefit from a corresponding lower threshold for eligibility for shared savings. We also explained our belief that applying the same MSR/MLR methodology in both of the risk-based tracks reduces complexity for CMS's operations and establishes more equal footing between the risk models. ACOs applying to the Track 1+ Model are also allowed the same choice of MSR/MLR to be applied for the duration of the ACO's agreement period under the Model.

ACOs applying to a two-sided model (currently, Track 2, Track 3 or the Track 1+ Model) may select from the following options:

- Zero percent MSR/MLR.
- Symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent.
- Symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under the one-sided model under § 425.604(b). The MSR is the same as the MSR that would apply in the one-sided model, and the MLR is equal to the negative MSR.

(2) Proposals for Timing and Selection of MSR/MLR

We considered what MSR/MLR options should be available for the BASIC track's glide path, as well as the timing of selection of the MSR/MLR for ACOs entering the glide path under a one-sided model and transitioning to a two-sided model during their agreement period under the BASIC track.

We propose that ACOs under the BASIC track would have the same MSR/MLR options as are currently available to ACOs under one-sided and two-sided models of the Shared Savings Program, as applicable to the model under which the ACO is participating along the BASIC track's glide path. We believe these thresholds continue to have importance to protect against savings and losses resulting from random variation, although we describe in section II.A.5.b of this proposed rule our consideration of an alternate approach

that would lower the MSR for low revenue ACOs. Further, providing the same MSR/MLR options for BASIC track ACOs under two-sided risk as ENHANCED track ACOs would be consistent with our current policy for Track 2 and Track 3 that allows ACOs to determine the level of risk they will accept while reducing complexity for CMS's operations and establishing more equal footing between the risk models.

Specifically, we propose that ACOs in a one-sided model of the BASIC track's glide path would have a variable MSR based on the ACO's number of assigned beneficiaries. We propose to apply the same variable MSR methodology as is used under § 425.604(b) for Track 1. We propose to specify this variable MSR methodology in a proposed new section of the regulations at § 425.605(b). We also propose to specify in § 425.605(b) the MSR/MLR options for ACOs under two-sided models of the BASIC track, consistent with previously described symmetrical MSR/MLR options currently available to ACOs in two-sided models of the Shared Savings Program and the Track 1+ Model (for example, as specified in § 425.610(b)).

Because we are proposing to discontinue Track 1, we believe it is necessary to update the provision governing the symmetrical MSR/MLR options for the ENHANCED track at § 425.610(b), which currently references the variable MSR methodology under Track 1. We propose to revise § 425.610(b)(1)(iii) to reference the requirements at § 425.605(b)(1) for a variable MSR under the BASIC track's glide path rather than the variable MSR under Track 1. Because we are also proposing to discontinue Track 2, concurrently with our proposal to discontinue Track 1, we do not believe it is necessary to revise the cross-reference in § 425.606(b)(1)(ii)(C) to the variable MSR methodology under Track 1.

We continue to believe that an ACO should select its MSR/MLR before assuming performance-based risk, and this selection should apply for the duration of its agreement period under risk. We believe that a policy that allows more frequent selection of the MSR/MLR within an agreement period under two-sided risk (such as prior to the start of each performance year) could leave the program vulnerable to gaming. For example, ACOs could revise their MSR/MLR selections once they have experience under performance-based risk in their current agreement period to maximize shared savings or to avoid shared losses.

However, in light of our proposal to require ACOs to move between a one-sided model (Level A or Level B) and a two-sided model (Level C, D, or E) during an agreement period in the BASIC track's glide path, we believe it is appropriate to allow ACOs to make their MSR/MLR selection during the application cycle preceding their first performance year in a two-sided model, generally during the calendar year before entry into risk. ACOs that enter the BASIC track's glide path under a one-sided model would still be inexperienced with performance-based risk, although they will have the opportunity to gain experience with the program, prior to making this selection. This approach would be another means for BASIC ACOs in the glide path to control their level of risk exposure.

Therefore, we propose to include a policy in the proposed new section of the regulations at § 425.605(b)(2) to allow ACOs under the BASIC track's glide path in Level A or Level B to choose the MSR/MLR to be applied before the start of their first performance year in a two-sided model. This selection would occur before the ACO enters Level C, D or E of the BASIC track's glide path, depending on whether the ACO is automatically transitioned to a two-sided model (Level C) or elects to more quickly transition to a two-sided model within the glide path (Level C, D, or E).

(3) Proposals for Modifying the MSR/MLR To Address Small Population Sizes

As discussed in the introduction to this section, the MSR and MLR protect against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than an actual change in performance. ACOs in two-sided risk models that have opted for a fixed MSR/MLR can choose a MSR/MLR of zero percent or a symmetrical MSR/MLR equal to 0.5 percent, 1.0 percent, 1.5 percent, or 2.0 percent. As discussed elsewhere in this proposed rule, we are proposing that ACOs in a two-sided model of the new BASIC track would have the same options in selecting their MSR/MLR, including the option of a variable MSR/MLR based on the number of beneficiaries assigned to the ACO.

Under the current regulations, for all ACOs in Track 1 and any ACO in a two-sided risk model that has elected a variable MSR/MLR, we determine the MSR and MLR (if applicable) for the performance year based on the number of beneficiaries assigned to the ACO for the performance year. For ACOs with at least 5,000 assigned beneficiaries in the performance year, the variable MSR can range from a high of 3.9 percent (for ACOs with at least 5,000 assigned beneficiaries) to a low of 2.0 percent (for ACOs with approximately 60,000 or more assigned beneficiaries). See § 425.604(b). For two-sided model ACOs under a variable MSR/MLR, the MLR is equal to the negative of the MSR.

Under section 1899(b)(2)(D) of the Act, in order to be eligible to participate in the Shared Savings Program an ACO must have at least 5,000 assigned beneficiaries. In earlier rulemaking, we established the requirements under § 425.110 to address situations in which an ACO met the 5,000 assigned beneficiary requirement at the start of its agreement period, but later falls below 5,000 assigned beneficiaries during a performance year. We refer readers to the November 2011 and June 2015 final rules and the CY 2017 PFS final rule for a discussion of the relevant background and related considerations (see 76 FR 67807 and 67808, 67959; 80 FR 32705 through 32707; 81 FR 80515 and 80516). CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the program's assignment methodology (§ 425.110(a)). CMS initially makes this assessment at the time of an ACO's application to the program. As specified in § 425.110(b), if at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the pre-termination actions described in § 425.216 and termination of the participation agreement by CMS under § 425.218. As a pre-termination action, CMS may require the ACO to submit a corrective action plan (CAP) to CMS for approval (§ 425.216). While under a CAP for having an assigned population below 5,000 assigned beneficiaries, an ACO remains eligible for shared savings and losses (§ 425.110(b)(1)). If the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS terminates the ACO's participation agreement and the ACO is not eligible to share in savings for that performance year (§ 425.110(b)(2)).

As specified in § 425.110(b)(1), if an ACO's performance year assigned beneficiary population falls below 5,000, the ACO remains eligible for shared savings/shared losses, but the following policies apply with respect to the ACO's MSR/MLR: (1) For ACOs subject to a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) will be set at a level consistent with the number of assigned

beneficiaries; (2) For ACOs with a fixed MSR/MLR, the MSR/MLR will remain fixed at the level consistent with the choice of MSR and MLR that the ACO made at the start of the agreement period.

To implement the requirement for the variable MSR and MLR (if applicable) to be set at a level consistent with the number of assigned beneficiaries, the CMS Office of the Actuary (OACT) calculates the MSR ranges for populations smaller than 5,000 assigned beneficiaries. The following examples are based on our operational experience: If an ACO's assigned beneficiary population drops to 3,000, the MSR would be set at 5 percent; if the population falls to 1,000 or 500, the MSR would correspondingly rise to 8.7 percent or 12.2 percent, respectively. These sharp increases in the MSR reflect the greater random variation that can occur when expenditures are calculated across a small number of assigned beneficiaries.

To date, the number of ACOs that have fallen below the 5,000-beneficiary threshold for a performance year has been relatively small. Among 432 ACOs that were reconciled in PY 2016, there were 12 ACOs with fewer than 5,000 assigned beneficiaries. In PY 2015 there were 15 (out of 392 ACOs) below the threshold and in PY 2014 there were 14 (out of 333 ACOs). While the majority of these ACOs had between 4,000 and 5,000 beneficiaries, we observed the performance year population fall as low as 513 for one ACO. Based on data available from fourth quarter 2017 program reports, which tend to provide a close approximation of final performance year assignment counts, over 4 percent of ACOs participating in PY 2017 are likely to fall below 5,000 assigned beneficiaries for the performance year, with several likely to be under 1,000.

Consistent with overall program participation trends, most ACOs that have fallen below the 5,000-beneficiary threshold in prior performance years, or that are anticipated to do so for PY 2017, have been in Track 1. These ACOs have thus automatically been subject to a variable MSR. With increased participation in performance-based risk models, however, we anticipate an increased likelihood of observing ACOs below the 5,000-beneficiary threshold that have a fixed MSR/MLR of plus or minus 2 percent or less.

Indeed, program data have demonstrated the popularity of the fixed MSR/MLR among ACOs in two-sided models. In PY 2016, the first year that ACOs in two-sided models were allowed to choose their MSR/MLR, 21 of 22 eligible ACOs selected one of the fixed options. Among the 42 Track 2 and Track 3 ACOs participating in PY 2017, 38 selected a MSR/MLR that does not vary with the ACO's number of assigned beneficiaries, including 11 that are subject to a MSR or MLR of zero percent. Among 101 ACOs participating in two-sided models in PY 2018, 80 are subject to one of the fixed options, including 18 with a MSR and MLR of zero percent.

While we continue to believe that ACOs operating under performance-based risk models should have flexibility in determining their exposure to risk through the MSR/MLR selection, we are concerned about the potential for rewarding ACOs with a static MSR/MLR that are unable to maintain a minimum population of 5,000 beneficiaries through the payment of shared savings, for expenditure variation that is likely the result of normal expenditure fluctuations, rather than the performance of the ACO. If the ACO's minimum population falls below 5,000, the ACO is no longer in compliance with program requirements. The reduction in the size of the ACO's assigned beneficiary population would also raise concerns that any shared savings payments made to the ACO would not reward true cost savings, but instead would pay for normal expenditure fluctuations. We note, however, that an ACO under performance-based risk potentially would be at greater risk of being liable for shared losses, also stemming from such normal expenditure variation. If an ACO's assigned population falls below the minimum requirement of 5,000 beneficiaries, a solution to improve the confidence that shared savings and shared losses do not represent normal variation, but meaningful changes in expenditures, would be to apply a symmetrical MSR/MLR that varies based on the number of beneficiaries assigned to the ACO.

The values for the variable MSR are shown in Table 8. As previously described, the MLR is equal to the negative MSR. In this table, the MSR ranges for population sizes varying between from 5,000 to over 60,000 assigned beneficiaries are consistent with the current approach to determining a variable MSR based on the size of the ACO's population (see § 425.604(b)), and the corresponding variable MLR. We have also added new values, calculated by the CMS OACT, for population sizes varying from one to 4,999, as shown in Table 8. For ACOs with populations between 500–4,999 beneficiaries, the MSR would range between 12.2 percent (for ACOs with 500 assigned beneficiaries) and 3.9 percent (for ACOs with 4,999 assigned beneficiaries). For ACOs with populations of 499 assigned beneficiaries or fewer, we would calculate the MSR to be equal to or greater than 12.2 percent, with the MSR value increasing as the ACO's assigned population decreases.

TABLE 8—DETERMINATION OF MSR BY NUMBER OF ASSIGNED BENEFICIARIES

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
1–499	≥12.2	
500–999	12.2	8.7
1,000–2,999	8.7	5.0
3,000–4,999	5.0	3.9
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0

TABLE 8—DETERMINATION OF MSR BY NUMBER OF ASSIGNED BENEFICIARIES—Continued

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
60,000 +	2.0	2.0

Therefore, we are proposing to modify § 425.110(b) to provide that we will use a variable MSR/MLR when performing shared savings and shared losses calculations if an ACO's assigned beneficiary population falls below 5,000 for the performance year, regardless of whether the ACO selected a fixed or variable MSR/MLR. We propose to use this approach beginning with performance years starting in 2019. The variable MSR/MLR would be determined using the same approach based on number of assigned beneficiaries that is currently used for two-sided model ACOs that have selected the variable option. If the ACO's assigned beneficiary population increases to 5,000 or more for subsequent performance years in the agreement period, the MSR/MLR would revert to the fixed level selected by the ACO at the start of the agreement period (or before moving to risk for ACOs on the BASIC track's glide path), if applicable.

While we believe this proposal would have a fairly limited reach in terms of number of ACOs impacted, we believe it is nonetheless important for protecting the integrity of the Trust Funds and better ensuring that the program is rewarding or penalizing ACOs for actual performance. The policy, if finalized, would make it more difficult for an ACO under performance-based risk that falls below the 5,000-beneficiary threshold to earn shared savings, but would also provide greater protection against owing shared losses.

We also propose to revise the regulations at § 425.110 to reorganize the provisions in paragraph (b), so that all current and proposed policies for determining the MSR and MLR would apply to all ACOs whose population fall below the 5,000-beneficiaries threshold which are reconciled for shared savings or losses, as opposed to being limited to ACOs under a CAP as provided in the existing provision at § 425.110(b)(1). Specifically we propose to move the current provisions on the determination of the MSR/MLR at paragraphs (b)(1)(i) and (ii) to a new provision at paragraph (b)(3) where we will also distinguish between the policies applicable to determining the MSR/MLR for performance years starting before January 1, 2019, and those that we are proposing to apply for performance years starting in 2019 and subsequent years.

We propose to specify the additional ranges for the MSR (when the ACO's population falls below 5,000 assigned beneficiaries) through revisions to the table at § 425.604(b), for use in determining an ACO's eligibility for shared savings for a performance year starting on January 1, 2019, and any remaining years of the current agreement period for ACOs under Track 1. We note these ranges are consistent with the program's current policy for setting the MSR and MLR (in the event a two-sided model ACO elected the variable MSR/MLR) when the population falls below 5,000 assigned beneficiaries, and therefore similar ranges would be applied in determining the MSR/MLR for performance year 2017 and 2018. These ranges in § 425.604(b) are cross-referenced in the regulations for Track 2 at § 425.606(b)(1)(ii)(C) and therefore would also apply to Track 2 ACOs if their population falls below 5,000 assigned beneficiaries. Further, as discussed in section II.A.6.b.2 of this proposed rule, we propose to specify under a new section of the regulations at § 425.605(b)(1) the range of MSR values that apply under the one-sided model of the BASIC track's glide path, which would also be used in determining the variable MSR/MLR for ACOs participating in two-sided models under the BASIC track and ENHANCED track. We seek comment on these proposals and specifically on the proposed MSR ranges for ACOs with fewer than 5,000 assigned beneficiaries, including the application of a MSR/MLR in excess of 12 percent, in the case of ACOs that have failed to meet the requirement to maintain a population of at least 5,000 assigned beneficiaries and have very small population sizes. In particular, we seek commenters' feedback on whether the proposed approach described in this section could improve accountability of ACOs.

We also note that the requirement of section 1899(b)(2)(D) of the Act, for an ACO to have at least 5,000 assigned beneficiaries, continues to apply. The additional consequences for ACOs with fewer than 5,000 assigned beneficiaries, as specified in § 425.110(b)(1) and (2) would also continue to apply. Under § 425.110(b)(2), ACOs are not eligible to share savings for a performance year in which they are terminated for noncompliance with the requirement to maintain a population of at least 5,000 assigned beneficiaries. As discussed in II.A.6.d of this proposed rule, we are proposing to revise our regulations governing the payment consequences of early termination to include policies applicable to involuntarily terminated ACOs. Under this proposed approach, two-sided model ACOs would be liable for a pro-rated share of any shared losses determined for the performance year during which a termination under § 425.110(b)(2) becomes effective.

c. ACO Repayment Mechanisms

(1) Background

We discussed in earlier rulemaking the requirement for ACOs applying to enter a two-sided model to demonstrate they have established an adequate repayment mechanism to provide CMS assurance of their ability to repay shared losses for which they may be liable upon reconciliation for each performance year.[18] The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in § 425.204(f), and we have provided additional program guidance on repayment mechanism arrangements.[19] Section 425.204(f) addresses various requirements for repayment mechanism arrangements: The nature of the repayment mechanism; when documentation of the repayment mechanism must be submitted to CMS; the amount of the repayment mechanism; replenishment of the repayment mechanism funds after their use; and the duration of the repayment mechanism arrangement.

[18] See 76 FR 67937 through 67940 (establishing the requirement for Track 2 ACOs). See also 80 FR 32781 through 32785 (adopting the same general requirements for Track 3 ACOs with respect to the repayment mechanism and discussing modifications to reduce burden of the repayment requirements on ACOs).

[19] Medicare Shared Savings Program & Medicare ACO Track 1+ Model, Repayment Mechanism Arrangements, Guidance Document (July 2017, version #6), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf* (herein Repayment Mechanism Arrangements Guidance).

Consistent with the requirements set forth in § 425.204(f)(2), in establishing a repayment mechanism for participation in a two-sided model of the Shared Savings Program, ACOs must select from one or more of the following three types of repayment arrangements: Funds placed in escrow; a line of credit as evidenced by a letter of credit that the Medicare program could draw upon; or a surety bond. Currently, our regulations do not specify any requirements regarding the institutions that may administer an escrow account or issue a line of credit or surety bond. Our regulations require an ACO to submit documentation of its repayment mechanism arrangement during the application or participation agreement renewal process and upon request thereafter.

The arrangement must be adequate to repay at least the minimum dollar amount specified by CMS, which is determined based on an estimation methodology that uses historical Medicare Parts A and B FFS expenditures for the ACO's assigned population. For Track 2 and Track 3 ACOs, the repayment mechanism must be equal to at least 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, as determined based on expenditures used to establish the ACO's benchmark for the applicable agreement period, as estimated by CMS at the time of application or participation agreement renewal (see § 425.204(f)(1)(ii), see also Repayment Mechanism Arrangements Guidance). In the Repayment Mechanism Arrangements Guidance, we describe in detail our approach to estimating the repayment mechanism amount for Track 2 and Track 3 ACOs and our experience with the magnitude of the dollar amounts.

More generally, program stakeholders have continued to identify the repayment mechanism requirement as a potential barrier for some ACOs to enter into performance-based risk tracks, particularly small, physician-only and rural ACOs that may lack access to the capital that is needed to establish a repayment mechanism with a large dollar amount. We revised the Track 1+ Model design in July 2017 (See Track 1+ Model Fact Sheet (Updated July 2017)), to allow for potentially lower repayment mechanism amounts for participating ACOs under a revenue-based loss sharing limit (that is, ACOs that do not include an ACO participant that is either (i) an IPPS hospital, cancer center, or rural hospital with more than 100 beds; or (ii) an ACO participant that is owned or operated by such a hospital or by an organization that owns or operates such a hospital). This policy provides greater consistency between the repayment mechanism amount and the level of risk assumed by revenue-based or benchmark-based ACOs and helps alleviate the burden of securing a higher repayment mechanism amount based on the ACO's benchmark expenditures, as required for Track 2 and Track 3 ACOs. We believe this approach is appropriate for this subset of Track 1+ Model ACOs because they are generally at risk for repaying a lower amount of shared losses than other ACOs that are subject to a benchmark-based loss sharing limit (that is, ACOs that include the types of ACO participants previously identified in this proposed rule). Therefore, under the Track 1+ Model, a bifurcated approach is used to determine the estimated amount of an ACO's repayment mechanism for consistency with the bifurcated approach to determining the loss sharing limit under the Track 1+ Model. For Track 1+ Model ACOs, CMS estimates the amount of the ACO's repayment mechanism as follows:

- *ACOs subject to the benchmark-based loss sharing limit:* The repayment mechanism amount is 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, as determined based on expenditures used to establish the ACO's benchmark for the applicable agreement period.
- *ACOs subject to the revenue-based loss sharing limit:* The repayment mechanism amount is the lower of (1) 2 percent of the ACO participants' total Medicare Parts A and B FFS revenue, or (2) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, as determined based on expenditures used to establish the ACO's benchmark.

Under § 425.204(f)(3), an ACO must replenish the amount of funds available through the repayment mechanism within 90 days after the repayment mechanism has been used to repay any portion of shared losses owed to CMS. In addition, our regulations require a repayment mechanism arrangement to remain in effect for a sufficient period of time after the conclusion of the agreement period to permit CMS to calculate and to collect the amount of shared losses owed by the ACO. As noted in our Repayment Mechanism Arrangements Guidance, we believe that this standard would be satisfied by an arrangement that terminates 24 months following the end of the agreement period.

(2) Proposals Regarding Repayment Mechanism Amounts

As previously noted, an ACO that is seeking to participate in a two-sided model must submit for CMS approval documentation supporting the adequacy of a mechanism for repaying shared losses, including demonstrating that the value of the arrangement is at least the minimum amount specified by CMS. We propose to modify § 425.204(f) to address concerns regarding the amount of the repayment mechanism, to specify the data used by CMS to determine the repayment mechanism amount, and to permit CMS to specify a new repayment mechanism amount annually based on changes in ACO participants.

In general, we believe that, like other ACOs participating in two-sided risk tracks, ACOs applying to participate in the BASIC track under performance-based risk should be required to provide CMS assurance of their ability to repay shared losses by establishing an adequate repayment mechanism. Consistent with the approach used under the Track 1+ Model, we believe the amount of the repayment mechanism should be potentially lower for BASIC track ACOs compared to the repayment mechanism amounts required for ACOs in Track 2 or the ENHANCED track. We would calculate a revenue-based repayment mechanism amount and a benchmark-based repayment mechanism amount for each BASIC track ACO and require the ACO to obtain a repayment mechanism for the lower of the two amounts described previously. We believe this aligns with our proposed approach for determining the loss sharing limit for ACOs participating in the BASIC track, described in section II.A.3.b. of this proposed rule. In addition, this approach balances concerns about the ability of ACOs to take on performance-based risk and repay any shared losses for which they may be liable with concerns about the burden imposed on ACOs seeking to enter and continue their participation in the BASIC track.

Previously, we have used historical data to calculate repayment mechanism amounts, typically using the same reference year to calculate the estimates consistently for all applicants to a two-sided model. As a basis for the estimate, we have typically used assignment and expenditure data from the most recent prior year for which 12 months of data are available, which tends to be benchmark year 2 for ACOs applying to enter the program or renew their participation agreement (for example, calendar year 2016 data for ACOs applying to enter participation

agreements beginning January 1, 2018). The Repayment Mechanism Arrangements Guidance includes a detailed description of how we have previously estimated 1 percent of the total per capita Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries based on the expenditures used to establish the ACO's benchmark. To continue calculating the estimates with expenditures used to calculate the benchmark, we would need to use different sets of historical data for ACOs applying to enter or renew an agreement and those transitioning to a performance-based risk track. That is because ACOs applying to start a new agreement period under the program and ACOs transitioning to risk within different years of their current agreement period will have different benchmark years. To avoid undue operational burden, we propose to use the most recent calendar year, for which 12 months of data is available to calculate repayment mechanism estimates for all ACOs applying to enter, or transitioning to, performance-based risk for a particular performance year. We believe this approach to using more recent historical data to estimate the repayment mechanism amount would more accurately approximate the level of losses for which the ACO could be liable regardless of whether the ACO is subject to a benchmark-based or revenue-based loss sharing limit.

Therefore, we are proposing to amend § 425.204(f)(4) to specify the methodologies and data used in calculating the repayment mechanism amounts for BASIC track, Track 2, and ENHANCED track ACOs. For an ACO in Track 2 or the ENHANCED track, we propose that the repayment mechanism amount must be equal to at least 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available. For a BASIC track ACO, the repayment mechanism amount must be equal to the lesser of (i) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (ii) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. For ACOs with a participant agreement start date of July 1, 2019, we also propose to calculate the repayment mechanism amount using expenditure data from the most recent calendar year for which 12 months of data are available.

Currently, we generally do not revise the estimated repayment mechanism amount for an ACO during its agreement period. For example, we typically do not revise the repayment mechanism amount during an ACO's agreement period to reflect annual changes in the ACO's certified ACO participant list. However, in the Track 1+ Model, CMS may require the ACO to adjust the repayment mechanism amount if changes in an ACO's participant composition occur within the ACO's agreement period that result in the application of relatively higher or lower loss sharing limits. As explained in the Track 1+ Model Fact Sheet, if the estimated repayment mechanism amount increases as a result of the ACO's change in composition, CMS would require the Track 1+ ACO to demonstrate its repayment mechanism is equal to this higher amount. If the estimated amount decreases as a result of its change in composition, CMS may permit the ACO to decrease the amount of its repayment mechanism (for example, if CMS also determines the ACO does not owe shared losses from the prior performance year under the Track 1+ Model).

We believe a similar approach may be appropriate to address changes in the ACO's composition over the course of an agreement period and to ensure the adequacy of an ACO's repayment mechanism as it enters higher levels of risk within the ENHANCED track or the BASIC track's glide path. During an agreement period, an ACO's composition of ACO participant TINs and the providers/suppliers enrolled in the ACO participant TINs may change. The repayment mechanism estimation methodology we previously described in this section uses data based on the ACO participant list, including estimated expenditures for the ACO's assigned population, and in the case of the proposed BASIC track, estimated revenue for ACO participant TINs. See for example, Repayment Mechanism Arrangements Guidance (describing the calculation of the repayment mechanism amount estimate). As a result, over time the initial repayment mechanism amount calculated by CMS may no longer represent the expenditure trends for the ACO's assigned population or ACO participant revenue and therefore may not be sufficient to ensure the ACO's ability to repay losses. For this reason, we believe it would be appropriate to periodically recalculate the amount of the repayment mechanism arrangement.

For agreement periods beginning on or after July 1, 2019, we propose to recalculate the estimated amount of the ACO's repayment mechanism arrangement before the second and each subsequent performance year in which the ACO is under a two-sided model in the BASIC track or ENHANCED track. If we determine the estimated amount of the ACO's repayment mechanism has increased, we may require the ACO to demonstrate the repayment mechanism arrangement covers at least an amount equal to this higher amount.

We propose to make this determination as part of the ACO's annual certification process, in which it finalizes changes to its ACO participant list prior to the start of each performance year. We would recalculate the estimate for the ACO's repayment mechanism based on the certified ACO participant list each year after the ACO begins participation in a two-sided model in the BASIC track or ENHANCED track. If the amount has increased substantially (for example, by at least 10 percent or $100,000, whichever is the lesser value), we would notify the ACO in writing and require the ACO to submit documentation for CMS approval to demonstrate that the funding for its repayment mechanism has been increased to reflect the recalculated repayment mechanism amount. We would require the ACO to make this demonstration within 90 days of being notified by CMS of the required increase.

We recognize that in some cases, the estimated amount may change insignificantly. Requiring an amendment to the ACO's arrangement (such as the case would be with a letter of credit or surety bond) would be overly burdensome and not necessary for reassuring CMS of the adequacy of the arrangement. Therefore, we propose to evaluate the amount of change in the ACO's repayment mechanism, comparing the newly estimated amount and the amount estimated for the most recent prior performance year. If this amount has increased by equal to or greater than either 10 percent or $100,000, whichever is the lesser value, we would require the ACO to demonstrate that it has increased the dollar amount of its arrangement to the recalculated amount. We solicit comments on whether a higher or lower change in the repayment mechanism estimate should trigger the ACO's obligation to increase its repayment mechanism amount.

However, unlike the Track 1+ Model, we propose that if the estimated amount decreases as a result of the ACO's

change in composition, we will not permit the ACO to decrease the amount of its repayment mechanism. The ACO repayment mechanism estimate does not account for an ACO's maximum liability amount and it is possible for an ACO to owe more in shared losses than is supported by the repayment mechanism arrangement. Because of this, we believe it is more protective of the Trust Funds to not permit decreases in the repayment mechanism amount, during an ACO's agreement period under a two-sided model, based on composition changes.

We believe the requirements for repayment mechanism amounts should account for the special circumstances of renewing ACOs, which would otherwise have to maintain two separate repayment mechanisms for overlapping periods of time. As discussed in section II.A.5.c.4, we propose to define ''renewing ACO'' to mean an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either: (1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or (2) an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program. We propose at § 425.204(f)(3)(iv) that a renewing ACO can use its existing repayment mechanism to demonstrate that it has the ability to repay losses that may be incurred for performance years in the next agreement period, as long as the ACO submits documentation that the term of the repayment mechanism has been extended and the amount of the repayment mechanism has been updated, if necessary. However, depending on the circumstances, a renewing ACO may have greater potential liability for shared losses under its existing agreement period compared to its potential liability for shared losses under a new agreement period. Therefore, we propose that if an ACO wishes to use its existing repayment mechanism to demonstrate its ability to repay losses in the next agreement period, the amount of the existing repayment mechanism must be equal to the greater of the following: (1) The amount calculated by CMS in accordance with the benchmark-based methodology or revenue-based methodology, as applicable by track (see proposed § 425.204(f)(4)(iv)); or (2) the repayment mechanism amount that the ACO was required to maintain during the last performance year of its current agreement. This proposal protects the financial integrity of the program by ensuring that a renewing ACO will remain capable of repaying losses incurred under its old agreement period.

We propose to consolidate at § 425.204(f)(4) all of our proposed policies, procedures, and requirements related to the amount of an ACO's repayment mechanism, including provisions regarding the calculation and recalculation of repayment mechanism amounts. We also propose to revise the regulations at § 425.204 to streamline and reorganize the provisions in paragraph (f), which we believe is necessary to incorporate these and other proposed requirements discussed in this proposed rule.

(3) Proposals Regarding Submission of Repayment Mechanism Documentation

Currently, ACOs applying to enter a performance-based risk track under the Shared Savings Program must meet the eligibility requirements, including demonstrating they have established an adequate repayment mechanism under § 425.204(f). We believe modifications to the existing repayment mechanism requirements are necessary to address circumstances that could arise if our proposed approach to allowing ACOs to enter or change risk tracks during the current agreement period is finalized. Specifically, we believe modifications would be necessary to reflect the possibility that an ACO that initially entered into an agreement period under the one-sided model years of the BASIC track's glide path will transition to performance-based risk within their agreement period, and thereby would become subject to the requirement to establish a repayment mechanism.

The current regulations specify that an ACO participating under a two-sided model must demonstrate the adequacy of its repayment mechanism prior to the start of each agreement period in which it takes risk and upon request thereafter (§ 425.204(f)(3)). We are revisiting this policy in light of our proposal to automatically transition ACOs in the BASIC track's glide path from a one-sided model to a two-sided model beginning in their third performance year, and also under our proposal that would allow BASIC ACOs to elect to transition to performance-based risk beginning in their second performance year of the glide path.

We believe ACOs participating in the BASIC track's glide path should be required to demonstrate they have established an adequate repayment mechanism, consistent with the requirement for ACOs applying to enter an agreement period under performance-based risk. Therefore, we are proposing to amend the regulations to provide that an ACO entering an agreement period in Levels C, D, or E of the BASIC track's glide path must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period and at such other times as requested by CMS. In addition, we are proposing that an ACO entering an agreement period in Level A or Level B of the BASIC track's glide path must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to a two-sided model (Level C, Level D, or Level E) of the BASIC track's glide path, and at such other times as requested by CMS.

We seek comment on these proposals.

(4) Proposal for Repayment Mechanism Duration

We acknowledge that the proposed change to an agreement period of at least 5 years will affect the term for the repayment mechanism. Under the program's current requirements, the repayment mechanism must be in effect for a sufficient period of time after the conclusion of the agreement period to permit CMS to calculate the amount of shared losses owed and to collect this amount from the ACO (§ 425.204(f)(4)).

We point readers to the June 2015 final rule for a discussion of the requirement for ACOs to demonstrate that they would be able to repay shared losses incurred at any time within the agreement period, and for a reasonable period of time after the end of each agreement period (the ''tail period''). We explained that this tail period must be sufficient to permit CMS to calculate the amount of any shared losses that may be owed by the ACO and to collect this amount from the ACO (see 80 FR 32783). This is necessary, in part, because financial reconciliation results are not available until the summer following the conclusion of the performance year. We have interpreted this requirement to be satisfied if the repayment mechanism arrangement will remain in effect for 24 months after the end of the agreement period (see Repayment Mechanism Arrangements Guidance). Once ACOs are notified of shared losses, based on financial reconciliation, they have 90 days to make payment in full (see §§ 425.606(h) and 425.610(h)).

We propose to specify at § 425.204(f)(6) the general rule that a repayment mechanism must be in effect for the duration of the ACO's

participation in a two-sided model plus 24 months after the conclusion of the agreement period. Based on our experience with repayment mechanisms, we believe ACOs will be able to work with financial institutions to establish repayment mechanism arrangements that will cover a 5-year agreement period plus a 24-month tail period. This proposed approach is consistent with the program's current guidance.

We propose some exceptions to this general rule. First, we propose that CMS may require an ACO to extend the duration of its repayment mechanism beyond the 24-month tail period if necessary to ensure that the ACO will repay CMS any shared losses for each of the performance years of the agreement period. We believe this may be necessary in rare circumstances to protect the financial integrity of the program.

Second, we believe the duration requirement should account for the special circumstances of renewing ACOs, which would otherwise have to maintain two separate repayment mechanisms for overlapping periods of time. As previously noted, we propose at § 425.204(f)(3)(iv) that a renewing ACO can choose to use its existing repayment mechanism to demonstrate that it has the ability to repay losses that may be incurred for performance years in the next agreement period, as long as the ACO submits documentation that the term of the repayment mechanism has been extended and the amount of the repayment mechanism has been increased, if necessary. We propose at § 425.204(f)(6) that the term of the existing repayment mechanism must be extended in these cases and that it must periodically be extended thereafter upon notice from CMS.

We are considering the amount of time by which we would require the existing repayment mechanism to be extended. As discussed in section II.A.5 of this proposed rule, renewing ACOs (as we propose to define that term at § 425.20) may have differing numbers of years remaining under their current repayment mechanism arrangements depending on whether the ACO is renewing at the conclusion of its existing agreement period or if the ACO is an early renewal (terminating its current agreement to enter a new agreement period without interruption in participation). We recognize that it may be difficult for ACOs that are completing the term of their current agreement period to extend an existing repayment mechanism by 7 years (that is, for the full 5-year agreement term plus 24 months). Therefore, we are considering whether the program would be adequately protected if we permitted the existing repayment mechanism to be extended long enough to cover the first 2 or 3 performance years of the new agreement period (that is, an extension of 4 or 5 years, respectively, including the 24-month tail period). We solicit comment on whether we should require a longer or shorter extension.

If we permit an ACO to extend its existing repayment mechanism for less than 7 years, we would require the ACO to extend the arrangement periodically upon notice from CMS. Under this approach, the ACO would eventually have a repayment mechanism arrangement that would not expire until at least 24 months after the end of the new agreement period. We seek comment on whether this approach should also apply to an ACO entering two-sided risk for the first time (that is, an ACO that is not renewing its participation agreement). We would continue to permit a renewing ACO to maintain two separate repayment mechanisms (one for the current agreement period and one for the new agreement period).

Under our proposal, if CMS notifies a renewing ACO that its repayment mechanism amount will be higher for the new agreement period, the ACO may either (i) establish a second repayment mechanism arrangement in the higher amount for 7 years (or for a lesser duration that we may specify in the final rule), or (ii) increase the amount of its existing repayment mechanism to the amount specified by CMS and extend the term of the repayment mechanism arrangement for an amount of time specified by CMS (7 years or for a lesser duration that we may specify in the final rule). On the other hand, if CMS notifies a renewing ACO that the repayment mechanism amount for its new agreement period is equal to or lower than its existing repayment mechanism amount, the ACO may similarly choose to extend the duration of its existing repayment mechanism instead of obtaining a second repayment mechanism for the new agreement period. However, in that case, the ACO would be required to maintain the repayment mechanism at the existing higher amount.

Third, we believe that the term of a repayment mechanism may terminate earlier than 24 months after the agreement period if it is no longer needed. Under certain conditions, we permit early termination of a repayment mechanism and release of the arrangement's remaining funds to the ACO. These conditions are specified in the Repayment Mechanism Arrangements Guidance, and we propose to include similar requirements at § 425.204(f)(6). Specifically, we propose that the repayment mechanism may be terminated at the earliest of the following conditions:

- The ACO has fully repaid CMS any shared losses owed for each of the performance years of the agreement period under a two-sided model;
- CMS has exhausted the amount reserved by the ACO's repayment mechanism and the arrangement does not need to be maintained to support the ACO's participation under the Shared Savings Program; or
- CMS determines that the ACO does not owe any shared losses under the Shared Savings Program for any of the performance years of the agreement period. For example, if a renewing ACO opts to establish a second repayment mechanism for its new agreement period, it may request to cancel the first repayment mechanism after reconciliation for the final performance year of its previous agreement period if it owes no shared losses for the final performance year and it has repaid all shared losses, if any, incurred during the previous agreement period.

We solicit comments on whether the provisions proposed at § 425.204(f)(6) are adequate to protect the financial integrity of the Shared Savings Program, to provide greater certainty to ACOs and financial institutions, and to facilitate the establishment of repayment mechanism arrangements.

(5) Proposals Regarding Institutions Issuing Repayment Mechanism Arrangements

We are also proposing additional requirements related to the financial institutions through which ACOs establish their repayment mechanism arrangements that would be applicable to all ACOs participating in a performance-based risk track. With the proposed changes to offer only the BASIC track and ENHANCED track for agreement periods beginning on July 1, 2019 and in subsequent years, we anticipate an increase in the number of repayment mechanism arrangements CMS will review with each annual application cycle. We believe the proposed new requirements regarding the financial institutions with which ACOs establish their repayment mechanisms would provide CMS greater certainty about the adequacy of repayment mechanism arrangements and ultimately ease the process for reviewing and approving the ACO's repayment mechanism arrangement documentation.

Currently, as described in the program's Repayment Mechanism Arrangements Guidance, CMS will accept an escrow account arrangement established with a bank that is insured by the Federal Deposit Insurance Corporation (FDIC), a letter of credit established at a FDIC-insured institution, and a surety bond issued by a company included on the U.S. Department of Treasury's list of certified (surety bond) companies (available at *https://www.fiscal.treasury.gov/fsreports/ref/suretyBnd/c570_a-z.htm*). We have found that arrangements issued by these institutions tend to be more conventional arrangements that conform to the program's requirements. However, we recognize that some ACOs may work with other types of financial institutions that may offer similarly acceptable products, but which may not conform to the standards described in our existing Repayment Mechanism Arrangements Guidance. For example, some ACOs may prefer to use a credit union to establish an escrow account or a letter of credit for purposes of meeting the repayment mechanism arrangements requirement, but credit unions are insured under the National Credit Union Share Insurance Fund program, rather than by the FDIC. Although the insuring entity is different, credit unions typically are insured up to the same insurance limit as FDIC-insured banks, and are otherwise capable of offering escrow accounts and letters of credit that meet program requirements. We also believe that incorporating more complete standards for repayment mechanisms into the regulations would provide additional clarity for ACOs regarding acceptable repayment mechanisms and will help to avoid situations where an ACO may obtain a repayment mechanism arrangement from an entity that ultimately is unable to pay CMS the value of the repayment mechanism in the event CMS seeks to use the arrangement to recoup shared losses for which the ACO is liable.

Since the June 2015 final rule, several ACO applicants have requested use of arrangements from entities other than those described in our Repayment Mechanism Arrangements Guidance, such as a letter of credit issued by the parent corporation of an ACO, and funds held in escrow by an attorney's office. In reviewing these requests, we found a similar level of complexity resulting from the suggested arrangements as we did with our earlier experiences reviewing alternative repayment arrangements, which were permitted during the initial years of the Shared Savings Program until the regulations were revised in the June 2015 final rule to remove the option to establish an appropriate alternative repayment mechanism. In proposing to eliminate this option, we explained that a request to use an alternative repayment mechanism increases administrative complexity for both ACOs and CMS during the application process and is more likely to be declined by CMS (see 79 FR 72832). Although our program guidance (as specified in Repayment Mechanism Arrangements Guidance, version 6, July 2017) encourages ACOs to obtain a repayment mechanism from a financial institution, these recent requests for approval of more novel repayment arrangements have alerted CMS to the potential risk that ACOs may seek approval of repayment mechanism arrangements from organizations other than those that CMS has determined are likely to be most financially sound and able to offer products that CMS can readily verify as appropriate repayment mechanisms that ensure the ACO's ability to repay any shared losses.

Therefore, we propose to revise § 425.204(f)(2) to specify the following requirements about the institution issuing the repayment mechanism arrangement: an ACO may demonstrate its ability to repay shared losses by placing funds in escrow with an insured institution, obtaining a surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies, or establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon) at an insured institution. We anticipate updating the Repayment Mechanism Arrangements Guidance to specify the types of institutions that would meet these new requirements. For example, in the case of funds placed in escrow and letters of credit, the repayment mechanism could be issued by an institution insured by either the Federal Deposit Insurance Corporation or the National Credit Union Share Insurance Fund. The proposed revisions would bring clarity to the program's requirements, which will assist ACOs in selecting, and reduce burden on CMS in reviewing and approving, repayment mechanism arrangements. We welcome commenters' suggestions on these proposed requirements for ACOs regarding the issuing institution for repayment mechanism arrangements.

d. Advance Notice for and Payment Consequences of Termination

(1) Background

Sections 425.218 and 425.220 of the regulations describe the Shared Savings Program's termination policies. Section 425.221, added by the June 2015 final rule, specifies the close-out procedures and payment consequences of early termination. Under § 425.218, CMS can terminate the participation agreement with an ACO when the ACO fails to comply with any of the requirements of the Shared Savings Program. As described in § 425.220, an ACO may also voluntarily terminate its participation agreement. The ACO must provide at least 60 days advance written notice to CMS and its ACO participants of its decision to terminate the participation agreement and the effective date of its termination.

The November 2011 final rule establishing the Shared Savings Program indicated at § 425.220(b) (although this provision was subsequently revised) that ACOs that voluntarily terminated during a performance year would not be eligible to share in savings for that year (76 FR 67980). The June 2015 final rule revised this policy to specify in § 425.221(b)(1) that if an ACO voluntarily terminates with an effective termination date of December 31st of the performance year, the ACO may share in savings only if it has completed all required close-out procedures by the deadline specified by CMS and has satisfied the criteria for sharing savings for the performance year. ACOs that voluntarily terminate with an effective date of termination prior to December 31st of a performance year and ACOs that are involuntarily terminated under § 425.218 are not eligible to share in savings for the performance year.

The current regulations also do not impose any liability for shared losses on two-sided model ACOs that terminate from the program prior to December 31 of a given performance year. As explained in the June 2015 final rule, the program currently has no methodology for partial year reconciliation (80 FR 32817). As a result, ACOs that voluntarily terminate before the end of the performance year are neither eligible to share in savings nor accountable for any shared losses.

The existing policies on termination and the payment consequences of early termination raise concerns for both stakeholders and CMS. First, stakeholders have raised concerns that the current requirement for 60 days advance notice of a voluntary termination is too long because it does not allow ACOs to make timely, informed decisions about their continued participation in the program. Further, we are concerned that under the current policy, ACOs in two-sided models that are projecting losses have an incentive to leave the program prior

to the end of a performance year, whereas ACOs that are projecting savings are likely to stay. Absent a change in our current policies on early termination, these incentives could have a detrimental effect on the Medicare Trust Funds.

(2) Proposals for Advance Notice of Voluntary Termination

We are sympathetic to stakeholder concerns that the existing requirement for a 60-day notification period may hamper ACOs' ability to make timely and informed decisions about their continued participation in the program. A key factor in the timing of ACOs' participation decisions is the availability of program reports. Financial reconciliation reports (showing CMS's determination of the ACO's eligibility for shared savings or losses) are typically made available in the summer following the conclusion of the calendar year performance year (late July—August of the subsequent calendar year). Due to the timing of the production of quarterly reports (with information on the ACO's assigned beneficiary population, and expenditure and utilization trends), an ACO contemplating a year-end termination typically only has two quarters of feedback for the current performance year to consider in its decision-making process. This is because quarterly reports are typically made available approximately 6 weeks after the end of the applicable calendar year quarter. For example, quarter 3 reports would be made available to ACOs in approximately mid-November of each performance year. These dates for delivery of program reports also interact with the application cycle timeline (with ACOs typically required to notify CMS of their intent to apply in May, typically before quarter 1 reports are available, and submit applications during the month of July, prior to receiving quarter 2 reports), as applicants seek to use financial reconciliation data for the prior performance year and quarterly report data for the current performance year to make participation decisions about their continued participation, particularly ACOs applying to renew their participation for a subsequent agreement period.

We believe that adopting a shorter notice requirement would provide ACOs with more flexibility to consider their options with respect to their continued participation in the program. We are therefore proposing to revise § 425.220 to reduce the minimum notification period from 60 to 30 days. Reducing the notice requirement to 30 days would typically allow ACOs considering a year-end termination to base their decision on three quarters of feedback reports instead of two, given current report production schedules.

(3) Proposals for Payment Consequences of Termination

In this section, we discuss payment consequences of early termination of an ACO's participation agreement. We reconsidered the program's current policies on payment consequences of termination under § 425.221 in light of our proposal to reduce the amount of advance notice from ACOs of their voluntarily termination of participation under § 425.220. While we believe that the proposal to shorten the notice period for voluntary termination under § 425.220 from 60 to 30 days would be beneficial to ACOs, we recognize that it may increase gaming among risk-bearing ACOs facing losses, as ACOs would have more time and information to predict their financial performance with greater accuracy.

To deter gaming while still providing flexibility for ACOs in two-sided models to make decisions about their continued participation in the program, we considered several policy alternatives to hold these ACOs accountable for some portion of the shared losses generated during the performance year in which they terminate their participation in the program.

We first considered a policy similar to that used in the Next Generation ACO (NGACO) Model whereby ACOs may terminate without penalty if they do so by providing notice to CMS on or before February 28, with an effective date 30 days after the date of the notice (March 30). ACOs that terminate after that date are subject to financial reconciliation. These ACOs are liable for any shared losses determined and are also eligible to share in savings. The NGACO Model adopted March 30 as the deadline for the effective termination date in order to align with timelines for the Quality Payment Program. Specifically, this date ensures that clinicians affiliated with a terminating NGACO will not be included in the March 31 snapshot date for QP determinations. However, while we acknowledge the merit of reducing provider uncertainty around Quality Payment Program eligibility, we also recognize that in the early part of the performance year, ACOs have a limited amount of information on which to base termination decisions. We are especially concerned that holding ACOs accountable for full shared losses may lead many organizations to leave the program early in the performance year, including those that would have ultimately been eligible for shared savings had they continued their participation. Post-termination, Shared Savings Program ACOs no longer have access to the same program resources that can help to facilitate care management, such as beneficiary-identifiable claims data or payment rule waivers, such as the SNF 3-day rule waiver. This could make it more challenging for these entities to reduce costs, possibly offsetting any benefits to the Medicare Trust Funds from reduced gaming.

Given the drawbacks of setting an early deadline for ACOs to withdraw without financial risk, we also considered a policy under which risk-bearing ACOs that voluntarily terminate with an effective date after June 30 of a performance year would be liable for a portion of any shared losses determined for the performance year. We believe that June 30 is a reasonable deadline for the effective date of termination as it allows ACOs time to accumulate more information and make decisions regarding their continued participation in the program. As is the case under current policy, clinicians affiliated with ACOs that terminate with an effective date between March 31 and June 30 would be captured in one or more QP determination snapshots. Clinicians determined to have QP status would lose their status as a result of the termination, and would instead be scored under MIPS using the APM scoring standard.

We propose to conduct financial reconciliation for all ACOs in two-sided models that voluntarily terminate after June 30. We propose to use the full 12 months of performance year expenditure data in performing reconciliation for terminated ACOs with partial year participation. For those ACOs that generate shared losses, we will pro-rate the shared loss amount by the number of months during the year in which the ACO was in the program. To calculate the pro-rated share of losses, CMS will multiply the amount of shared losses calculated for the performance year by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12. We would count any month in which the ACO had at least one day of participation. Therefore, an ACO with an effective date of termination any time in July would be liable for 7/12 of any shared losses determined, while an ACO with an effective date of termination any time in August would be liable for 8/12, and so forth. An ACO with an effective date of

termination in December would be liable for the entirety of shared losses. Terminated ACOs would continue to receive aggregate data reports following termination, but, as under current policy, would lose access to beneficiary-level claims data and any payment rule waivers.

We believe this approach provides an incentive for ACOs to continue to control growth in expenditures and report quality for the relevant performance year even after they leave the program, as both can reduce the amount of shared losses owed. Increasing the proportion of shared losses owed with the number of months in the year that the ACO remains in the program also helps to counteract the potential for gaming, as ACOs that wait to base their termination decision on additional information are liable for a higher portion of any shared losses that are incurred. This approach also reflects the fact that later-terminating ACOs may have enjoyed program flexibilities (for example, the SNF 3-day rule waiver) for a longer period of time.

We also considered the payment consequences of early termination for ACOs that are involuntarily terminated by CMS under § 425.218. Although these ACOs are not choosing to leave the program of their own accord and thus are not using termination as a means of avoiding their responsibility for shared losses, we believe they should not be excused from responsibility for some portion of shared losses simply because they failed to comply with program requirements. Further, we believe it is more appropriate to hold involuntarily terminated ACOs accountable for a portion of shared losses during any portion of the performance year. Since involuntary terminations can occur throughout the performance year, establishing a cut-off date for determining the payment consequences for these ACOs could allow some ACOs to avoid accountability for their losses. Therefore, we propose to pro-rate shared losses for ACOs in two-sided models that are involuntarily terminated by CMS under § 425.218 for any portion of the performance year during which the termination becomes effective. We propose the same methodology as previously described for pro-rating shared losses for voluntarily terminated ACOs would also apply to involuntarily terminated ACOs.

We considered whether to allow ACOs voluntarily terminating after June 30 but before December 31 an opportunity to share in a portion of any shared saving earned. However, we decided to limit the proposed changes to shared losses. While we recognize that this approach may appear to favor CMS, we believe that ACOs expecting to generate savings are less likely to terminate early in the first place. Under the program's current regulations at § 425.221(b)(1), ACOs that voluntarily terminate effective December 31 and that meet the current criteria in § 425.221 may still share in savings.

We propose to amend § 425.221 to provide that ACOs in two-sided models that are terminated by CMS under § 425.218 or certain ACOs that voluntarily terminate under § 425.220 will be liable for a pro-rated amount of any shared losses determined, with the pro-rated amount reflecting the number of months during the performance year that the ACO was in the program. We propose to apply this policy to ACOs in two-sided models for performance years beginning in 2019 and subsequent performance years.

We also propose to specify in the regulations at § 425.221 the payment consequences of termination during calendar year 2019 for ACOs preparing to enter or participating under agreements beginning July 1, 2019 (see section II.A.7 of this proposed rule).

First, as discussed in detail in section II.A.7 of this proposed rule, we would reconcile ACOs based on the respective 6-month performance year methodology for their participation during a 6-month portion of 2019 in which they are either under a current agreement period beginning prior to 2019, or under a new agreement period beginning July 1, 2019. We propose an ACO would be eligible to receive shared savings for a 6-month performance year during 2019, if they complete the term of this performance year, regardless of whether they choose to continue their participation in the program. That is, we would reconcile: ACOs that started a first or second agreement period January 1, 2016 that extend their agreement period for a fourth performance year, and complete this performance year (concluding June 30, 2019); and ACOs that enter an agreement period July 1, 2019 and terminate December 31, 2019, the final calendar day of their first performance year (defined as a 6-month period).

For an ACO that participates for a portion of a 6-month performance year during 2019 (January 1, 2019 through June 30, 2019, July 1, 2019 through December 31, 2019) we propose the following: (1) If the ACO terminates its participation agreement effective before the end of the performance year, we would not reconcile the ACO for shared savings or shared losses (if a two-sided model ACO); (2) if CMS terminates a two-sided model ACO's participation agreement effective before the end of the performance year, the ACO would not be eligible for shared savings and we would reconcile the ACO for shared losses and pro-rate the amount reflecting the number of months during the performance year that the ACO was in the program.

To determine pro-rated shared losses for a portion of the 6-month performance year, we would determine shared losses incurred during calendar year 2019 and multiply this amount by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12. We would count any month in which the ACO had at least one day of participation. Therefore, if an ACO that started a first or second agreement period January 1, 2016 extended its agreement period for a 6-month performance year from January 1, 2019 through June 30, 2019, and was terminated by CMS with an effective date of termination of May 1, 2019 the ACO would be liable for 5/12 of any shared losses determined. If a July 1, 2019 starter was terminated by CMS with an effective date of termination of November 1, 2019, the ACO would also be liable for 5/12 of any shared losses determined. An ACO with an effective date of termination in December would be liable for the entirety of shared losses.

Second, ACOs that are starting a 12-month performance year in 2019 would have the option to participate for the first 6 months of the year prior to terminating their current agreement and enter a new agreement period beginning July 1, 2019. This includes ACOs that would be starting their 2nd or 3rd performance year of an agreement period in 2019, as well as ACOs that deferred renewal under § 425.200(e). We propose that ACOs with an effective date of termination of June 30, 2019 that enter a new agreement period beginning July 1, 2019, are eligible for pro-rated shared savings or shared losses for the 6-month period from January 1, 2019 through June 30, 2019 determined according to § 425.609.

We believe some ACOs may act quickly to enter one of the new participation options made available under the proposed redesign of the program (if finalized). ACOs that complete the 6-month period of participation in 2019 should have the opportunity to share in the savings or be accountable for the losses for this period. However, certain ACOs may ultimately realize they are not yet prepared to participate under a new

agreement beginning July 1, 2019 and seek to terminate quickly. Although we would encourage ACOs to consider making the transition to one of the newly available participation options in 2019 in order to more quickly enter a participation agreement based on the proposed polices (if finalized), we also do not want to unduly bind ACOs that aggressively pursue these new options. We believe the proposed approach provides a means for ACOs to terminate their participation prior to renewing their participation for an agreement period beginning July 1, 2019 or to quickly terminate from a new agreement period beginning July 1, 2019 without the concern of liability for shared losses for a portion of the year.

We also propose to revise the regulations at § 425.221 to streamline and reorganize the provisions in paragraph (b), which we believe is necessary to incorporate these proposed requirements. We seek comment on these proposals and the alternative policies discussed in this section.

7. Participation Options for Agreement Periods Beginning in 2019

a. Overview

In the November 2011 final rule establishing the Shared Savings Program, we implemented an approach for accepting and reviewing applications from ACOs for participation in the program on an annual basis, with agreement periods beginning January 1 of each calendar year. We also finalized an approach to offer two application periods for the first year of the program, allowing for an April 1, 2012 start date and July 1, 2012 start date. In establishing these alternative start dates for the program's first year, we explained that the statute does not prescribe a particular application period or specify a start date for ACO agreement periods (see 76 FR 67835 through 67837). We considered concerns raised by commenters about a January 1, 2012 start date, which would have closely followed the November 2011 publication of the final rule. Specifically, commenters were concerned about the ability of potential ACOs to organize, complete, and submit an application in time to be accepted into the first cohort as well as our ability to effectively review applications by January 1, 2012. Comments also suggested that larger integrated health care systems would be able to meet the application requirements on short notice while small and rural entities might find this timeline more difficult and could be unable to meet the newly-established application requirements for a January 1 start date (76 FR 67836).

We believe the considerations that informed our decision to establish alternative start dates at the inception of the Shared Savings Program also are relevant in determining the timing for making the proposed new participation options available. We believe postponing the start date for agreement periods under these new participation options until later in 2019 would allow ACOs time to consider the new participation options and prepare for program changes; make investments and other business decisions about participation; obtain buy-in from their governing bodies and executives; complete and submit an application that conforms to the new participation options if our proposals are finalized; and resolve any deficiencies and provider network issues that may be identified, including as a result of program integrity and law enforcement screening. Postponing the start date for new agreement periods would also allow both new applicants and ACOs currently participating in the program an opportunity to make any changes to the structure and composition of their ACO as may be necessary to comply with the new program requirements for the ACO's preferred participation option, if changes to the participation options are finalized as proposed.

Therefore, we propose to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the BASIC track or the ENHANCED track. We anticipate the application cycle for the July 1, 2019 start date would begin in early 2019. We are forgoing the application cycle that otherwise would take place during calendar year 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements, initial use of the SNF 3-day rule waiver (as further discussed in section II.A.7.c.1 of this proposed rule), and entry into the Track 1+ Model (as further discussed in section II.F of this proposed rule). Although several ACOs that entered initial agreements beginning in 2015 deferred renewal into a second agreement period by 1 year in accordance with § 425.200(e) and will begin participating in a new 3-year agreement period beginning January 1, 2019 under a performance-based risk track, applications would not be accepted from other ACOs for a new agreement period beginning on January 1, 2019. We propose the July 1, 2019 start date as a one-time opportunity, and thereafter we would resume our typical process of offering an annual application cycle that allows for review and approval of applications in advance of a January 1 agreement start date. We would therefore anticipate also offering an application cycle in 2019 for a January 1, 2020 start date for new, 5-year participation agreements, and continuing to offer an annual start date of January 1 thereafter. We are aware that a delayed application due date for an agreement period beginning in 2019 could affect parties that plan to participate in the Shared Savings Program for performance year 2019 and are relying on the pre-participation waiver. Guidance for affected parties will be posted on the CMS website.

Under the current Shared Savings Program regulations, the policies for determining financial and quality performance are based on an expectation that a performance year will have 12 months that correspond to the calendar year. Beneficiary assignment also depends on use of a 12-month assignment window, with retrospective assignment based on the 12-month calendar year performance year, and prospective assignment based on an offset assignment window before the start of the performance year. Given the calendar year basis for performance years under the current regulations, we considered how to address (1) the possible 6-month lapse in participation that could result for ACOs that entered a first or second 3-year agreement period beginning on January 1, 2016, due to the lack of availability of an application cycle for a January 1, 2019 start date, and (2) the July 1 start date for agreement periods starting in 2019.

To address the implications of a midyear start date on program participation and applicable program requirements, we considered our previous experience with the program's initial entrants, April 1, 2012 starters and July 1, 2012 starters. In particular, we considered our approach for determining these ACOs' first performance year results (see § 425.608). The first performance year for April 1 and July 1 starters was defined as 21 and 18 months respectively (see § 425.200(c)(2)). The methodology we used to determine shared savings and losses for these ACOs' first performance year consisted of an optional interim payment calculation based on the ACO's first 12 months of participation and a final reconciliation occurring at the end of the ACO's first performance year. This final reconciliation took into account the 12 months covered by the interim payment period as well as the remaining 6 or 9 months of the performance year, thereby allowing us to determine the overall savings or losses for the ACO's first performance

year. All ACOs opting for an interim payment reconciliation, including ACOs participating under Track 1, were required to assure CMS of their ability to repay monies determined to be owed upon final first year reconciliation. For Track 2 ACOs, the adequate repayment mechanism required for entry into a performance-based risk arrangement was considered to be sufficient to also assure return of any overpayment of shared savings under the interim payment calculation. Track 1 ACOs electing interim payment were similarly required to demonstrate an adequate repayment mechanism for this purpose. (See 76 FR 67942 through 67944).

This interim payment calculation approach used in the program's first year resulted in relatively few ACOs being eligible for payment based on their first twelve months of program participation. Few Track 1 ACOs established the required repayment mechanism in order to be able to receive an interim payment of shared savings, if earned. Not all Track 2 ACOs, which were required to establish repayment mechanisms as part of their participation in a two-sided model, elected to receive payment for shared savings or to be held accountable for shared losses based on an interim payment calculation. Of the 114 ACOs reconciled for a performance year beginning on April 1 or July 1, 2012, only 16 requested an interim payment calculation in combination with having established the required repayment mechanism. Of these 16 ACOs, 9 were eligible for an interim payment of shared savings, of which one Track 1 ACO was required to return the payment based on final results for the performance year. One Track 2 ACO repaid interim shared losses which were ultimately returned to the ACO based on its final results for the performance year.

This approach to interim and final reconciliation was developed for the first two cohorts of ACOs, beginning in the same year and to which the same program requirements applied. The program has since evolved to include different benchmarking methodologies (depending on whether an ACO is in its first agreement period, or second agreement period beginning in 2016 or in 2017 and subsequent years) and different assignment methodologies (prospective assignment and preliminary prospective assignment with retrospective reconciliation), among other changes. We are concerned about introducing further complexity into program calculations by proposing to follow a similar approach of offering an extended performance year with the option for an interim payment calculation with final reconciliation for ACOs affected by the delayed application cycle for agreement periods starting in 2019.

Instead, we propose to use an approach that would maintain financial reconciliation and quality performance determinations based on a 12-month calendar year period, but would pro-rate shared savings/shared losses for each potential 6-month period of participation during 2019, as described in this section. See section II.A.7.b. of this proposed rule for a detailed discussion of this methodology.

Accordingly, our proposed approach for implementing the proposed July 1, 2019 start date would include the following opportunities for ACOs, based on their agreement period start date:

ACOs entering an agreement period beginning on July 1, 2019, would be in a participation agreement for a term of 5 years and 6 months, of which the first performance year would be defined as 6 months (July 1, 2019 through December 31, 2019), and the 5 remaining performance years of the agreement period would each consist of a 12-month calendar year.

ACOs that entered a first or second agreement period with a start date of January 1, 2016, may elect to extend their agreement period for an optional fourth performance year, defined as the 6-month period from January 1, 2019 through June 30, 2019. This election to extend the agreement period is voluntary and an ACO could choose not to make this election and therefore conclude its participation in the program with the expiration of its current agreement period on December 31, 2018.

We propose that the ACO's voluntary election to extend its agreement period must be made in the form and manner and according to the timeframe established by CMS, and that an ACO executive who has the authority to legally bind the ACO must certify the election. If finalized, we anticipate this election process would begin in 2018 following the publication of the final rule, as part of the annual certification process in advance of 2019 (described in section II.A.7.c.2. of this proposed rule). We note that this optional 6-month agreement period extension is a one-time exception for ACOs with agreements expiring on December 31, 2018 and would not be available to other ACOs that are currently participating in a 3-year agreement in the program, or to future program entrants.

Under the existing provision at § 425.210, the ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. Further, all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program's regulations, including, but not limited to, those specified in the participation agreement with CMS. An ACO that elects to extend its participation agreement by 6 months must notify its ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities of this continuation of participation and must require their continued compliance with the program's requirements for the 6-month performance year from January 1, 2019 through June 30, 2019.

An existing ACO that wants to quickly move to a new participation agreement under the BASIC track or the ENHANCED track could voluntarily terminate its participation agreement with an effective date of termination of June 30, 2019, and apply to enter a new agreement period with a July 1, 2019 start date to continue its participation in the program. This includes 2017 starters, 2018 starters, and 2015 starters that deferred renewal by 1 year, and entered into a second agreement period under Track 2 or Track 3 beginning on January 1, 2019. If the ACO's application is approved by CMS, the ACO could enter a new agreement period beginning July 1, 2019. (As discussed in section II.A.5. of this proposed rule, we would consider these ACOs to be early renewals.) ACOs currently in an agreement period that includes a 12-month performance year 2019 that choose to terminate their current participation agreement effective June 30, 2019, and enter a new agreement period beginning on July 1, 2019, would be reconciled for their performance during the first 6 months of 2019. As described in section II.A.5 of this proposed rule, an ACO's participation options for the July 1, 2019 start date would depend on whether the ACO is a low revenue or high revenue ACO and the ACO's experience with performance-based risk Medicare ACO initiatives. An early renewal ACO would be considered to be entering its next consecutive agreement period for purposes of the applicability of policies that phase-in over time (the weight used in the regional benchmark adjustment,

equal weighting of the benchmark years, and the quality performance standard).

As discussed in section II.A.2. of this proposed rule, the proposed modifications to the definition of ''agreement period'' in § 425.20 are intended to broaden the definition to generally refer to the term of the participation agreement. We propose to add a provision at § 425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016 that elects to extend its agreement period until June 30, 2019, and this election is made in the form and manner and according to the timeframe established by CMS, and certified by an ACO executive who has the authority to legally bind the ACO. For consistency, we also propose minor formatting changes to the existing provision at § 425.200(b)(2) to italicize the header text. We note that as described in section II.A.2. of this proposed rule, we are proposing modifications to § 425.200(b)(3) as part of discontinuing the deferred renewal participation option. In addition, we propose to add a provision at § 425.200(b)(4) to specify that, for agreement periods beginning in 2019 the start date is—(1) January 1, 2019 and the term of the participation agreement is 3 years for ACOs whose first agreement period began in 2015 and who deferred renewal of their participation agreement under § 425.200(e); or (2) July 1, 2019, and the term of the participation agreement is 5 years and 6 months. We propose to add a provision at § 425.200(b)(5) specifying that, for agreement periods beginning in 2020 and subsequent years, the term of the participation agreement is 5 years.

We also propose to revise the definition of ''performance year'' in § 425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement. We therefore also propose revisions to § 425.200(c) to make necessary formatting changes and specify additional exceptions to the definition of performance year as a 12-month period. Specifically, we propose to add a provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019. Similarly, we propose to add a provision specifying that for an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019.

In light of the proposed modifications to § 425.200(c) to establish two 6-month performance years during calendar year 2019, we believe it is also appropriate to revise the regulation at § 425.200(d), which reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in a 6-month performance year during calendar year 2019.

As an alternative to the proposal to offer an agreement period of 5 years and 6 months beginning July 1, 2019 (made up of 6 performance years, the first of which is 6 months in duration), we considered whether to offer instead an agreement period of five performance years (including a first performance year of 6 months). Under this alternative the agreement period would be 4 years and 6 months in duration. As previously described, in section II.A.2 of this proposed rule in connection with our proposal to extend the agreement period from 3 years to 5 years, program results have shown that ACOs tend to perform better the longer they are in the program and longer agreement periods provide additional time for ACOs to perform against a benchmark based on historical data from the 3 years prior to their start date. Further, the proposed changes to the benchmarking methodology would result in more accurate benchmarks and mitigate the effects of reliance on increasingly older historical data as the agreement period progresses. We believe these considerations are also relevant to the proposed one-time exception to allow for a longer agreement period of 5 years and 6 months for ACOs that enter a new agreement period on July 1, 2019.

We also considered forgoing an application cycle for a 2019 start date altogether and allowing ACOs to enter agreement periods for the BASIC track and ENHANCED track for the first time beginning in January 1, 2020. This approach would allow ACOs additional time to consider the redesign of the program, make organizational and operational plans, and implement business and investment decisions, and would avoid the complexity of needing to determine performance based on 6-month performance years during calendar year 2019. However, our proposed approach of offering an application cycle during 2019 for an agreement period start date of July 1, 2019, would allow for a more rapid progression of ACOs to the redesigned participation options, starting in mid-2019. Further, under this alternative, we would also want to offer ACOs that started a first or second agreement period on January 1, 2016, a means to continue their participation between the conclusion of their current 3-year agreement (December 31, 2018) and the start of their next agreement period (January 1, 2020), should the ACO wish to continue in the program. Under an alternative that would postpone the start date for the new participation options to January 1, 2020, we would allow ACOs that started a first or second agreement period on January 1, 2016, to elect a 12-month extension of their current agreement period to cover the duration of calendar year 2019.

We seek comment on these proposals and the related considerations, as well as the alternatives considered.

b. Methodology for Determining Financial and Quality Performance for the 6-Month Performance Years During 2019

(1) Overview

In this section we describe the proposed methodology for determining financial and quality performance for the two 6-month performance years during calendar year 2019: The 6-month performance year from January 1, 2019, to June 30, 2019; and the 6-month performance year from July 1, 2019, to December 31, 2019. We propose to specify the methodologies for reconciling these 6-month performance years during 2019 in a new section of the regulations at § 425.609. Although we propose to use the same overall approach to determining ACO financial and quality performance for these two periods, the specific policies used to calculate factors used in making these determinations would differ based on the ACO's track, its agreement period start date, and the agreement period in which the ACO participates (for factors that phase-in over multiple agreement periods).

We note that ACOs in an agreement period that includes a 12-month performance year 2019 would have the option to terminate their current participation agreements with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019. We propose to reconcile the performance of these ACOs during the first 6 months of 2019 using the same approach that we are proposing to use to determine performance for the 6-month performance year from January 1, 2019,

through June 30, 2019, for ACOs that started a first or second agreement period on January 1, 2016, that elect to extend their current agreement periods for this 6-month performance year. We propose to specify this approach to determining performance for these ACOs in a new section of the regulations at § 425.609 and in revisions to § 425.221 describing the payment consequences of early termination for ACOs that terminate their participation agreement with an effective termination date of June 30, 2019, and enter a new agreement period beginning July 1, 2019.

After the conclusion of calendar year 2019, CMS would reconcile the financial and quality performance of ACOs that participated in the Shared Savings Program during 2019. For ACOs that extended their agreement period for the 6-month performance year from January 1, 2019, through June 30, 2019, or ACOs that terminated their agreement period early on June 30, 2019, and entered a new agreement period beginning on July 1, 2019, CMS would first reconcile the ACO based on its performance during the entire 12-month calendar year, and then as discussed elsewhere in this section, pro-rate the calendar year shared savings or shared losses to reflect the ACO's participation in that 6-month period. In a separate calculation, CMS would reconcile an ACO that participated for a 6-month performance year from July 1, 2019, through December 31, 2019, for the 12-month calendar year in a similar manner, and pro-rate the shared savings or shared losses to reflect the ACO's participation during that 6-month performance year. We discuss these calculations in detail in section II.A.7.b.2. (for the 6-month period from January 1, 2019 through June 30, 2019) and section II.A.7.b.3. (for the 6-month period from July 1, 2019 through December 31, 2019). Further, we note that this proposed approach to reconciling ACO performance for a 6-month performance year (or performance period) during 2019 would not alter the methodology that would be applied to determine financial performance for ACOs that complete a 12 month performance year corresponding to calendar year 2019.

We note that in discussing these 6-month periods, we use two references, ''6-month performance year'' and ''performance period.'' According to our proposed revisions to § 425.200(c), we use the term ''6-month performance year'' to refer to the following: (1) The fourth performance year from January 1, 2019 through June 30, 2019 for ACOs that started a first or second agreement period January 1, 2016 and extend their current agreement period for this 6-month period; and (2) the first performance year from July 1, 2019 through December 31, 2019, for ACOs that enter an agreement period beginning on July 1, 2019. For an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and enters a new agreement period beginning on July 1, 2019, we refer to the 6-month period from January 1, 2019 through June 30, 2019, as a ''performance period''.

Under the proposed policies, we would calculate shared savings or shared losses applicable to an ACO, by comparing the expenditures for the ACO's performance year assigned beneficiaries for calendar year 2019 to the ACO's historical benchmark updated to calendar year 2019. If the difference is positive and is greater than or equal to the MSR and the ACO has met the quality performance standard, the ACO would be eligible for shared savings. If the ACO is in a two-sided model and the difference between the updated benchmark and assigned beneficiary expenditures is negative and is greater than or equal to the MLR (in absolute value terms), the ACO would be liable for shared losses. ACOs would share in first dollar savings and losses based on the applicable final sharing rate or loss sharing rate according to their track of participation for the applicable agreement period, and taking into account the ACO's quality performance for 2019. We would adjust the amount of shared savings for sequestration. We would cap the amount of shared savings at the applicable performance payment limit for the ACO's track and cap the amount of shared losses at the applicable loss sharing limit for the ACO's track. We would then pro-rate shared savings or shared losses by multiplying by one-half, which represents the fraction of the calendar year covered by the 6-month performance year (or performance period). This pro-rated amount would be the final amount of shared savings earned or shared losses owed by the ACO for the applicable 6-month performance year (or performance period).

We believe this proposed approach would allow continuity in program operations (including operations that occur on a calendar year basis) for ACOs that have either one or two 6-month performance years (or performance period) within calendar year 2019. Specifically, the proposed approach would allow for payment reconciliation to remain on a calendar year basis, which would be most consistent with the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, risk adjustment, county expenditures and regional adjustments. Deviating from a 12 month reconciliation calculation by using fewer than 12 months of performance year expenditures could interject actuarial biases relative to the benchmark expenditures, which are based on 12 month benchmark years. As a result, we believe this approach to reconciling ACOs based on a 12 month period would protect the actuarial soundness of the financial reconciliation methodology. We also believe the alignment of the proposed approach with the standard methodology used to perform the same calculations for 12 month performance years that correspond to a calendar year will make it easier for ACOs and other program stakeholders to understand the proposed methodology.

As is the case with typical calendar year reconciliations in the Shared Savings Program, we anticipate results with respect to participation during calendar year 2019 would be made available to ACOs in summer 2020. This would allow those ACOs that are eligible to share in savings as a result of their participation in the program during calendar year 2019 to receive payment of shared savings following the conclusion of the calendar year consistent with the standard process and timing for annual payment reconciliation under the program. As discussed in detail in section II.A.7.c.6. of this proposed rule, we propose to provide separate reconciliation reports for each 6-month performance year (or performance period) and would pay shared savings or recoup shared losses separately for each 6-month performance year (or performance period) during 2019 based on these results.

Furthermore, this approach would avoid a more burdensome interim payment process that could accompany an alternative proposal to instead implement, for example, an 18-month performance year from July 1, 2019 to December 31, 2020. Consistent with the 18- and 21-month performance years offered for the first cohorts of Shared Savings Program ACOs, such a policy could require ACOs to establish a repayment mechanism that otherwise might not be required, create uncertainty over whether the ACO may ultimately need to repay CMS based on final results for the extended performance year, and delay ACOs seeing a return on their investment in

program participation if eligible for shared savings.

We believe the proposals to determine shared savings and shared losses for the 6-month performance years starting on January 1, 2019, and July 1, 2019 (or the 6-month performance period from January 1, 2019, through June 30, 2019, for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019), using expenditures for the entire calendar year 2019 and then pro-rating these amounts to reflect the shorter performance year, require the use of our authority under section 1899(i)(3) of the Act to use other payment models. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. We believe the proposed approach to calculating the expenditures for assigned beneficiaries over the full calendar year, comparing this amount to the updated benchmark for 2019, and then pro-rating any shared savings (or shared losses, which already are implemented using our authority under section 1899(i)(3) of the Act) for the 6-month performance year (or performance period) involves an adjustment to the estimated average per capita Medicare Part A and Part B FFS expenditures determined under section 1899(d)(1)(B)(i) of the Act that is not based on beneficiary characteristics. Such an adjustment is not contemplated under the plain language of section 1899(d)(1)(B)(i) of the Act. As a result, we believe it is necessary to use our authority under section 1899(i)(3) of the Act to calculate performance year expenditures and determine the final amount of any shared savings (or shared losses) for a 6-month performance year (or performance period) during 2019, in the proposed manner.

In order to use our authority under section 1899(i)(3) of the Act to adopt an alternative payment methodology to calculate shared savings and shared losses for the proposed 6-month performance years (or performance period) during 2019, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. We believe the proposed approach of allowing ACOs that started a first or second agreement period on January 1, 2016, to extend their agreement period for a 6-month performance year and of allowing entry into the program's redesigned participation options beginning on July 1, 2019, if finalized, would support continued participation by current ACOs that must renew their agreements, while also resulting in more rapid progression to two-sided risk by ACOs within current agreement periods and ACOs entering the program for an initial agreement period. As discussed in the Regulatory Impact Analysis (section IV. of this proposed rule), we believe this approach would continue to allow for lower growth in Medicare FFS expenditures based on projected participation trends. Therefore, we do not believe that the proposed methodology for determining shared savings or shared losses for ACOs in a 6-month performance year (or performance period) during 2019 would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we believe that the proposed approach to measuring ACO quality performance for a 6-month performance year (or performance period) based on quality data reported for calendar year 2019 maintains accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs would also have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they must pay in tracks where the loss sharing rate is determined based on the ACO's quality performance. Therefore, we believe this proposed approach to reconciling ACOs for a 6-month performance year (or performance period) during 2019 would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries.

(2) Proposals for Determining Performance for the 6-Month Performance Year From January 1, 2019, Through June 30, 2019

In this section, we describe our proposed approach to determining an ACO's performance for the 6-month performance year from January 1, 2019, through June 30, 2019. These proposed policies would also apply to ACOs that begin a 12-month performance year on January 1, 2019, but elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (early renewals). Our proposed policies address the following: (1) The ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries; (3) the quality reporting period; (4) the benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark; and (5) the methodology for determining shared savings and shared losses. We propose to specify these policies for reconciling the 6-month period from January 1, 2019, through June 30, 2019 in paragraph (b) of a new section of the regulations at § 425.609.

We propose to use the ACO participant list for the performance year beginning January 1, 2019, to determine beneficiary assignment as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400. As discussed in section II.A.7.c of this proposed rule, we propose to allow all ACOs, including ACOs entering a 6-month performance year, to make changes to their ACO participant list in advance of the performance year beginning January 1, 2019.

To determine beneficiary assignment, we propose to consider the allowed charges for primary care services furnished to the beneficiary during a 12 month assignment window, allowing for a 3 month claims run out. For the 6-month performance year from January 1, 2019 through June 30, 2019, we propose to determine the assigned population using the following assignment windows:

- For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be calendar year 2019.
- For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year we could use an assignment window from October 1, 2017, through September 30, 2018, to align with the off-set assignment window typically used to determine prospective assignment prior to the start of a calendar year performance year. Beneficiaries would remain prospectively assigned to the ACO at the end of calendar year 2019 unless they

meet any of the exclusion criteria under § 425.401(b) during the calendar year.

We note that this is the same approach that is used to determine assignment under the program's current regulations. Therefore, it would also be used to determine assignment for the performance year beginning on January 1, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, for purposes of determining their performance during the performance period from January 1, 2019 through June 30, 2019.

As discussed in section II.A.7.c. of this proposed rule, to determine ACO performance during a 6-month performance year, we propose to use the ACO's quality performance for the 2019 reporting period, and to calculate the ACO's quality performance score as provided in § 425.502. For early renewal ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, we would determine quality performance for the performance period from January 1, 2019, through June 30, 2019, in the same manner as for ACOs with a 6-month performance year from January 1, 2019, through June 30, 2019, that enter a new agreement period beginning on July 1, 2019. As described in section II.A.7.c.4. of this proposed rule, we propose using a different quality measure sampling methodology depending on whether an ACO participates in both a 6-month performance year (or performance period) beginning January 1, 2019 and a 6-month performance year beginning July 1, 2019, or only participates in a 6-month performance year from January 1, 2019 through June 30, 2019.

Consistent with current program policy, we would determine assignment for the benchmark years based on the most recent certified ACO participant list for the ACO effective for the performance year beginning January 1, 2019. This would be the participant list the ACO certified prior to the start of its agreement period unless the ACO has made changes to its ACO participant list during its agreement period as provided in § 425.118(b). If the ACO has made subsequent changes to its ACO participant list, we would recalculate the historical benchmark using the most recent certified ACO participant list. See the Medicare Shared Savings Program, ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf.*

For the 6-month performance year from January 1, 2019, through June 30, 2019, we would calculate the benchmark and assigned beneficiary expenditures as though the performance year were the entire calendar year. The ACO's historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period in the program. We would apply the methodology for establishing, updating and adjusting the ACO's historical benchmark as specified in § 425.602 (for ACOs in a first agreement period) or § 425.603 (for ACOs in a second agreement period), except that data from calendar year 2019 would be used in place of data for the 6-month performance year in certain calculations, as follows:

- The benchmark would be adjusted for changes in severity and case mix between benchmark year 3 and calendar year 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).
- The benchmark would be updated to calendar year 2019 according to the methodology for using growth in national Medicare FFS expenditures for assignable beneficiaries described under § 425.602(b) (for ACOs in a first agreement period) and § 425.603(b) (for ACOs in a second agreement period beginning January 1, 2016), or the methodology for using growth in regional Medicare FFS expenditures described under § 425.603(d) (for ACOs in a second agreement period beginning January 1 of 2017, 2018, or 2019).

We note this approach is already used to adjust and update the historical benchmark each performance year under the program's current regulations. Therefore we would use this same approach to determine the benchmark for the performance period from January 1, 2019, through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

For determining performance during the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, we would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO's track under the terms of the participation agreement that was in effect on January 1, 2019: § 425.604 (Track 1), § 425.606 (Track 2) or § 425.610 (Track 3) and, as applicable, the terms of the ACO's participation agreement for the Track 1+ Model authorized under section 1115A of the Act. (See discussion in section II.F of this proposed rule concerning applicability of proposed policies to Track 1+ Model ACOs). However, some exceptions to the otherwise applicable methodology are needed because we are proposing to calculate the expenditures for assigned beneficiaries over the full calendar year 2019 for purposes of determining shared savings and shared losses for the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019. We propose to use the following steps to calculate shared savings and shared losses:

- Average per capita Medicare expenditures for Parts A and B services for calendar year 2019 would be calculated for the ACO's performance year assigned beneficiary population.
- We would compare these expenditures to the ACO's updated benchmark determined for the calendar year as previously described.
- We would apply the MSR and MLR (if applicable).

++ The ACO's assigned beneficiary population for the performance year starting on January 1, 2019, would be used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population is below 5,000 beneficiaries, the MSR/MLR would be determined based on the number of assigned beneficiaries as proposed in section II.A.6.b. of this proposed rule.

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during calendar year 2019 must be below its updated benchmark for the year by at least the MSR established for the ACO.

++ To be responsible for sharing losses with the Medicare program, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during calendar year 2019 must be above its updated benchmark for the year by at least the MLR established for the ACO.

- We would determine the shared savings amount if we determine the ACO met or exceeded the MSR, and if the ACO met the minimum quality performance standards established under § 425.502 and as described in this section of this proposed rule, and

otherwise maintained its eligibility to participate in the Shared Savings Program. We would determine the shared losses amount if we determine the ACO met or exceeded the MLR. To determine these amounts, we would do the following:

++ We would apply the final sharing rate or loss sharing rate to first dollar savings or losses.

++ For ACOs that generated savings that met or exceeded the MSR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable final sharing rate based on the ACO's track and its quality performance under § 425.502.

++ For ACOs that generated losses that met or exceeded the MLR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable shared loss rate based on the ACO's track and its quality performance under § 425.502 (for ACOs in tracks where the loss sharing rate is determined based on the ACO's quality performance).

• We would adjust the shared savings amount for sequestration by reducing by 2 percent and compare the sequestration-adjusted shared savings amount to the applicable performance payment limit based on the ACO's track.

• We would compare the shared losses amount to the applicable loss sharing limit based on the ACO's track.

• We would pro-rate any shared savings amount, as adjusted for sequestration and the performance payment limit, or any shared losses amount, as adjusted for the loss sharing limit, by multiplying by one half, which represents the fraction of the calendar year covered by the 6-month performance year (or performance period). This pro-rated amount would be the final amount of shared savings that would be paid to the ACO for the 6-month performance year (or performance period) or the final amount of shared losses that would be owed by the ACO for the 6-month performance year (or performance period).

We seek comment on these proposals.

(3) Proposals for Determining Performance for the 6-Month Performance Year From July 1, 2019, Through December 31, 2019

In this section, we describe our proposed approach to determining an ACO's performance for the 6-month performance year from July 1, 2019, through December 31, 2019. Our proposed policies address the following: (1) The ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries for the 6-month performance year; (3) the quality reporting period for the 6-month performance year; (4) the benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark; and (5) the methodology for determining shared savings and shared losses for the ACO for the performance year. We propose to specify the methodology for reconciling the 6-month performance year from July 1, 2019, through December 31, 2019, in paragraph (c) of a new section of the regulations at § 425.609.

We note that in determining performance for the 6-month performance year from July 1, 2019 through December 31, 2019, we would follow the same general methodological steps for calculating pro-rated shared savings and shared losses as described in section II.A.7.b.2 of this proposed rule for the 6-month performance year from January 1, 2019 through June 30, 2019. However, for example, the applicable benchmarking methodology, which is based on the ACO's agreement period in the program, and financial model, which is based on the track in which the ACO is participating, would be different.

We propose to use the ACO participant list for the performance year beginning July 1, 2019, to determine beneficiary assignment, consistent with the assignment methodology the ACO selected at the start of its agreement period under proposed § 425.400(a)(4)(ii). As discussed in section II.A.7.c of this proposed rule, this would be the ACO participant list that was certified as part of the ACO's application to enter an agreement period beginning on July 1, 2019.

To determine beneficiary assignment, we propose to consider the allowed charges for primary care services furnished to the beneficiary during a 12 month assignment window, allowing for a 3 month claims run out. For the 6-month performance year from July 1, 2019 through December 31, 2019, we propose to determine the assigned population using the following assignment windows:

• For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be calendar year 2019.

• For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available. We would use an assignment window before the start of the agreement period on July 1, 2019. For example, we could use an assignment window from April 30, 2018, through March 31, 2019. The 3 month gap between the end of the assignment window and the start of the performance year would be consistent with the typical gap for calendar year performance years that begin on January 1. Beneficiaries would remain prospectively assigned to the ACO at the end of calendar year 2019 unless they meet any of the exclusion criteria under § 425.401(b) during the calendar year.

As discussed in section II.A.7.c of this proposed rule, to determine ACO performance during either 6-month performance year, we propose to use the ACO's quality performance for the 2019 reporting period, and to calculate the ACO's quality performance score as provided in § 425.502.

Consistent with current program policy, we would determine assignment for the benchmark years based on the ACO's certified ACO participant list for the agreement period beginning July 1, 2019.

For the 6-month performance year from July 1, 2019, through December 31, 2019, we would calculate the benchmark and assigned beneficiary expenditures as though the performance year were the entire calendar year. The ACO's historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period in the program. We would apply the methodology for establishing, updating and adjusting the ACO's historical benchmark as specified in proposed § 425.601, except that data from calendar year 2019 would be used in place of data for the 6-month performance year in certain calculations, as follows:

• The benchmark would be adjusted for changes in severity and case mix between benchmark year 3 and calendar year 2019 based on growth in prospective HCC risk scores, subject to a symmetrical cap of positive or negative 3 percent that would apply for the agreement period such that the adjustment between BY3 and any performance year in the agreement period would never be more than 3 percent in either direction. See discussion in section II.D.2 of this proposed rule.

• The benchmark would be updated to calendar year 2019 according to the methodology described under proposed § 425.601(b) using a blend of national and regional growth rates.

For determining performance during the 6-month performance year from July 1, 2019, through December 31, 2019, we would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO's track under its agreement period beginning on July 1, 2019: The proposed BASIC track (§ 425.605) or ENHANCED track (§ 425.610). However, some exceptions to the otherwise applicable methodology are needed because we are proposing to calculate the expenditures for assigned beneficiaries over the full calendar year 2019 for purposes of determining shared savings and shared losses for the 6-month performance year from July 1, 2019 through December 31, 2019. We propose to use the following steps to calculate shared savings and shared losses:

- Average per capita Medicare expenditures for Parts A and B services for calendar year 2019 would be calculated for the ACO's performance year assigned beneficiary population. Additionally, when calculating calendar year 2019 expenditures to be used in determining performance for the July 1, 2019 through December 31, 2019 performance year, we would include expenditures for all assigned beneficiaries that are alive as of January 1, 2019, including those with a date of death prior to July 1, 2019, except prospectively assigned beneficiaries that are excluded under § 425.401(b). The inclusion of beneficiaries with a date of death before July 1, 2019, is necessary to maintain consistency with benchmark year and regional expenditure adjustments and associated trend and update factor calculations.
- We would compare these expenditures to the ACO's updated benchmark determined for the calendar year as previously described.
- We would apply the MSR and MLR (if applicable).

++ The ACO's assigned beneficiary population for the performance year starting on July 1, 2019, would be used to determine the MSR for one-sided model ACOs (under Level A or Level B of the BASIC track) and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population is below 5,000 beneficiaries, the MSR/MLR would be determined based on the number of assigned beneficiaries as proposed in section II.A.6.b. of this proposed rule.

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during calendar year 2019 must be below its updated benchmark for the year by at least the MSR established for the ACO.

++ To be responsible for sharing losses with the Medicare program, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during calendar year 2019 must be above its updated benchmark for the year by at least the MLR established for the ACO.

- We would determine the shared savings amount if we determine the ACO met or exceeded the MSR, and if the ACO met the minimum quality performance standards established under § 425.502 and as described in this section of this proposed rule, and otherwise maintained its eligibility to participate in the Shared Savings Program. We would determine the shared losses amount if we determine the ACO met or exceeded the MLR. To determine these amounts, we would do the following:

++ We would apply the final sharing rate or loss sharing rate to first dollar savings or losses.

++ For ACOs that generated savings that met or exceeded the MSR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable final sharing rate based on the ACO's track and its quality performance under § 425.502.

++ For ACOs that generated losses that met or exceeded the MLR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable shared loss rate based on the ACO's track and its quality performance under § 425.502 (for ACOs in the ENHANCED track where the loss sharing rate is determined based on the ACO's quality performance).

- We would adjust the shared savings amount for sequestration by reducing by 2 percent and compare the sequestration-adjusted shared savings amount to the applicable performance payment limit based on the ACO's track.
- We would compare the shared losses amount to the applicable loss sharing limit based on the ACO's track.
- We would pro-rate any shared savings amount, as adjusted for sequestration and the performance payment limit, or any shared losses amount, as adjusted for the loss sharing limit, by multiplying by one half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount would be the final amount of shared savings that would be paid to the ACO for the 6-month performance year or the final amount of shared losses that would be owed by the ACO for the 6-month performance year.

We seek comment on these proposals.

c. Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year

In general, unless otherwise stated, we are proposing that program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO's chosen participation track and based on the ACO's agreement start date would be applicable to an ACO participating in a 6-month performance year. This would allow routine program operations to continue to apply for ACOs participating under these shorter performance years. Further, it would ensure consistency in the applicability and implementation of our requirements across all program participants, including ACOs participating in 6-month performance years. As we described in section II.A.7.b of this proposed rule, limited exceptions to our policies for determining financial and quality performance are necessary to ensure calculations can continue to be performed on a calendar year basis and using the most relevant data.

In this section, we describe our consideration of program participation options affected by our decision to forgo an application cycle in calendar year 2018 for a January 1, 2019 start date, and the proposal to offer instead an application cycle in calendar year 2019 for a July 1, 2019 start date. We discuss program policies that would need to be modified to allow for the proposed 6-month performance years within calendar year 2019, and related proposals to revise the program's regulations to allow for these modifications.

(1) Unavailability of an Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning January 1, 2019

Eligible ACOs may apply for use of a SNF 3-day rule waiver at the time of application for an initial agreement or to renew their participation. Further, ACOs within a current agreement period under Track 3, or the Track 1+ Model as described in sections II.B.2.a and II.F of this proposed rule, may apply for a SNF 3-day rule waiver, which if approved would begin at the start of their next performance year. As discussed in section II.B.2.a of this proposed rule, we propose to allow the

SNF 3-day rule waiver under the Shared Savings Program to be more broadly available to BASIC track ACOs (under a two-sided model) and ENHANCED track ACOs, regardless of their choice of beneficiary assignment methodology.

In light of our decision to forgo an application cycle in calendar year 2018 for a January 1, 2019 agreement start date, we also would not offer an opportunity for ACOs to apply for a start date of January 1, 2019, for initial use of a SNF 3-day rule waiver. The application cycle for the July 1, 2019 start date would be the next opportunity for eligible ACOs to begin use of a waiver, if they apply for and are approved to use the waiver as part of the application cycle for the July 1, 2019 start date. This would extend to ACOs within existing agreement periods in Track 3 that would, under 12 month performance years, not otherwise have the opportunity to apply to begin use of the waiver until January 1, 2020. We believe the existing regulation at § 425.612(b), which requires applications for waivers to be submitted to CMS in the form and manner and by a deadline specified by CMS, provides the flexibility to accommodate a July 1, 2019 SNF 3-day rule waiver start date for eligible ACOs in a performance year beginning on January 1, 2019. As a result, we are not proposing any corresponding revisions to this provision at this time.

(2) Annual Certifications and ACO Participant List Modifications

At the end of each performance year, ACOs complete an annual certification process. At the same time as this annual certification process, CMS also requires ACOs to review, certify and electronically sign official program documents to support the ACO's participation in the upcoming performance year.

Requirements for this annual certification, and other certifications that occur on an annual basis, continue to apply to all currently participating ACOs in advance of the performance year beginning on January 1, 2019. In the case of ACOs that participate for a portion of calendar year 2019 under one agreement and enter a new agreement period starting on July 1, 2019, the certifications made in advance of the performance year starting on January 1, 2019, would have relevance only for the 6-month period from January 1, 2019, to June 30, 2019. These ACOs would need to complete another certification as part of completing the requirements to enter a new agreement period beginning on July 1, 2019, which would be applicable for the duration of their first performance year under the new agreement period, spanning July 1, 2019 to December 31, 2019.

Each ACO certifies its list of ACO participant TINs before the start of its agreement period, before every performance year thereafter, and at such other times as specified by CMS in accordance with § 425.118(a). The addition of ACO participants must occur prior to the start of the performance year in which these additions become effective. ACO participant must be deleted from the ACO participant list within 30 days after termination of the ACO participant agreement, and such deletion is effective as of the termination date of the ACO participant agreement. Absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used for the duration of the performance year. An ACO's certified ACO participant list for a performance year is used, for example, to determine beneficiary assignment for the performance year and therefore also the ACO's quality reporting samples and financial performance. See § 425.118(b)(3) and see also Medicare Shared Savings Program ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf.* These policies would apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a 6-month performance year beginning on January 1, 2019, would have the opportunity during 2018 to make changes to their ACO participant list to be effective for the 6-month performance year from January 1, 2019, to June 30, 2019. If these ACOs elect to continue their participation in the program for a new agreement period starting on July 1, 2019, they would have an opportunity to submit a new ACO participant list as part of their renewal application for the July 1, 2019 start date.

An ACO that enters a new agreement period beginning on July 1, 2019, would submit and certify its ACO participant list for the agreement period beginning on July 1, 2019, according to the requirements in § 425.118(a). The ACO's approved ACO participant list would remain in effect for the full performance year from July 1, 2019, to December 31, 2019. These ACOs would have the opportunity to add or delete ACO participants prior to the start of the next performance year. Any additions to the ACO participant list that are approved by CMS would become effective at the start of performance year 2020.

The program's current regulations prevent duplication of shared savings payments. Under § 425.114, ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in another Medicare initiative that involves shared savings. In addition, under § 425.306(b)(2), each ACO participant that submits claims for services used to determine the ACO's assigned population must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims run out for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment, then: (i) CMS will not consider any services billed through the TIN of the ACO participant when performing assignment for the benchmark or performance year; and (ii) the ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

We note the following examples, regarding ACO participants that submit claims for services that are used assignment, and that are participating in a Shared Savings Program ACO for a 12-month performance year during 2019 (such as a 2017 starter, 2018 starter, or 2015 starter that deferred renewal until 2019).

If the ACO remains in the program under its current agreement past June 30, 2019, these ACO participants would not be eligible to be included on the ACO participant list of another ACO applying to enter a new agreement period under the program beginning on July 1, 2019. An ACO participant in these circumstances could be added to the ACO participant list of a July 1, 2019 starter effective for the performance year beginning on January 1, 2020, if it is no longer participating in the other Shared Savings Program ACO and is not participating in another initiative identified in § 425.114(a).

If an ACO starting a 12-month performance year on January 1, 2019, terminates its participation agreement with an effective date of termination of June 30, 2019, the effective end date of the ACO participants' participation would also be June 30, 2019. Such ACOs that elect to enter a new agreement period beginning on July 1, 2019, can make ACO participant list

changes that would be applicable for their new agreement period. This means that the ACO participants of the terminating ACO could choose to be added to the ACO participant list of another July 1, 2019 starter, effective for the performance year beginning July 1, 2019.

(3) Repayment Mechanism Requirements

ACOs must demonstrate that they have in place an adequate repayment mechanism prior to entering a two-sided model. The repayment mechanism must be in effect for the duration of an ACO's participation in a two-sided model and for 24 months following the conclusion of the agreement period. (See discussion in section II.A.6.c of this proposed rule.)

We note that ACOs that started a first or second agreement period January 1, 2016 in a two-sided model would have in place under current program policies a repayment mechanism arrangement that would cover the 3 years between January 1, 2016 and December 31, 2018 plus a 24-month tail period until December 31, 2020. In the case of an ACO with an agreement period ending December 31, 2018, that extends its agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, we would require the ACO to extend the term of its repayment mechanism so that it would be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period (that is, until June 30, 2021). This will allow us sufficient time to perform financial calculations for the 6-month performance year from January 1, 2019 through June 30, 2019 and to use the arrangement to collect shared losses for that performance year, if necessary. This policy is consistent with the policy proposed in section II.A.6.c and at § 425.204(f)(6)(i), which provides that a repayment mechanism must be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period.

Consistent with our proposed policy described in section II.A.6.c and § 425.204(f)(4)(iv), a renewing ACO that is under a two-sided model and entering a new agreement period beginning July 1, 2019 would be permitted to use its existing repayment mechanism to establish its ability to repay shared losses incurred for performance years in its new agreement period. As previously described, we would require the ACO to extend the term of the existing repayment mechanism by an amount of time specified by CMS and, if necessary, to increase the amount of the repayment mechanism to reflect the new repayment mechanism amount.

We are proposing that, for agreement periods beginning on or after July 1, 2019, we would recalculate the amount of the ACO's repayment mechanism before the second and each subsequent performance year in the agreement period, based on the ACO's certified ACO participant list for the relevant performance year. Therefore, for an ACO that enters a new agreement period beginning July 1, 2019, we would calculate the amount of the repayment mechanism for the new agreement period in accordance with our proposed regulation at § 425.204(f)(4). Before the start of performance year 2020, we would recalculate the amount of the ACO's repayment mechanism. Depending on how much the recalculated amount exceeds the existing repayment mechanism amount, we would require the ACO to increase its repayment mechanism amount, consistent with our proposed approach described in section II.A.6.c of this proposed rule and § 425.204(f)(4)(iii).

(4) Proposals for Quality Reporting and Quality Measure Sampling

In order to determine an ACO's quality performance during either 6-month performance year during 2019, we propose to use the ACO's quality performance for the 2019 reporting period as determined under § 425.502. For ACOs that participate in only one of the 6-month performance years (such as ACOs that started a first or second agreement period on January 1, 2016 that extend their agreement period by 6 months and do not continue in the program past June 30, 2019, or ACOs that enter an initial agreement period beginning on July 1, 2019), we would also account for the ACO's quality performance using quality measure data reported for the 12-month calendar year. As we previously described in section II.A.7.b.2 of this proposed rule, ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, would also be required to complete quality reporting for the 2019 reporting period, and we would determine quality performance for the performance period from January 1, 2019, through June 30, 2019, in the same manner as for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019, that enter a new agreement period beginning on July 1, 2019.

We believe the following considerations support this proposed approach. For one, use of a 12 month period for quality measure assessment maintains alignment with the program's existing quality measurement approach, and aligns with the proposed use of 12 months of expenditure data (for calendar year 2019) in determining the ACO's financial performance. Also, this approach would continue to align the program's quality reporting period with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019. Second, the measure specifications for the quality measures used under the program require 12 months of data. See for example, the Shared Savings Program ACO 2018 Quality Measures, Narrative Specification Document (January 20, 2018), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2018-reporting-year-narrative-specifications.pdf.* Third, in light of our proposal to use 12 months of expenditures (based on calendar year 2019) in determining shared savings and shared losses for a 6-month performance year, we believe it is also appropriate to hold ACOs accountable for the quality of the care furnished to their assigned beneficiaries during this same time frame. Fourth, and lastly, using an annual quality reporting cycle for the 6-month performance year would avoid the need to introduce new reporting requirements, and therefore potential additional burden on ACOs, that would arise from a requirement that ACOs report quality separately for each 6-month performance year during calendar year 2019.

The ACO participant list is used to determine beneficiary assignment for purposes of generating the quality reporting samples. Beneficiary assignment is performed using the applicable assignment methodology under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. The samples for claims-based measures are typically determined based on the assignment list for calendar year quarter 4. The sample for quality measures reported through the CMS web interface is typically determined based on the beneficiary assignment list for calendar year quarter 3. The CAHPS for ACOs survey sample is typically determined based on the beneficiary assignment list for calendar year quarter 2.

As described in section II.A.7.c.2. of this proposed rule, ACOs in either 6-

month performance year during 2019 may use a different ACO participant list for each performance year (for example, in the case of an ACO that started a first or second agreement period on January 1, 2016, that extends its current agreement period by 6 months, and then makes changes to its ACO participant list as part of its renewal application for a July 1, 2019 start date). As discussed in sections II.A.7.b.2 (January 2019–June 2019) and II.A.7.b.3 (July 2019–December 2019), different assignment methodologies and assignment windows would be used to assign beneficiaries to ACOs for the two 6-month performance years during 2019. Therefore, we considered which ACO participant list and assignment methodology to use to identify the samples of beneficiaries for quality reporting for the entire 2019 reporting period for ACOs participating in one or both of the 6-month performance years during 2019 (or performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019).

For purposes of determining the quality reporting samples for the 2019 reporting period, we propose to use the ACO's most recent certified ACO participant list available at the time the quality reporting samples are generated, and the assignment methodology most recently applicable to the ACO for a 2019 performance year. We believe the use of the ACO's most recent ACO participant list to assign beneficiaries according to the assignment methodology applicable based on the ACO's most recent participation in the program during 2019 would result in the most relevant beneficiary samples for 2019 quality reporting. For instance, for purposes of measures reported by ACOs through the CMS web interface, ACOs must work together with their ACO participants and ACO providers/suppliers to abstract data from medical records for reporting. In the case of an ACO that started a new agreement period on July 1, 2019, basing assignment for the CMS web interface quality reporting sample on the most recent ACO participant list would allow this coordination to occur between the ACO and its current ACO participant TINs, rather than requiring the ACO to coordinate with ACO participants from a prior performance year that may no longer be included on the ACO participant list for the agreement period beginning on July 1, 2019. Further, basing the sample for the CAHPS for ACOs survey on the most recent ACO participant list could ensure the ACO receives feedback from the ACO's assigned beneficiaries on their experience of care with ACO participants and ACO providers/suppliers based on the ACO's current participant list, rather than based on its prior ACO participant list. This could allow for more meaningful care coordination improvements by the ACO in response to the feedback from the survey. Additionally, we believe this proposed approach to determining the ACO's quality reporting samples is also appropriate for an ACO that participates in only one 6-month performance year during 2019, because the most recent certified ACO participant list applicable for the performance year, would also be the certified ACO participant list that is used to determine financial performance.

We propose to specify the ACO participant lists that would be used in determining the quality reporting samples for measuring quality performance for the 6-month performance years in a new section of the regulations at § 425.609. Specifically we propose to use the following approach to determine the ACO participant list, assignment methodology and assignment window that would be used to generate the quality reporting samples for measuring quality performance of ACOs participating in a 6-month performance year (or performance period) during 2019.

For ACOs that enter an agreement period beginning on July 1, 2019, including new ACOs, ACOs that extended their prior participation agreement for the 6-month performance year from January 1, 2019, to June 30, 2019, and ACOs that start a 12-month performance year on January 1, 2019, and terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019, we propose to use the certified ACO participant list for the performance year starting on July 1, 2019, to determine the quality reporting samples for the 2019 reporting period. This most recent certified ACO participant list would therefore be used to determine the quality reporting samples for the 2019 reporting year, which would be used to determine performance for the 6-month performance year from January 1, 2019, to June 30, 2019 (or performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019) and the 6-month performance year from July 1, 2019, to December 31, 2019.

Beneficiary assignment for purposes of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from July 1, 2019, through December 31, 2019, under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. We anticipate the assignment windows for the quality reporting samples would be as follows based on our operational experience: (1) Samples for claims-based measures would be determined based on the assignment list for calendar year quarter 4; (2) the sample for CMS web interface measures would be determined based on the assignment list for calendar year quarter 3, which equates to the ACO's first quarter of it is 6-month performance year beginning on July 1, 2019; and (3) the sample for the CAHPS for ACOs survey would be determined based on the initial prospective or preliminary prospective assignment list for the 6-month performance year beginning on July 1, 2019.

We believe it is necessary to use the initial assignment list for the CAHPS for ACOs survey sample, to make use of the most recent available prospective assignment list data and quarterly preliminary prospective assignment data for ACOs for the 6-month performance year beginning on July 1, 2019. Further, for CMS web interface measures and claims-based measures, the proposed approach would be consistent with the current methodology for determining the samples.

If an ACO extends its participation to the first 6 months of 2019, but does not enter a new agreement period beginning on July 1, 2019, we propose to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. Beneficiary assignment for purpose of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. We anticipate the assignment windows for the quality reporting samples would be as follows based on our operational experience: (1) Samples for claims-based measures

would be determined based on the assignment list for calendar year quarter 4; (2) the sample for CMS web interface measures would be determined based on the assignment list for calendar year quarter 3; and (3) the sample for the CAHPS for ACOs survey would be determined based on the assignment list for calendar year quarter 2. This approach maintains alignment with the assignment windows currently used for establishing quality reporting samples for these measures.

(5) Proposals for Applicability of Extreme and Uncontrollable Circumstances Policies

We propose in section II.E.4 of this proposed rule to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial and quality performance results for performance year 2017 to performance year 2018 and subsequent years. As specified in section II.E.4, if this proposal is finalized, these policies would apply to ACOs participating in each of the 6-month performance years during 2019 (or the 6-month performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019). We also propose that for ACOs that are involuntarily terminated during a 6-month performance year, pro-rated shared losses for the 6-month performance year would be determined based on assigned beneficiary expenditures for the full calendar year 2019 and then would be pro-rated to account for the partial year of participation prior to the involuntary termination (according to section II.A.6.d of this proposed rule) and the impact of extreme and uncontrollable circumstances on the ACO (if applicable).

(6) Proposals for Payment and Recoupment for 6-Month Performance Years

We propose to provide separate reconciliation reports for each 6-month performance year, and we would pay shared savings or recoup shared losses separately for each 6-month performance year. Since we propose to perform financial reconciliation for both 6-month performance years during 2019 after the end of calendar year 2019, we anticipate that financial performance reports for both of these 6-month performance years would be available in Summer 2020, similar to the expected timeframe for issuing financial performance reports for the 12-month 2019 performance year (and for 12-month performance years generally).

We propose to apply the same policies regarding notification of shared savings payment and shared losses, and the timing of repayment of shared losses, to ACOs in 6-month performance years that apply under our current regulations to ACOs in 12-month performance years. We propose to specify in a new regulation at § 425.609 that CMS would notify the ACO of shared savings or shared losses for each reconciliation, consistent with the notification requirements specified in § 425.604(f), proposed § 425.605(e), § 425.606(h), and § 425.610(h). Specifically, we propose that: (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due; (2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program; (3) if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

Because we anticipate results for both 6-month performance years would be available at approximately the same time, there is a possibility that an ACO could be eligible for shared savings for one 6-month performance year and liable for shared losses for the other 6-month performance year. Although the same 12-month period would be used to determine performance, the outcome for each partial calendar year performance year could be different because of differences in the ACO's assigned population (for example, resulting from potentially different ACO participant lists and the use of different assignment methodologies), different benchmark amounts resulting from the different benchmarking methodologies applicable to each agreement period, and/or differences in the ACO's track of participation.

In earlier rulemaking, we considered the circumstance where, over the course of its participation in the Shared Savings Program, an ACO may earn shared savings in some years and incur losses in other years. We considered whether the full amount of shared savings payments should be paid in the year in which they accrue, or whether some portion should be withheld to offset potential future losses. However, we did not finalize a withhold from shared savings. See 76 FR 67941 through 67942. Instead, an ACO's repayment mechanism provides a possible source of recoupment for CMS should the ACO fail to timely pay shared losses within the 90 day repayment window.

We revisited these considerations about withholding shared savings payments in light of our proposed approach to determining ACO performance for the two 6-month performance years at approximately the same time following the conclusion of calendar year 2019. We propose to conduct reconciliation for each 6-month performance year at the same time. After reconciliation for both 6-month performance years is complete, we would furnish notice of shared savings or shared losses due for each performance year at the same time, either in a single notice or two separate notices. For ACOs that have mixed results for the two 6-month performance years of 2019, being eligible for a shared savings payment for one performance year and owing shared losses for the other performance year, we propose to reduce the shared savings payment for one 6-month performance year by the amount of any shared losses owed for the other 6-month performance year. This approach would guard against CMS making a payment to an organization that has an unpaid debt to the Medicare program, and therefore would be protective of the Trust Funds. We believe this approach would also be less burdensome for ACOs, for example, in the event that the ACO's shared losses are completely offset by the ACO's shared savings. We note that this approach to offsetting shared losses against any shared savings could result in a balance of either unpaid shared losses that must be repaid, or a remainder of shared savings that the ACO would be eligible to receive.

We propose to specify these policies on payment and recoupment for ACOs in 6-month performance years within calendar year 2019 in a new section of the regulations at § 425.609(e).

(7) Proposals for Automatic Transition of ACOs Under the BASIC Track's Glide Path

Under our proposed design of the BASIC track's glide path, ACOs that enter the glide path at Levels A through D would be automatically advanced to the next level of the glide path at the start of each subsequent performance year of the agreement period. The five levels of the glide path would phase-in over the duration of an ACO's agreement period. The design of the BASIC track's glide path is therefore tied to the duration of the agreement period.

With our proposal to offer agreement periods of 5 years and 6 months to ACOs with July 2019 start dates, we believe it is necessary to address how we would apply the policy for moving

ACOs along the glide path in an agreement period with a duration of more than 5 years. We propose a one-time exception to be specified in § 425.600, whereby the automatic advancement policy would not apply to the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning July 1, 2019. For performance year 2020, the ACO would remain in the same level of the BASIC track's glide path it entered for the 6-month performance year beginning July 1, 2019, unless the ACO uses the proposed flexibility to advance to a higher level of risk and potential reward more quickly. The ACO would automatically advance to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period, unless the ACO chooses to advance more quickly. This proposed approach would allow a modest increase in the amount of time initial entrants in the BASIC track's glide path could remain under a particular level, including a one-sided model.

(8) Interactions With the Quality Payment Program

We took into consideration how the proposed July 1, 2019 start date could interact with other Medicare initiatives, particularly the Quality Payment Program timelines relating to participation in APMs. In the CY 2018 Quality Payment Program final rule with comment period, we finalized a policy for APMs that start or end during the QP Performance Period. Specifically, under § 414.1425(c)(7)(i), for Advanced APMs that start during the QP Performance Period and are actively tested for at least 60 continuous days during a QP Performance Period, CMS will make QP determinations and Partial QP determinations for eligible clinicians in the Advanced APM using claims data for services furnished during those dates on which the Advanced APM is actively tested. This means that an APM (such as a two-sided model of the Shared Savings Program) would need to begin operations by July 1 of a given performance year in order to be actively tested for at least 60 continuous days before August 31—the last date on which QP determinations are made during a QP Performance Period (as specified in § 414.1425(b)(1)). We therefore believe that our proposed July 1, 2019 start date for the proposed new participation options under the Shared Savings Program would align with Quality Payment Program rules and requirements for participation in Advanced APMs.

(9) Proposals for Sharing CY 2019 Aggregate Data With ACOs in 6-month Performance Year From January 2019 Through June 2019

Under the program's current regulations in § 425.702, we share aggregate data with ACOs during the agreement period. This includes providing data at the beginning of each performance year and quarterly during the agreement period. For ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement for an additional 6-month performance year from January 1, 2019, through June 30, 2019, and ACOs that participate in the first 6 months of a 12-month performance year 2019 but then terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning July 1, 2019, we propose to continue to deliver aggregate reports for all four quarters of calendar year 2019 based on the ACO participant list in effect for the first 6 months of the year. This would allow ACOs a more complete understanding of the Medicare FFS beneficiary population that is the basis for reconciliation for the first 6 months of the year. This would allow ACOs to receive data including demographic characteristics and expenditure/utilization trends for their assigned population. We believe this proposed approach would allow us to maintain transparency by providing ACOs with data that relates to the entire period for which the expenditures for the beneficiaries who are assigned to the ACO for the 6-month performance year (or performance period) would be compared to the ACO's benchmark (before pro-rating any shared savings or shared losses to reflect the length of the performance year), and maintain consistency with the reports delivered to ACOs that participate in a 12-month performance year 2019. Otherwise, we could be limited to providing ACOs with aggregate reports only for the first and second quarters of 2019, even though the proposed reconciliation would involve consideration of expenditures occurring outside this period during 2019. We propose to specify this policy in revisions to § 425.702.

(10) Proposals for Technical or Conforming Changes To Allow for 6-Month Performance Years

We propose to make certain technical, conforming changes to the following provisions, including additional changes to provisions discussed elsewhere in this proposed rule, to reflect our proposal to add a new provision at § 425.609 to govern the calculation of the financial results for 6-month performance years within calendar year 2019.

We propose that the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations (§ 425.315) would apply with respect to applicable program determinations for performance years within calendar year 2019. We propose to amend § 425.315 to incorporate references to the methodology for determining performance for 6-month performance years within calendar year 2019, as specified in § 425.609.

We propose to add a reference to § 425.609 in § 425.100 in order to include ACOs that participate in a 6-month performance year during 2019 in the general description of ACOs that are eligible to receive payments for shared savings under the program.

In § 425.204(g), we propose to add a reference to § 425.609 to allow for consideration of claims billed under merged and acquired entities' TINs for purposes of establishing an ACO's benchmark for an agreement period that includes a 6-month performance year.

In § 425.400(a)(1)(ii), describing the step-wise process for determining beneficiary assignment for each performance year, we propose to also specify that this process would apply to ACOs participating in a 6-month performance year within calendar year 2019, and that assignment would be determined based on the beneficiary's utilization of primary care services during the entirety of calendar year 2019, as specified in § 425.609.

In § 425.400(c)(1)(iv), on the use of certain Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) codes in determining beneficiary assignment, as proposed to be revised in section II.E.3 of this proposed rule, we propose to further revise the provision to specify that it will be used in determining assignment for performance years starting on January 1, 2019, and subsequent years.

In § 425.401(b), describing the exclusion of beneficiaries from an ACO's prospective assignment list at the end of a performance year or benchmark year and quarterly each performance year, we propose to specify that these exclusions would occur at the end of calendar year 2019 for purposes of determining assignment to an ACO in a 6-month performance year in accordance with §§ 425.400(a)(3)(ii) and 425.609.

As part of the proposed revisions to § 425.402(e)(2), which, as described in section II.E.2 of this proposed rule, specifies that beneficiaries who have designated a provider or supplier outside the ACO as responsible for coordinating their overall care will not be added to the ACO's list of assigned beneficiaries for a performance year under the claims-based assignment methodology, we propose to allow the same policy to apply to ACOs participating in a 6-month performance year during calendar year 2019.

In § 425.404(b), on the special assignment conditions for ACOs including FQHCs and RHCs that are used determining beneficiary assignment, we propose to revise the provision to specify its applicability in determining assignment for performance years starting on January 1, 2019, and subsequent performance years.

We also propose to incorporate references to § 425.609 in the regulations that govern establishing, adjusting, and updating the benchmark, including proposed § 425.601, and the existing provisions at § 425.602, and § 425.603, to specify that the annual risk adjustment and update to the ACO's historical benchmark for the 6-month performance years during 2019 would use factors based on the entirety of calendar year 2019. For clarity and simplicity, we propose to add a paragraph to each of these sections to explain the following: (1) Regarding the annual risk adjustment applied to the historical benchmark, when CMS adjusts the benchmark for the 6-month performance years described in § 425.609, the adjustment will reflect the change in severity and case mix between benchmark year 3 and calendar year 2019; (2) Regarding the annual update to the historical benchmark, when CMS updates the benchmark for the 6-month performance years described in § 425.609, the update to the benchmark will be based on growth between benchmark year 3 and calendar year 2019.

We propose to incorporate references to § 425.609 in the following provisions regarding the calculation of shared savings and shared losses, § 425.604, proposed § 425.605, § 425.606, and § 425.610. For clarity and simplicity, we propose to add a paragraph to each of these sections explaining that shared savings or shared losses for the 6-month performance years are calculated as described in § 425.609. That is, all calculations will be performed using calendar year 2019 data in place of performance year data.

B. Fee-for-Service Benefit Enhancements

1. Background

As discussed in earlier rulemaking (for example, 80 FR 32759) and previously in this proposed rule, we believe that models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change than one-sided models. We believe that two-sided performance-based risk provides stronger incentives for ACOs to achieve savings and, as discussed in detail in the Regulatory Impact Analysis (see section IV. of this proposed rule), our experience with the program indicates that ACOs in two-sided models generally perform better than ACOs that participate under a one-sided model. We believe that ACOs that bear financial risk have a heightened incentive to restrain wasteful spending by their ACO participants and ACO providers/suppliers. This, in turn, may reduce the likelihood of over-utilization of services. We believe that relieving these ACOs of the burden of certain statutory and regulatory requirements may provide ACOs with additional flexibility to innovate further, which could in turn lead to even greater cost savings, without inappropriate risk to program integrity.

In the December 2014 proposed rule (79 FR 72816 through 72826), we discussed in detail a number of specific payment rules and other program requirements for which we believed waivers could be necessary under section 1899(f) of the Act to permit effective implementation of two-sided performance-based risk models in the Shared Savings Program. We invited comments on how these waivers could support ACOs' efforts to increase quality and decrease costs under two-sided risk arrangements. Based on review of these comments, in the June 2015 final rule (80 FR 32800 through 32808), we finalized a waiver of the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to the provision of Medicare-covered post-hospital extended care services for beneficiaries who are prospectively assigned to ACOs that participate in Track 3 (§ 425.612). We refer to this waiver as the SNF 3-day rule waiver. We established the SNF 3-day rule waiver to provide an additional incentive for ACOs to take on risk by offering greater flexibility for ACOs that have accepted the higher level of performance-based risk under Track 3 to provide necessary care for beneficiaries in the most appropriate care setting.

Section 50324 of the Bipartisan Budget Act added section 1899(l) of the Act (42 U.S.C. 1395jjj(l)) to provide certain Shared Savings Program ACOs the ability to provide telehealth services. Specifically, beginning January 1, 2020, for telehealth services furnished by a physician or practitioner participating in an applicable ACO, the home of a beneficiary is treated as an originating site described in section 1834(m)(4)(C)(ii) and the geographic limitation under section 1834(m)(4)(C)(i) of the Act does not apply with respect to an originating site described in section 1834(m)(4)(C)(ii), including the home of the beneficiary.

In this proposed rule, we propose modifications to the existing SNF 3-day rule waiver and propose to establish regulations to govern telehealth services furnished in accordance with section 1899(l) of the Act to prospectively assigned beneficiaries by physicians and practitioners participating in certain applicable ACOs. We also propose to use our authority under section 1899(f) to waive the requirements of section 1834(m)(4)(C)(i) and (ii) as necessary to provide for a 90-day grace period to allow for payment for telehealth services furnished to a beneficiary who was prospectively assigned to an applicable ACO, but was subsequently excluded from assignment to the ACO. We also propose to require that ACO participants hold beneficiaries financially harmless for telehealth services that are not provided in compliance with section 1899(l) of the Act or during the 90-day grace period, as discussed below.

2. Proposed Revisions

a. Shared Savings Program SNF 3-Day Rule Waiver

(1) Background

The SNF 3-day rule waiver under § 425.612 allows for Medicare payment for otherwise covered SNF services when ACO providers/suppliers participating in eligible Track 3 ACOs admit eligible prospectively assigned beneficiaries, or certain excluded beneficiaries during a grace period, to an eligible SNF affiliate without a 3-day prior inpatient hospitalization. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply. This waiver became available starting January 1, 2017, and all ACOs participating under Track 3 or applying to participate under Track 3 are eligible to apply for the waiver.

We limited the waiver to ACOs that elect to participate under Track 3 because these ACOs are participating under two-sided risk and, under the prospective assignment methodology

used in Track 3, beneficiaries are assigned to the ACO at the start of the performance year and remain assigned for the entire year, unless they are excluded. Thus it is clearer to the ACO which beneficiaries are eligible to receive services under the waiver than it would be to an ACO under Track 1 or Track 2, which use a preliminary prospective assignment methodology with retrospective reconciliation (80 FR 32804). We continue to believe that it is appropriate to limit the waiver to ACOs participating under a two-sided risk model because, as discussed in the background to this section, models under which ACOs bear a degree of financial risk hold greater potential than one-sided models to induce more meaningful systematic change, promote accountability for a patient population and coordination of patient medical care, and encourage investment in redesigned care processes. As a result, models under which ACOs bear a degree of financial risk provide a stronger incentive for ACOs not to over utilize services than do one-sided models. We also continue to believe it is important to establish clear policies as to the availability of the SNF 3-day rule waiver for coverage of SNF services furnished to a particular beneficiary without a prior 3 day inpatient stay to permit the ACOs and their SNF affiliates to comply with the conditions of the waiver and to facilitate our ability to monitor for misuse. However, we now believe it would also be feasible to establish such clarity for ACOs electing to participate in a two-sided risk model under a preliminary prospective assignment methodology with retrospective reconciliation.

Under preliminary prospective assignment with retrospective reconciliation, ACOs are given up-front information about their preliminarily assigned FFS beneficiary population. This information is updated quarterly to help ACOs refine their care coordination activities. Under the expanded criteria for sharing data with ACOs finalized in the June 2015 final rule, beginning with performance year 2016, we have provided ACOs under preliminary prospective assignment with quarterly and annual assignment lists that identify the beneficiaries who are preliminarily prospectively assigned, as well as beneficiaries who have received at least one primary care service in the most recent 12-month period from an ACO participant that submits claims for services used in the assignment methodology (see § 425.702(c)(1)(ii)(A), and related discussion in 80 FR 32734 through 32737). The specific beneficiaries preliminarily assigned to an ACO during each quarter can vary.

(2) Proposals

As described in section II.A.4.c. of this proposed rule, we propose to allow ACOs to select the beneficiary assignment methodology to be applied at the start of their agreement period (prospective assignment or preliminary prospective assignment with retrospective reconciliation) and the opportunity to elect to change this selection prior to the start of each performance year. Further, as described in sections II.A.3 and II.A.4.b of this proposed rule, we propose that BASIC track ACOs entering the track's glide path under a one-sided model will be automatically transitioned to a two-sided model during their agreement period and may elect to enter two-sided risk more quickly (prior to the start of their agreement period or as part of an annual election to move to a higher level of risk within the BASIC track).

In light of these proposed flexibilities for program participation, as well as our experience in providing ACOs under preliminary prospective assignment with data on populations of beneficiaries, we now believe it would be appropriate to expand eligibility for the SNF 3-day rule waiver to include ACOs participating in a two-sided model under preliminary prospective assignment. As explained in this section, we originally excluded Track 2 ACOs, which participate under two-sided risk, from eligibility for the SNF 3-day rule waiver because beneficiaries are assigned to Track 2 ACOs using a preliminary prospective assignment methodology with retrospective reconciliation and thus it could be unclear to ACOs which beneficiaries would be eligible to receive services under the waiver. We now believe risk-bearing ACOs selecting preliminary prospective assignment with retrospective reconciliation should be offered the same tools and flexibility to increase quality and decrease costs that are available to ACOs electing prospective assignment, to the maximum extent possible. We believe it would be possible to provide ACOs that select preliminary prospective assignment with retrospective reconciliation with more clarity regarding which beneficiaries may be eligible to receive services under the waiver if we were to establish a cumulative list of beneficiaries preliminarily assigned to the ACO during the performance year. We believe it would be appropriate to establish such a cumulative list because the beneficiaries preliminarily assigned to an ACO may vary during each quarter of a performance year.

Under preliminary prospective assignment with retrospective reconciliation, once a beneficiary receives at least one primary care service furnished by an ACO participant, the ACO has an incentive to coordinate care of the Medicare beneficiary, including SNF services, for the remainder of the performance year because of the potential for the beneficiary to be assigned to the ACO for the performance year. Under our proposed approach, we would not remove preliminarily prospectively assigned beneficiaries from the list of beneficiaries eligible to receive SNF services under the waiver on a quarterly basis. Instead, once a beneficiary is listed as preliminarily prospectively assigned to an eligible ACO for the performance year, according to the assignment lists provided by CMS to an ACO at the beginning of each performance year and for quarters 1, 2, and 3 of each performance year, then the SNF 3-day rule waiver would remain available with respect to otherwise covered SNF services furnished to that beneficiary by a SNF affiliate of the ACO, consistent with the requirements of § 425.612(a), for the remainder of the performance year.

We propose that the waiver would be limited to SNF services provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year, and that a beneficiary would no longer be eligible to receive covered services under the waiver if he or she subsequently enrolls in a Medicare group (private) health plan or is otherwise no longer enrolled in Part A and Part B. In other words, ACOs participating in a performance-based risk track and under preliminary prospective assignment with retrospective reconciliation would receive an initial performance year assignment list followed by assignment lists for quarters 1, 2, and 3 of each performance year, and the SNF 3-day rule waiver would be available with respect to all beneficiaries who have been identified as preliminarily prospectively assigned to the ACO on one or more of these four assignment lists, unless they enroll in a Medicare group health plan or are no longer enrolled in both Part A and Part B. Providers and suppliers are expected to confirm a beneficiary's health insurance coverage to determine if they are eligible for FFS benefits. In addition, we note that under existing Medicare payment policies, services furnished to Medicare beneficiaries outside the U.S. are not

payable except under very limited circumstances. Therefore, in general, a waiver-eligible beneficiary who resides outside the U.S. during a performance year would technically remain eligible to receive SNF services furnished in accordance with the waiver, but SNF services furnished to the beneficiary outside the U.S. would not be payable.

We note that our proposal to allow preliminarily prospectively assigned beneficiaries to remain eligible for the SNF 3-day rule waiver until the end of the performance year may include beneficiaries who ultimately are excluded from assignment to the ACO based upon their assignment to another Shared Savings Program ACO or their alignment with an entity participating in another shared savings initiative. Thus, a beneficiary may be eligible for admission under a SNF 3-day rule waiver based on being preliminarily prospectively assigned to more than one ACO during a performance year. As previously discussed, we believe ACOs that bear a degree of financial risk have a strong incentive to manage the care for all beneficiaries who appear on any preliminary prospective assignment list during the year and to continue to focus on furnishing appropriate levels of care because they do not know which beneficiaries ultimately will be assigned to the ACO for the performance year. Further, because there remains the possibility that a beneficiary could be preliminarily prospectively assigned to an ACO at the beginning of the year, not preliminarily assigned in a subsequent quarter, but then retrospectively assigned to the ACO at the end of the performance year, we believe it is appropriate that preliminarily prospectively assigned beneficiaries remain eligible to receive services under the SNF 3-day rule waiver for the remainder of the performance year to aid ACOs in coordinating the care of their entire beneficiary population. Because the ACO will ultimately be held responsible for the quality and costs of the care furnished to all beneficiaries who are assigned at the end of the performance year, we believe the ACO should have the flexibility to use the SNF 3-day rule waiver to permit any beneficiary who has been identified as preliminarily prospectively assigned to the ACO during the performance year to receive covered SNF services without a prior 3 day hospital stay when clinically appropriate. For this reason, we do not believe it is necessary to extend the 90-day grace period that applies to beneficiaries assigned to waiver-approved ACOs participating under the prospective assignment methodology to include beneficiaries who are preliminarily prospectively assigned to a waiver-approved ACO. Rather, beneficiaries who are preliminarily prospectively assigned a to waiver-approved ACO will remain eligible to receive services furnished in accordance with the SNF 3-day rule waiver for the remainder of that performance year unless they enroll in a Medicare group health plan or are otherwise no longer enrolled in Part A and Part B. In addition, in order to help protect beneficiaries from incurring significant financial liability for SNF services received without a prior 3-day inpatient stay after an ACO's termination date, we would also like to clarify that an ACO must include, as a part of the notice of termination to ACO participants under § 425.221(a)(1)(i), a statement that its ACO participants, ACO providers/suppliers, and SNF affiliates may no longer use the SNF 3-day rule waiver after the ACO's date of termination. We would also like to clarify that if a beneficiary is admitted to a SNF prior to an ACO's termination date, and all requirements of the SNF 3-day rule waiver are met, the SNF services furnished without a prior 3-day stay would be covered under the SNF 3-day rule waiver.

In summary, we propose to revise the regulations at § 425.612(a)(1) to expand eligibility for the SNF 3-day rule waiver to include ACOs participating in a two-sided model under preliminary prospective assignment with retrospective reconciliation. The SNF 3-day rule waiver would be available for such ACOs with respect to all beneficiaries who have been identified as preliminarily prospectively assigned to the ACO on the initial performance year assignment list or on one or more assignment lists for quarters 1, 2, and 3 of the performance year, for SNF services provided after the beneficiary first appeared on one of the assignment lists for the applicable performance year. The beneficiary would remain eligible to receive SNF services furnished in accordance with the waiver unless he or she is no longer eligible for assignment to the ACO because he or she is no longer enrolled in both Part A and Part B or has enrolled in a Medicare group health plan.

Finally, stakeholders representing rural health providers have pointed out that the SNF 3-day rule waiver is not currently available for SNF services furnished by critical access hospitals and other small, rural hospitals operating under a swing bed agreement. Section 1883 of the Act permits certain small, rural hospitals to enter into a swing bed agreement, under which the hospital can use its beds, as needed, to provide either acute or SNF care. As defined in the regulations at 42 CFR 413.114, a swing bed hospital is a hospital or CAH participating in Medicare that has CMS approval to provide post-hospital SNF care and meets certain requirements. These stakeholders indicate that because there are fewer SNFs in rural areas, there are fewer opportunities for rural ACOs to enter into agreements with SNF affiliates. These stakeholders also believe that the current policy may disadvantage beneficiaries living in rural areas who may not be in close proximity to a SNF and would need to travel longer distances to benefit from the SNF 3-day rule waiver. The stakeholders requested that we revise the regulations to permit providers that furnish SNF services under a swing bed agreement to be eligible to partner with ACOs for purposes of the SNF 3-day rule waiver.

In order to furnish SNF services under a swing bed agreement, hospitals must be substantially in compliance with the SNF participation requirements specified at 42 CFR 482.58(b), whereas CAHs must be substantially in compliance with the SNF participation requirements specified at 42 CFR 485.645(d). However, currently, providers furnishing SNF services under a swing bed agreement are not eligible to partner and enter into written agreements with ACOs for purposes of the SNF 3-day rule waiver because: (1) The SNF 3-day rule waiver under the Shared Savings Program regulations at § 425.612(a)(1) waives the requirement for a 3-day prior inpatient hospitalization only with respect to otherwise covered SNF services furnished by an eligible SNF and does not extend to otherwise covered post-hospital extended care services furnished by a provider under a swing bed agreement; and (2) CAHs and other rural hospitals furnishing SNF services under swing bed agreements are not included in the CMS 5-star Quality Rating System and, therefore, cannot meet the requirement at § 425.612(a)(1)(iii)(A) that, to be eligible to partner with an ACO for purposes of the SNF 3-day rule waiver, the SNF must have and maintain an overall rating of 3 or higher under the CMS 5-star Quality Rating System.

For the reasons described in the June 2015 final rule (80 FR 32804), we believe it is necessary to offer ACOs participating under two-sided risk models additional tools and flexibility to manage and coordinate care for their assigned beneficiaries, including the flexibility to admit a beneficiary for

SNF-level care without a prior 3-day inpatient hospital stay. We agree with stakeholders that there are fewer SNFs in rural areas. Therefore, we agree with rural stakeholders that risk-bearing ACOs in rural areas would be better able to coordinate and manage care, and thus to control unnecessary costs, if the SNF 3-day rule waiver extended to otherwise covered SNF services provided by a hospital or CAH under a swing bed agreement. We believe this proposal would primarily benefit ACOs located in rural areas because most CAHs and hospitals that are approved to furnish post-acute SNF-level care via a swing bed agreement are located in rural areas. Consistent with this proposal, we also propose to revise the regulations governing the SNF 3-day rule waiver at § 425.612(a)(1) to indicate that, for purposes of determining eligibility to partner with an ACO for the SNF 3-day rule waiver, SNFs include providers furnishing SNF services under swing bed arrangements. In addition, we propose to revise § 425.612(a)(1)(iii)(A) to specify that the minimum 3-star rating requirement applies only if the provider furnishing SNF services is eligible to be included in the CMS 5-star Quality Rating System. We do not have a comparable data element to the CMS 5-star Quality Rating System for hospitals and CAHs under swing bed agreements; however, under § 425.612(d)(2), we monitor and audit the use of payment waivers in accordance with § 425.316. We will continue to monitor the use of the SNF 3-Day Rule Waiver and reserve the right to terminate an ACO's SNF 3-day rule waiver if the waiver is used inappropriately or beneficiaries are not receiving appropriate care.

Additionally, we note the possibility that a beneficiary could be admitted to a hospital or CAH, have an inpatient stay of less than 3 days, and then be admitted to the same hospital or CAH under its swing bed agreement. As previously discussed, we believe ACOs that bear a degree of financial risk have a stronger incentive not to over utilize services and have an incentive to recommend a beneficiary for admission to a SNF only when it is medically appropriate. We also note this scenario could occur when a beneficiary meets the generally applicable 3-day stay requirement. Thus, we do not believe extending the SNF 3-day rule waiver to include services furnished by a hospital or CAH under a swing bed agreement would create a new gaming opportunity.

To reduce burden and confusion for eligible ACOs not currently approved for a SNF 3-day rule waiver, we are proposing that these revisions would be applicable for SNF 3-day rule waivers approved for performance years beginning on July 1, 2019, and in subsequent years. This would allow for one, as opposed to multiple, application deadlines thus reducing the overall burden for ACOs applying for the waiver and prevent confusion over ACO outreach and communication materials related to application deadlines. Because we are forgoing the application cycle for a January 1, 2019 start date, we are proposing to apply the revisions to ACOs approved to use the SNF 3-day rule waiver for performance years beginning on July 1, 2019, and in subsequent years. This includes both ACOs that start a new agreement period under the proposed new participation options on July 1, 2019, and those ACOs that are applying for a waiver during the term of an existing participation agreement. For ACOs currently participating in the Shared Savings Program with an agreement period beginning in 2017 or 2018, that have previously been approved for a SNF 3-day rule waiver, the proposed revisions to the SNF 3-day rule waiver would be applicable starting on July 1, 2019, and for all subsequent performance years. ACOs with an approved SNF 3-day rule waiver would be able to modify their 2019 SNF affiliate list for the performance year beginning on January 1, 2019; however, they would not be able to add a hospital or CAH operating under a swing bed agreement to their SNF affiliate list until the July 1, 2019 change request review cycle. CMS would notify all ACOs, including ACOs with a 12 month performance year 2019, of the schedule for this change request review cycle.

Consistent with these proposed revisions to the SNF 3-day rule waiver, we are proposing to add a new provision at § 425.612(a)(1)(vi) to allow ACOs participating in performance-based risk within the BASIC track or ACOs participating in Track 3 or the ENHANCED track to request to use the SNF 3-day rule waiver. We are not proposing to make the revisions to the SNF 3-day rule waiver applicable for Track 2 ACOs because we are proposing to phase out Track 2, as discussed at section II.A.2 of this proposed rule. ACOs currently participating under Track 2 that choose to terminate their existing participation agreement and reapply to the Shared Savings Program under the ENHANCED track or BASIC track, at the highest level of risk and potential reward, as described under II.A.2 of this proposed rule, would be eligible to apply for the SNF 3-day rule waiver.

For the reasons discussed in this section, we believe that the proposed modifications of the SNF 3-day rule waiver would provide additional incentives for ACOs to participate in the Shared Savings Program under performance-based risk and are necessary to support ACO efforts to increase quality and decrease costs under performance-based risk arrangements. We invite comments on these proposals and related issues.

b. Billing and Payment for Telehealth Services

(1) Background

Under section 1834(m) of the Act, Medicare pays for certain Part B telehealth services furnished by a physician or practitioner under certain conditions, even though the physician or practitioner is not in the same location as the beneficiary. As of 2018, the telehealth services must be furnished to a beneficiary located in one of the types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the originating site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. An originating site is the location at which a beneficiary who is eligible to receive a telehealth service is located at the time the service is furnished via a telecommunications system.

Generally, for Medicare payment to be made for telehealth services under the PFS, several conditions must be met (§ 410.78(b)). Specifically, the service must be on the Medicare list of telehealth services and must meet all of the following requirements for payment:

- The telehealth service must be furnished via an interactive telecommunications system, as defined at § 410.78(a)(3). CMS pays for telehealth services provided through asynchronous (that is, store and forward) technologies, defined at § 410.78(a)(1), only for Federal telemedicine demonstration programs conducted in Alaska or Hawaii.
- The service must be furnished to an eligible beneficiary by a physician or other practitioner specified at § 410.78(b)(2) who is licensed to furnish the service under State law as specified at § 410.78(b)(1).
- The eligible beneficiary must be located at an originating site at the time the service being furnished via a telecommunications system occurs. The eligible originating sites are specified in section 1834(m)(4)(C)(ii) of the Act and § 410.78(b)(3) and, for telehealth services furnished during 2018, include the following: the office of a physician or practitioner, a CAH, RHC, FQHC,

hospital, hospital-based or CAH-based renal dialysis center (including satellites), SNF, and community mental health center.

• As of 2018, the originating site must be in a location specified in section 1834(m)(4)(C)(i) of the Act and § 410.78(b)(4). The site must be located in a health professional shortage area that is either outside of a Metropolitan Statistical Area (MSA) or within a rural census tract of an MSA, located in a county that is not included in an MSA, or be participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from, the Secretary of Health and Human Services as of December 31, 2000.

When these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service.

Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. A list of Medicare telehealth services is available through the CMS website (at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html*). Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. CMS does not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Under the Next Generation ACO Model, the Innovation Center has been testing a Telehealth Expansion Benefit Enhancement under which CMS has waived the geographic and originating site requirements for services that are on the list of telehealth services when furnished to aligned beneficiaries by eligible telehealth practitioners (see the CMS website at *https://innovation.cms.gov/Files/x/nextgenaco-telehealthwaiver.pdf*). The purpose of this waiver is to test whether giving participating ACOs the flexibility to furnish telehealth services in more geographic areas and from the beneficiary's home will lower costs, improve quality, and better engage beneficiaries in their care.

Next Generation ACOs encouraged CMS to broaden the telehealth waiver under the Next Generation ACO Model to test the use of asynchronous technologies to increase access to care and further support coordination of care for certain dermatology and ophthalmology services. Therefore, effective for 2018, the Telehealth Expansion Benefit Enhancement under the Next Generation ACO Model has been amended to include a waiver of the requirement under section 1834(m)(1) and § 410.78(b) that telehealth services be furnished via a ''interactive telecommunications system'' as that term is defined under § 410.78(a)(3) in order to permit coverage of certain teledermatology and teleophthalmology services furnished using asynchronous technologies.

(2) Provisions of the Bipartisan Budget Act for Telehealth in the Shared Savings Program

Section 50324 of the Bipartisan Budget Act of 2018 amends section 1899 of the Act to add a new subsection (l) to provide certain ACOs the ability to expand the use of telehealth. The Bipartisan Budget Act provides that, with respect to telehealth services for which payment would otherwise be made that are furnished on or after January 1, 2020 by a physician or practitioner participating in an applicable ACO to a Medicare FFS beneficiary prospectively assigned to the applicable ACO, the following shall apply: (1) The home of a beneficiary shall be treated as an originating site described in section 1834(m)(4)(C)(ii) of the Act, and (2) the geographic limitation under section 1834(m)(4)(C)(i) of the Act shall not apply with respect to an originating site, including the home of a beneficiary, subject to State licensing requirements. The Bipartisan Budget Act defines the home of a beneficiary as the place of residence used as the home of a Medicare FFS beneficiary.

The Bipartisan Budget Act defines an ''applicable ACO'' as an ACO participating in a two-sided model of the Shared Savings Program (as described in § 425.600(a)) or a two-sided model tested or expanded under section 1115A of the Act, for which FFS beneficiaries are assigned to the ACO using a prospective assignment method.

The Bipartisan Budget Act also provides that, in the case where the home of the beneficiary is the originating site, there shall be no facility fee paid to the originating site. It further provides that no payment may be made for telehealth services furnished in the home of the beneficiary when such services are inappropriate to furnish in the home setting, such as services that are typically furnished in inpatient settings such as a hospital.

Lastly, the Bipartisan Budget Act requires the Secretary to conduct a study on the implementation of section 1899(l) of the Act that includes an analysis of the utilization of, and expenditures for, telehealth services under section 1899(l). No later than January 1, 2026, the Secretary must submit a report to Congress containing the results of the study, together with recommendations for legislation and administrative action as the Secretary determines appropriate.

(3) Proposals

We propose to add a new section of the Shared Savings Program regulations at § 425.613 to govern the payment for certain telehealth services furnished, in accordance with section 1899(l) of the Act, as added by the Bipartisan Budget Act. As required by section 1899(l) of the Act, we propose to treat the beneficiary's home as an originating site and not to apply the originating site geographic restrictions under section 1834(m)(4)(C)(i) of the Act for telehealth services furnished by a physician or practitioner participating in an applicable ACO. Thus, we propose to make payment to a physician or practitioner billing though the TIN of an ACO participant in an applicable ACO for furnishing otherwise covered telehealth services to beneficiaries prospectively assigned to the applicable ACO, including when the originating site is the beneficiary's home and without regard to the geographic limitations under section 1834(m)(4)(C)(i) of the Act. As we note in section II.A.4 of this proposed rule, the Shared Savings Program offers two similar, but distinct, assignment methodologies, prospective assignment and preliminary prospective assignment with retrospective reconciliation. We propose to apply these policies regarding payment for telehealth services to ACOs under a two-sided model that participate under the prospective assignment method. We believe that these ACOs meet the definition of applicable ACO under section 1899(l)(2)(A) of the Act. Because final assignment is not performed under the preliminary prospective assignment methodology until after the end of the performance year, we do not believe it is ''a prospective assignment method'' as required under section 1899(l)(2)(A)(ii). Although we do not believe that ACOs that participate under the preliminary prospective assignment with retrospective reconciliation method meet the definition of an applicable ACO, we welcome comments on our interpretation of this provision.

We propose that the policies governing telehealth services furnished in accordance with section 1899(l) of the Act would be effective for telehealth

services furnished in performance years beginning in 2020 and subsequent years by physicians or practitioners participating in ACOs that are operating under a two-sided model with a prospective assignment methodology for the applicable performance year. This would include physicians and practitioners participating in ACOs with a prospective assignment method for a performance year in the ENHANCED track (including Track 3 ACOs with an agreement period starting in 2018 or on January 1, 2019), or in levels C, D, or E of the BASIC track. Because ACOs participating in the Track 1+ Model are participating in a two-sided model tested under section 1115A and use prospective assignment, we note that physicians and practitioners participating in Track 1+ ACOs would also be able to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act. Physicians and practitioners participating in Track 2 ACOs would not be able to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act because Track 2 ACOs do not participate under a prospective assignment methodology. Additionally, the ability to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act would not extend beyond the term of the ACO's participation agreement. If CMS terminates an ACO's participation agreement under § 425.218, then the ability of physicians and other practitioners billing through the TIN of an ACO participant to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act will end on the date specified in the notice of termination. Further, to help protect beneficiaries from potential exposure to significant financial responsibility. We would also like to clarify that an ACO must include, as a part of its notice of termination to ACO participants under § 425.221(a)(1)(i), a statement that physicians and other practitioners who bill through the TIN of an ACO participant can no longer furnish and be paid for telehealth services in accordance with section 1899(l) of the Act after the ACO's date of termination.

As discussed in section II.A.4 of this proposed rule, we propose to allow ACOs in the BASIC and ENHANCED tracks the opportunity to change their beneficiary assignment methodology on an annual basis. As a result, the ability of physicians and other practitioners billing through the TIN of an ACO participant in these ACOs to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act could change from year to year depending on the ACO's choice of assignment methodology. Should an ACO in the BASIC track or ENHANCED track change from the prospective assignment methodology to preliminary prospective assignment methodology with retrospective reconciliation for a performance year, the ACO would no longer satisfy the requirements to be an applicable ACO for that year and physicians and other practitioners billing through the TIN of an ACO participant in that ACO could only furnish and be paid for telehealth services if the services meet all applicable requirements, including the originating site requirements, under section 1834(m)(4)(C) of the Act.

We propose that the beneficiary's home would be a permissible originating site type for telehealth services furnished by a physician or practitioner participating in an applicable ACO. Under this proposal, in addition to being eligible for payment for telehealth services when the originating site is one of the types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act, a physician or other practitioner billing through the TIN of an ACO participant in an applicable ACO could also furnish and be paid for such services when the originating site is the beneficiary's home (assuming all other requirements are met). As discussed earlier, section 1899(l)(1)(A) of the Act, as added by section 50324 of the Bipartisan Budget Act, defines a beneficiary's home to be the place of residence used as the home of the beneficiary. In addition, we propose that Medicare would not pay a facility fee when the originating site for a telehealth service is the beneficiary's home.

Further, we propose that the geographic limitations under section 1834(m)(4)(C)(i) of the Act would not apply to any originating site, including a beneficiary's home, for telehealth services furnished by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO. This would mean that a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO could furnish and be paid for telehealth services when the beneficiary receives those services while located at an originating site in an urban area that is within an MSA, assuming all other requirements are met. We also propose to require that, consistent with section 1899(l)(1)(B) of the Act, the originating site must comply with State licensing requirements.

We propose that the treatment of the beneficiary's home as an originating site and the non-application of the originating site geographic restrictions would be applicable only to payments for services on the list of Medicare telehealth services. The approved list of telehealth services is maintained on our website and is subject to annual updates (*https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html*). However, as provided in section 1899(l)(3)(B) of the Act, in the case where the beneficiary's home is the originating site, Medicare will not pay for telehealth services that are inappropriate to be furnished in the home even if the services are on the approved list of telehealth services. Therefore, we propose that ACO participants must not submit claims for services specified as inpatient only when the service is furnished as a telehealth service and the beneficiary's home is the originating site. For example, CPT codes G0406, G0407, G0408, G0425, G0426, and G0427 are used for reporting inpatient hospital visits and are included on the 2018 approved telehealth list. As described in Chapter 12, section 190.3.1, of the Medicare Claims Processing Manual,[20] Medicare pays for inpatient or emergency department telehealth services furnished to beneficiaries located in a hospital or SNF; therefore, consistent with the current FFS telehealth requirements, we believe it would be inappropriate for an ACO participant to submit a claim for an inpatient telehealth visit when the originating site is the beneficiary's home.

We are concerned about potential beneficiary financial liability for telehealth services provided to beneficiaries excluded from assignment under the Shared Savings Program. A beneficiary prospectively assigned to an applicable ACO at the beginning of a performance year can subsequently be excluded from assignment if he or she meets the exclusion criteria specified under § 425.401(b). To address delays in communicating beneficiary exclusions from the assignment list, the Telehealth Expansion Benefit Enhancement under the Next Generation ACO Model provides for a 90-day grace period that functionally acts as an extension of beneficiary eligibility to receive services under the Benefit Enhancement and permits some additional time for the ACO to receive quarterly exclusion lists

[20] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

from CMS and communicate beneficiary exclusions to its participants. We also provide for a 90-day grace period with respect to the Shared Savings Program SNF 3-day rule waiver under § 425.612(a)(1), which allows for coverage of qualifying SNF services furnished to a beneficiary who was prospectively assigned to an ACO that has been approved for the waiver at the beginning of the performance year, but was excluded in the most recent quarterly update to the ACO's prospective assignment list.

Based upon the experience in the Next Generation ACO Model, we believe it would be inadvisable not to provide some protection for beneficiaries who are prospectively assigned to an applicable ACO at the start of the year, but are subsequently excluded from assignment. It is not operationally feasible for CMS to notify the ACO and for the ACO, in turn, to notify its ACO participants and ACO providers/suppliers immediately of the beneficiary's exclusion. The lag in communication may then cause a physician or practitioner billing under the TIN of an ACO participant to unknowingly furnish a telehealth service to a beneficiary who no longer qualifies to receive telehealth services under section 1899(l) of the Act. Therefore, we are proposing to use our waiver authority under section 1899(f) of the Act to waive the originating site requirements in section 1834(m)(4)(C) of the Act as necessary to provide for a 90-day grace period for payment of otherwise covered telehealth services, to allow sufficient time for CMS to notify an applicable ACO of any beneficiary exclusions, and for the ACO then to inform its ACO participants and ACO providers/suppliers of those exclusions. We believe it is necessary, to protect beneficiaries from potential financial liability related to use of telehealth services furnished by physicians and other practitioners billing through the TIN of an ACO participant in an applicable ACO, to establish this 90-day grace period in the case of a prospectively assigned beneficiary who is later excluded from assignment to an applicable ACO.

More specifically, we propose to waive the originating site requirements in section 1834(m)(4)(C) of the Act to allow for coverage of telehealth services furnished by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO to an excluded beneficiary within 90 days following the date that CMS delivers the relevant quarterly exclusion list under § 425.401(b). We propose to amend § 425.612 to add a new paragraph (f) establishing the terms and conditions of this waiver. This waiver would permit us to make payment for otherwise covered telehealth services furnished during a 90 day grace period to beneficiaries who were initially on an applicable ACO's list of prospectively assigned beneficiaries for the performance year, but were subsequently excluded during the performance year. Under the terms of this waiver, CMS would make payments for telehealth services furnished to such a beneficiary as if they were telehealth services authorized under section 1899(l) of the Act if the following conditions are met:

- The beneficiary was prospectively assigned to an applicable ACO at the beginning of the relevant performance year, but was excluded in the most recent quarterly update to the assignment list under § 425.401(b);
- The telehealth services are furnished to the beneficiary by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO within 90 days following the date that CMS delivers the quarterly exclusion list to the applicable ACO.
- But for the beneficiary's exclusion from the applicable ACO's assignment list, CMS would have made payment to the ACO participant for such services under section 1899(l) of the Act.

In addition, we are concerned that there could be scenarios where a beneficiary could be charged for non-covered telehealth services that were a result of an inappropriate attempt to furnish and be paid for telehealth services under section 1899(l) of the Act by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO. Specifically, we are concerned that a beneficiary could be charged for non-covered telehealth services if a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO were to attempt to furnish a telehealth service that would be otherwise covered under section 1899(l) of the Act to a FFS beneficiary who is not prospectively assigned to the applicable ACO, and payment for the telehealth service is denied because the beneficiary is not eligible to receive telehealth services furnished under section 1899(l) of the Act. We believe this situation could occur as a result of a breakdown in one or more processes of the applicable ACO and its ACO participants. For example, the ACO participant may not verify that the beneficiary appears on the ACO's prospective assignment list, as required under section 1899(l) of the Act, prior to furnishing a telehealth service. In this scenario, Medicare would deny payment of the telehealth service claim because the beneficiary did not meet the requirement of being prospectively assigned to an applicable ACO. We are concerned that, once the claim is rejected, the beneficiary may not be protected from financial liability, and thus could be charged by the ACO participant for non-covered telehealth services that were a result of an inappropriate attempt to furnish telehealth services under section 1899(l), potentially subjecting the beneficiary to significant financial liability. In this circumstance, we propose to assume that the physician or other practitioner's intent was to rely upon section 1899(l) of the Act. We believe this is a reasonable assumption because, as a physician or practitioner billing under the TIN of an ACO participant in an applicable ACO, the healthcare provider should be well aware of the rules regarding furnishing telehealth services and, by submitting the claim, demonstrated an expectation that CMS would pay for telehealth services that would otherwise have been rejected for lack of meeting the originating site requirements in section 1834(m)(4)(C) of the Act. We believe that in this scenario, the rejection of the claim could easily have been avoided if the ACO and the ACO participant had procedures in place to confirm that the requirements for furnishing such telehealth services were satisfied. Because each of these entities is in a better position than the beneficiary to know the requirements of the Shared Savings Program and to ensure that they are met, we believe that the applicable ACO and/or its ACO participants should be accountable for such denials and the ACO participant should be prevented from charging the beneficiary for the non-covered telehealth service. Therefore, we propose that in the event that CMS makes no payment for telehealth services furnished to a FFS beneficiary and billed through the TIN of an ACO participant in an applicable ACO and the only reason the claim was non-covered is because the beneficiary was not prospectively assigned to the ACO or was not in the 90 day grace period, all of the following beneficiary protections would apply:

- The ACO participant must not charge the beneficiary for the expenses incurred for such services;
- The ACO participant must return to the beneficiary any monies collected for such services; and
- The ACO may be subject to compliance actions, including being required to submit a corrective action plan (CAP) under § 425.216(b) for CMS

approval. If the ACO is required to submit a CAP and, after being given an opportunity to act upon the CAP, the ACO fails to implement the CAP or demonstrate improved performance upon completion of the CAP, we may terminate the participation agreement as specified under § 425.216(b)(2). These proposed beneficiary protections are reflected in the proposed new regulation at § 425.613, which implements the requirements of section 1899(l) of the Act and establishes the policies governing the use of telehealth services by applicable ACOs and their ACO participants and ACO providers/suppliers.

We note that we are not proposing at this time to establish any waiver of section 1834(m)(1) to permit payment for telehealth services delivered through asynchronous technologies because we do not have sufficient experience with the waiver that is being tested under the Next Generation ACO Model, to inform whether such a waiver would be necessary for purposes of implementing the Shared Savings Program. We may consider this issue further through future rulemaking after we gain additional experience with the use of asynchronous technologies through the Next Generation ACO Model. We welcome comments on these proposals for implementing the requirements of section 1899(l) of the Act, as added by the Bipartisan Budget Act, and related issues.

Our proposed policies concerning the applicability of the SNF 3-day rule waiver and expanded use of telehealth services in accordance with section 1899(l) of the Act by track are summarized in Table 9.

TABLE 9—AVAILABILITY OF PROPOSED PAYMENT AND PROGRAM POLICIES TO ACOS BY TRACK

Policy	Policy description	Track 1 (One-sided model; propose to discontinue)	Track 2 (Two-sided model; propose to discontinue)	Track 1+ model (two-sided model)	BASIC track (proposed new track)	ENHANCED track (proposed; current track 3 financial model)
Telehealth Services furnished in accordance with § 1899(l) of the Act.	Removes geographic limitations and allows the beneficiary's home to serve as originating site for prospectively assigned beneficiaries.	N/A (because this is a one-sided model under preliminary prospective assignment).	N/A (because under preliminary prospective assignment).	Proposed requirements for performance year 2020 and onward (prospective assignment) [1].	Proposed requirements for performance year 2020 and onward, applicable for performance years under a two-sided model (prospective assignment).	Proposed requirements for performance year 2020 and onward (prospective assignment)
SNF 3-Day Rule Waiver [2].	Waives the requirement for a 3-day inpatient stay prior to admission to a SNF affiliate.	N/A (unavailable under current policy).	N/A (unavailable under current policy).	Current policy (prospective assignment).	Proposed for performance years beginning on July 1, 2019 and subsequent years, eligible for performance years under a two-sided model (prospective or preliminary prospective assignment).	Proposed for performance years beginning on July 1, 2019 and subsequent years (prospective or preliminary prospective assignment)

Notes: [1] An amendment to the Track 1+ Model Participation Agreement would be required to apply the proposed policies regarding the use of telehealth services under § 1899(l) to Track 1+ Model ACOs as described in section II.F of this proposed rule.

[2] As discussed in section II.A.7.c and II.F of this proposed rule, Track 3 ACOs and Track 1+ Model ACOs participating in a performance year beginning on January 1, 2019, may apply for a SNF 3-day rule waiver effective on July 1, 2019. We expect this application cycle would coincide with the application cycle for new agreement periods beginning on July 1, 2019.

C. Providing Tools To Strengthen Beneficiary Engagement

1. Background on Beneficiary Engagement

Section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to promote . . . patient engagement.'' Strengthening beneficiary engagement is one of the agency's goals to help transform our health care system into one that delivers better care, smarter spending and healthier people, and that puts the beneficiary at the center of care. We stated in the November 2011 final rule that the term ''patient engagement'' means the active participation of patients and their families in the process of making medical decisions (76 FR 67828). The regulation at § 425.112 details the patient-centeredness criteria for the Shared Savings Program, and requires that ACOs implement processes to promote patient engagement (§ 425.112(b)(2)).

In addition, Congress recently passed section 50341 of the Bipartisan Budget Act of 2018, which amends section 1899 of the Act, to allow certain ACOs to each establish a beneficiary incentive program for assigned beneficiaries who receive qualifying primary-care services in order to encourage Medicare FFS beneficiaries to obtain medically necessary primary care services. In order to implement the amendments to section 1899 of the Act, and consistent with our goal to strengthen beneficiary engagement, we are proposing policies to allow any ACO in Track 2, levels C, D, or E of the BASIC track, or the ENHANCED track to establish a CMS-approved beneficiary incentive program to provide incentive payments to

eligible beneficiaries who receive qualifying services.

Furthermore, we are proposing to revise policies related to beneficiary notifications. Specifically, we propose to require additional content for beneficiary notifications and that beneficiaries receive such notices at the first primary care visit of each performance year. Finally, we are seeking comment on whether we should create an alternative beneficiary assignment methodology, in order to promote beneficiary free choice, under which a beneficiary would be assigned to an ACO if the beneficiary has ''opted-in'' to assignment to the ACO.

2. Beneficiary Incentives

a. Overview

We believe that patient engagement is an important part of motivating and encouraging more active participation by beneficiaries in their health care. We believe ACOs that engage beneficiaries in the management of their health care may experience greater success in the Shared Savings Program. In the November 2011 final rule (see 76 FR 67958), we noted that some commenters had suggested that beneficiary engagement and coordination of care could be enhanced by providing additional incentives to beneficiaries that would potentially motivate and encourage beneficiaries to become actively involved in their care. One commenter gave the example of supplying scales to beneficiaries with congestive heart failure to help them better manage this chronic disease. Other commenters were concerned that certain beneficiary incentives such as gifts, cash, or other remuneration could be inappropriate incentives for receiving services or remaining assigned to an ACO or with a particular ACO participant or ACO provider/supplier.

In the November 2011 final rule, we finalized a provision at § 425.304(a)(1) that prohibits ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities from providing gifts or other remuneration to beneficiaries as incentives for (i) receiving items and services from or remaining in an ACO or with ACO providers/suppliers in a particular ACO, or (ii) receiving items or services from ACO participants or ACO providers/suppliers. However, in response to comments, we finalized a provision at § 425.304(a)(2) to provide that, subject to compliance with all other applicable laws and regulations, an ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to beneficiaries if there is a reasonable connection between the items or services and the medical care of the beneficiary, and the items or services are preventive care items or services, or advance a clinical goal of the beneficiary, including adherence to a treatment regime; adherence to a drug regime; adherence to a follow-up care plan; or management of a chronic disease or condition. For example, an ACO provider may give a blood pressure monitor to a beneficiary with hypertension in order to encourage regular blood pressure monitoring and thus educate and engage the beneficiary to be more proactive in his or her disease management. In this instance, such a gift would not be considered an improper incentive to encourage the beneficiary to remain with an ACO, ACO participant, or ACO provider/supplier.

We note that nothing precludes ACOs, ACO participants, or ACO providers/suppliers from offering a beneficiary an incentive to promote his or her clinical care if the incentive does not violate the Federal anti-kickback statute (section 1128B(b) of the Act), the civil monetary penalties law provision relating to beneficiary inducements (section 1128A(a)(5) of the Act, known as the Beneficiary Inducements CMP), or other applicable law. For additional information on beneficiary incentives that may be permissible under the Federal anti-kickback statute and the Beneficiary Inducements CMP, see the final rule published by the Office of Inspector General (OIG) on December 7, 2016 titled ''Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements'' (81 FR 88368), as well as other resources that can be found on the OIG website at *oig.hhs.gov.*

We believe that the regulation at § 425.304(a)(2) already provides ACOs with a considerable amount of flexibility to offer beneficiary incentives to encourage patient engagement, promote care coordination, and achieve the objectives of the Shared Savings Program. Further, ACOs, ACO participants, and ACO providers/suppliers need not furnish beneficiary incentives under § 425.304(a)(2) to every beneficiary; they have the flexibility to offer incentives on a targeted basis to beneficiaries who, for example, are most likely to achieve the clinical goal that the incentive is intended to advance. Although the appropriateness of any in-kind beneficiary incentives must be determined on a case-by-case basis, we believe a wide variety of incentives could be acceptable under § 425.304, including, for example, the following:

- Vouchers for over-the-counter medications recommended by a health care provider.
- Prepaid, non-transferable vouchers that are redeemable for transportation services solely to and from an appointment with a health care provider.
- Items and services to support management of a chronic disease or condition, such as home air-filtering systems or bedroom air-conditioning for asthmatic patients, and home improvements such as railing installation or other home modifications to prevent re-injury.
- Wellness program memberships, seminars, and classes.
- Electronic systems that alert family caregivers when a family member with dementia wanders away from home.
- Vouchers for those with chronic diseases to access chronic disease self-management, pain management and falls prevention programs.
- Vouchers for those with malnutrition to access meals programs.
- Phone applications, calendars or other methods for reminding patients to take their medications and promote patient adherence to treatment regimes.

As the previously mentioned examples indicate, we consider vouchers, that is, certificates that can be exchanged for particular goods or services (for example, a certificate for one free gym class at a local gym), to be ''in-kind items or services'' under § 425.304(a)(2). Accordingly, an ACO may offer vouchers as beneficiary incentives under § 425.304(a)(2) so long as the vouchers meet all the other requirements of § 425.304(a)(2).

In addition, for purposes of the Shared Savings Program, we consider gift cards that are in the nature of a voucher, that is, gift cards that can be used only for particular goods or services, to be ''in-kind items or services'' that can be offered under § 425.304(a)(2), provided that the requirements of § 425.304(a)(2) are satisfied. A gift card that is not in the nature of a voucher, however, such as a gift card to a general store, would not meet the requirements for ''in-kind item or service'' under § 425.304(a)(2). Furthermore, we consider a gift card that can be used like cash, for example, a VISA or Amazon ''gift card,'' to be a ''cash equivalent'' that can be offered only as an incentive payment under an approved beneficiary incentive program,

provided that all of the criteria set forth in § 425.304(c), as proposed, are satisfied. We emphasize that, as previously stated, the determination and appropriateness of any in-kind beneficiary incentive must be determined on a case-by-case basis.

Although we believe that ACOs, ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities are already permitted to furnish a broad range of beneficiary incentives under § 425.304(a)(2) (including the previously mentioned examples), stakeholders have advocated that ACOs be permitted to offer a more flexible, expanded range of beneficiary incentives that are not currently allowable under § 425.304. In particular, stakeholders seek to offer monetary incentives that beneficiaries could use to purchase retail items, which would not qualify as in-kind items or services under § 425.304.

b. Provisions of the Bipartisan Budget Act for ACO Beneficiary Incentive Programs

As previously noted, in order to encourage Medicare FFS beneficiaries to obtain medically necessary primary care services, the recent amendments to section 1899 of the Act permit certain ACOs to establish beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying primary care services. We believe that such amendments will empower individuals and caregivers in care delivery. Specifically, the Bipartisan Budget Act adds section 1899(m)(1)(A) of the Act, which allows ACOs to apply to operate an ACO beneficiary incentive program. The Bipartisan Budget Act also adds a new subsection (m)(2) to section 1899 of the Act, which provides clarification regarding the general features, implementation, duration, and scope of approved ACO beneficiary incentive programs. In addition, the Bipartisan Budget Act adds section 1899(b)(2)(I) of the Act, which requires ACOs that seek to operate a beneficiary incentive program to apply to operate the program at such time, in such manner, and with such information as the Secretary may require.

Section 1899(m)(1)(A) of the Act, as added by the Bipartisan Budget Act, allows ACOs participating in certain payment models described in section 1899(m)(2)(B) of the Act to apply to establish an ACO beneficiary incentive program to provide incentive payments to Medicare FFS beneficiaries who are furnished qualifying services. Section 1899(m)(1)(A) of the Act also specifies that the Secretary shall permit an ACO to establish such a program at the Secretary's discretion and subject to such requirements, including program integrity requirements, as the Secretary determines necessary.

Section 1899(m)(1)(B) of the Act requires the Secretary to implement the ACO beneficiary incentive program provisions under section 1899(m) of the Act on a date determined appropriate by the Secretary, but no earlier than January 1, 2019 and no later than January 1, 2020. In addition, section 1899(m)(2)(A) of the Act, as added by the Bipartisan Budget Act, specifies that an ACO beneficiary incentive program shall be conducted for a period of time (of not less than 1 year) as the Secretary may approve, subject to the termination of the ACO beneficiary incentive program by the Secretary.

Section 1899(m)(2)(H) of the Act provides that the Secretary may terminate an ACO beneficiary incentive program at any time for reasons determined appropriate by the Secretary. In addition, the Bipartisan Budget Act amended section 1899(g)(6) of the Act to provide that there shall be no administrative or judicial review under section 1869 or 1878 of the Act, or otherwise, of the termination of an ACO beneficiary incentive program.

Section 1899(m)(2)(B) of the Act requires that an ACO beneficiary incentive program provide incentive payments to all of the following Medicare FFS beneficiaries who are furnished qualifying services by the ACO: (1) Medicare FFS beneficiaries who are preliminarily prospectively or prospectively assigned (or otherwise assigned, as determined by the Secretary) to an ACO in a Track 2 or Track 3 payment model described in § 425.600(a) (or in any successor regulation) and (2) Medicare FFS beneficiaries who are assigned to an ACO, as determined by the Secretary, in any future payment models involving two-sided risk.

Section 1899(m)(2)(C) of the Act, as added by the Bipartisan Budget Act, defines a qualifying service, for which incentive payments may be made to beneficiaries, as a primary care service, as defined in § 425.20 (or in any successor regulation), with respect to which coinsurance applies under Medicare part B. Section 1899(m)(2)(C) of the Act also provides that a qualifying service is a service furnished through an ACO by: (1) An ACO professional described in section 1899(h)(1)(A) of the Act who has a primary care specialty designation included in the definition of primary care physician under § 425.20 (or any successor regulation) (2) an ACO professional described in section 1899(h)(1)(B) of the Act; or (3) a FQHC or RHC (as such terms are defined in section 1861(aa) of the Act).

As added by the Bipartisan Budget Act, section 1899(m)(2)(D) of the Act provides that an incentive payment made by an ACO under an ACO beneficiary incentive program shall be in an amount up to $20, with the maximum amount updated annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year. Section 1899(m)(2)(D) of the Act also requires that an incentive payment be in the same amount for each Medicare FFS beneficiary regardless of the enrollment of the beneficiary in a Medicare supplemental policy (described in section 1882(g)(1) of the Act), in a State Medicaid plan under Title XIX or a waiver of such a plan, or in any other health insurance policy or health benefit plan. Finally, section 1899(m)(2)(D) of the Act requires that an incentive payment be made for each qualifying service furnished to a beneficiary during a period specified by the Secretary and that an incentive payment be made no later than 30 days after a qualifying service is furnished to the beneficiary.

Section 1899(m)(2)(E) of the Act, as added by the Bipartisan Budget Act, provides that no separate payment shall be made to an ACO for the costs, including the costs of incentive payments, of carrying out an ACO beneficiary incentive program. The section further provides that this requirement shall not be construed as prohibiting an ACO from using shared savings received under the Shared Savings Program to carry out an ACO beneficiary incentive program. In addition, section 1899(m)(2)(F) of the Act provides that incentive payments made by an ACO under an ACO beneficiary incentive program shall be disregarded for purposes of calculating benchmarks, estimated average per capita Medicare expenditures, and shared savings for purposes of the Shared Savings Program.

As added by the Bipartisan Budget Act, section 1899(m)(2)(G) of the Act provides that an ACO conducting an ACO beneficiary incentive program shall, at such times and in such format as the Secretary may require, report to the Secretary such information and retain such documentation as the Secretary may require, including the amount and frequency of incentive payments made and the number of Medicare FFS beneficiaries receiving such payments.

Finally, section 1899(m)(3) of the Act excludes payments under an ACO beneficiary incentive program from being considered income or resources or otherwise taken into account for purposes of: (1) Determining eligibility for benefits or assistance under any Federal program or State or local program financed with Federal funds; or (2) any Federal or State laws relating to taxation.

c. Proposals for Beneficiary Incentive Programs

In order to implement the changes set forth in section 1899(b)(2) and (m) of the Act, we are proposing to add regulation text at § 425.304(c) that would allow ACOs participating under certain two-sided models to establish beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying services. In developing our proposed policy, we have considered the statutory provisions set forth in section 1899(b)(2) and (m) of the Act, as amended, as well as the following: The application process for establishing a beneficiary incentive program; who can furnish an incentive payment; the amount, timing, and frequency of an incentive payment; how an incentive payment may be financed, and necessary program integrity requirements. We address each of these considerations in this proposed rule.

As previously explained, section 1899(m)(1)(A) of the Act authorizes ''an ACO participating under this section under a payment model described in clause (i) or (ii) of paragraph (2)(B)'' to establish an ACO beneficiary incentive program. In turn, section 1899(m)(2)(B)(i) of the Act describes ACOs participating in ''Track 2 and Track 3 payment models as described in section 425.600(a) . . . (or in any successor regulation).'' Section 1899(m)(2)(B)(ii) of the Act describes ACOs participating in ''any future payment models involving two-sided risk.'' As discussed in section II.A.2 of this proposed rule, we are proposing to (1) discontinue Track 2 as a participation option and limit its availability to agreement periods beginning before July 1, 2019; (2) rename Track 3 the ''ENHANCED track''; and (3) require ACOs with agreement periods beginning July 1, 2019 and in subsequent years to enter either the ENHANCED track (which entails two-sided risk) or the new BASIC track (in which Levels A and B have one-sided risk and Levels C, D, and E have two-sided risk). As noted in proposed § 425.600(a)(3), for purposes of the Shared Savings Program, all references to the ENHANCED track would be deemed to include Track 3; the terms are synonymous. Accordingly, Track 2 and ENHANCED track ACOs are described under section 1899(m)(2)(B)(i) of the Act, and ACOs in Levels C, D, or E of the BASIC track are described under section 1899(m)(2)(B)(ii) of the Act. As a result, Track 2 ACOs, ENHANCED track ACOs, and ACOs in Levels, C, D, or E of the BASIC track are authorized to establish beneficiary incentive programs under section 1899(m)(1)(A) of the Act.

Section 1899(m)(1)(B) of the Act states that the ''Secretary shall implement this subsection on a date determined appropriate by the Secretary. Such date shall be no earlier than January 1, 2019, and no later than January 1, 2020.'' We propose to allow ACOs to establish a beneficiary incentive program beginning no earlier than July 1, 2019. As discussed later in this section, ACOs that are approved to operate a beneficiary incentive program shall conduct the program for at least 1 year as required by section 1899(m)(2)(A) of the Act unless CMS terminates the ACO's beneficiary incentive program. This means, for example, that an ACO currently participating in the Shared Savings Program under Track 2 or Track 3 whose agreement period expires on December 31, 2019 would be ineligible to operate a beneficiary incentive program starting on July 1, 2019 because the ACO would have only 6 months of its agreement remaining as of July 1, 2019. The ACO could, however, start a beneficiary incentive program on January 1, 2020 (assuming it renews its agreement).

We considered the operational impact of having both a midyear beneficiary incentive program cycle (for ACOs that seek to establish a beneficiary incentive program beginning on July 1, 2019) and a calendar year beneficiary incentive program cycle (for ACOs that seek to establish a beneficiary incentive program beginning on January 1, 2020, or a later January 1 start date). We believe it could be confusing for ACOs, and difficult for CMS to monitor approved beneficiary incentive programs, if some ACOs begin their beneficiary incentive programs in July 2019 and other ACOs begin their beneficiary incentive programs in January 2020. For example, under this approach, annual certifications regarding intent to continue a beneficiary incentive program (as further discussed herein) would be provided by ACOs at different times of the year, depending on when each ACO established its beneficiary incentive program. To address this, we believe it is necessary to require ACOs that establish a beneficiary incentive program on July 1, 2019 to commit to an initial beneficiary incentive program term of 18 months (with certifications required near the conclusion of the 18-month period and for each consecutive 12-month period thereafter). However, any ACO that establishes a beneficiary incentive program beginning on January 1 of a performance year would be required to commit to an initial beneficiary incentive program term of 12 months. This would allow the term cycles of all ACO beneficiary incentive programs to later ''sync'' so that they all operate on a calendar year beginning on January 1, 2021. As an alternative, we considered permitting all ACOs to establish a beneficiary incentive program beginning January 1, 2020. However, we believe that some ACOs may prefer to establish a beneficiary incentive program on July 1, 2019, rather than delay until January 1, 2020.

The statute does not prescribe procedures that ACOs must adhere to in applying to establish a beneficiary incentive program. In addition, beyond the requirement that ACOs participate in Track 2, Track 3 (which, as we previously discussed, will be renamed the ''ENHANCED track'') or a ''future payment model involving two-sided risk'' (sections 1899(m)(2)(B)(i) and (ii) of the Act), the new provisions do not describe what factors we should consider in evaluating whether an ACO should be permitted to establish a beneficiary incentive program. Instead, section 1899(m)(1)(A) of the Act states that the ''Secretary shall permit such an ACO to establish such a program at the Secretary's discretion and subject to such requirements . . . as the Secretary determines necessary.'' We propose that the application for the beneficiary incentive program be in a form and manner specified by CMS, which may be separate from the application to participate in the Shared Savings Program. We would provide additional information regarding the application on our website.

We propose to permit eligible ACOs to apply to establish a beneficiary incentive program during the July 1, 2019 application cycle or during a future annual application cycle for the Shared Savings Program. In addition, we propose to permit an eligible ACO that is mid-agreement to apply to establish a beneficiary incentive program during the application cycle prior to the performance year in which the ACO chooses to begin implementing its beneficiary incentive program. This would apply to ACOs that enter a two-sided model at the start of an agreement period but that do not apply to establish

a beneficiary incentive program at the time of their initial or renewal application to the Shared Savings Program. This means, for example, that an ACO that enters the Shared Savings Program under a two-sided model but that does not seek to offer a beneficiary incentive program until its second performance year could apply to offer a beneficiary incentive program during the application cycle in advance of its second performance year. This would also apply to ACOs that enter the BASIC track's glide path under a one-sided model and that apply to establish a beneficiary incentive program beginning with a performance year under a two-sided model (see discussion in sections II.A.3.b and II.A.4.b of this proposed rule).

An ACO would be required to operate its beneficiary incentive program effective at the beginning of the performance year following CMS's approval of the ACO's application to establish the beneficiary incentive program. The ACO would then be required to operate the approved beneficiary incentive program for the entirety of such 12-month performance year (for ACOs that establish a beneficiary incentive program on January 1, 2020, or a later January 1 start date) or for an initial 18-month period (for ACOs that establish a beneficiary incentive program on July 1, 2019).

An ACO with an approved beneficiary incentive program application would be permitted to operate its beneficiary incentive program for any consecutive performance year if it complies with certain certification requirements. Specifically, an ACO that seeks to continue to offer its beneficiary incentive program beyond the initial 12-month or 18-month term (as previously discussed) would be required to certify, in the form and manner and by a deadline specified by CMS, its intent to continue to operate its beneficiary incentive program for the entirety of the next performance year, and that its beneficiary incentive program continues to meet all applicable requirements. CMS may terminate a beneficiary incentive program, in accordance with § 425.304(c)(7), as proposed, if an ACO fails to provide such certification. We believe this certification requirement is necessary for CMS to monitor beneficiary incentive programs. CMS would provide further information regarding the annual certification process through subregulatory guidance.

In addition to the application and certification requirements previously described, we are considering whether an ACO that offers a beneficiary incentive program should be required to notify CMS of any modification to its beneficiary incentive program prior to implementing such modification. We solicit comments on this issue.

With respect to who may receive an incentive payment, a FFS beneficiary would be eligible to receive an incentive payment if the beneficiary is assigned to an ACO through either preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2), or prospective assignment, as described in § 425.400(a)(3). We note that Track 2 is under preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2). In addition, as discussed in section II.A.4 of this proposed rule, we propose to permit BASIC track and ENHANCED track ACOs to enter an agreement period under preliminary prospective assignment, as described in § 425.400(a)(2), or under prospective assignment, as described in § 425.400(a)(3). Further, a beneficiary may choose to voluntarily align with an ACO, and, if eligible for assignment, the beneficiary would be prospectively assigned to the ACO (regardless of track) for the performance year under § 425.402(e)(1). Therefore, consistent with our policy regarding which ACOs may establish a beneficiary incentive program, any beneficiary assigned to an ACO that is participating under Track 2; Levels C, D, or E of the BASIC track; or the ENHANCED track may receive an incentive payment under that ACO's CMS-approved beneficiary incentive program.

Section 1899(m)(2)(C) of the Act sets forth the definition of a qualifying service for purposes of the beneficiary incentive program. We mirror the language in the proposed regulation text noting that ''a qualifying service is a primary care service,'' as defined in § 425.20, ''with respect to which coinsurance applies under part B,'' furnished through an ACO by ''an ACO professional who has a primary care specialty designation included in the definition of primary care physician'' under § 425.20; an ACO professional who is a physician assistant, nurse practitioner, or clinical nurse specialist; or a FQHC or RHC. This means that any service furnished by an ACO professional who is a physician but does not have a specialty designation included in the definition of primary care physician would not be considered a qualifying service for which an incentive payment may be furnished.

With respect to the amount of any incentive payment, section 1899(m)(2)(D)(i) of the Act provides that an incentive payment made by an ACO in accordance with a beneficiary incentive program shall be ''in an amount up to $20.'' Accordingly, we propose to incorporate a $20 incentive payment limit into the regulation. We also propose to adopt the provision at section 1899(m)(2)(D)(i) of the Act, which provides that the $20 maximum amount must be ''updated annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.'' To avoid minor changes in the updated maximum amount, however, we believe it is necessary to round the updated maximum incentive payment amount to the nearest whole dollar. We have reflected this policy in our proposed regulations text. We would post the updated maximum payment amount on the Shared Savings Program website and/or in a guidance regarding beneficiary incentive programs.

We also propose to adopt the requirement that the incentive payment be ''in the same amount for each Medicare fee-for-service beneficiary'' without regard to enrollment of such a beneficiary in a Medicare supplemental policy, in a State Medicaid plan, or a waiver of such a plan, or in any other health insurance policy or health plan. (Section 1899(m)(2)(D)(ii) of the Act.) Accordingly, all incentive payments distributed by an ACO under its beneficiary incentive program must be of equal monetary value. In other words, an ACO would not be permitted to offer higher-valued incentive payments for particular qualifying services or to particular beneficiaries. However, an ACO may provide different types of incentive payments (for example, a gift card to some beneficiaries and a check to others) depending on a beneficiary's preference, so long as all incentive payments offered by the ACO under its beneficiary incentive program are of equal monetary value.

Furthermore, as required by section 1899(m)(2)(D)(iii) of the Act, we propose that an ACO furnish an incentive payment to an eligible beneficiary each time the beneficiary receives a qualifying service. In addition, in accordance with section 1899(m)(2)(D)(iv) of the Act, we propose to require that each incentive payment be ''made no later than 30 days after a qualifying service is furnished to such a beneficiary.''

We have considered the individuals and entities that should be permitted to offer incentive payments to beneficiaries under a beneficiary incentive program. We note that section 1899(m)(2)(D) of the Act, which addresses incentive

payments, contemplates that incentive payments be furnished directly by an ACO to a beneficiary. In addition, we believe this requirement is necessary because the ACO is in the best position to ensure that any incentive payments offered are distributed only to eligible beneficiaries and that other program requirements are met. We are therefore proposing to require that the ACO legal entity, and not ACO participants or ACO providers/suppliers, furnish the incentive payments directly to beneficiaries. We seek comment, however, on other potential methods for distributing an incentive payment to a beneficiary.

As previously explained, section 1899(m)(1)(A) of the Act allows the Secretary to establish ''program integrity requirements, as the Secretary deems necessary.'' Given the significant fraud and abuse concerns associated with offering cash incentives, we believe it is necessary to prohibit ACOs from distributing incentive payments to beneficiaries in the form of cash. Cash incentive payments would be inherently difficult to track for reporting and auditing purposes since they would not necessarily be tied to documents providing written evidence that a cash incentive payment was furnished to an eligible beneficiary for a qualifying service. The inability to trace a cash incentive would make it difficult for CMS to ensure that an ACO has uniformly furnished incentive payments to all eligible beneficiaries and has not made excessive payments or otherwise used incentive payments to improperly attract ''healthier'' beneficiaries while disadvantaging beneficiaries who are less healthy or have a disability. Therefore, we propose to require that incentive payments be in the form of a cash equivalent, which includes instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards.

In addition, we have considered record retention requirements related to beneficiary incentive programs. Section 1899(m)(2)(G) of the Act provides that an ACO ''conducting an ACO Beneficiary Incentive Program . . . shall, at such times and in such format as the Secretary may require . . . retain such documentation as the Secretary may require, including the amount and frequency of incentive payments made and the number of Medicare fee-for-service beneficiaries receiving such payments.'' We believe it is important for an ACO to be accountable for its beneficiary incentive program and to mitigate any gaming, fraud, or waste that may occur as a result of its beneficiary incentive program. Accordingly, we propose that any ACO that implements a beneficiary incentive program maintain records that include the following information: Identification of each beneficiary that received an incentive payment, including name and HICN or Medicare beneficiary identifier; the type (such as check or debit card) and amount (that is, the value) of each incentive payment made to each beneficiary; the date each beneficiary received a qualifying service and the HCPCS code for the corresponding service; the identification of the ACO provider/supplier that furnished the qualifying service; and the date the ACO provided each incentive payment to each beneficiary. An ACO that establishes a beneficiary incentive program would be required to maintain and make available such records in accordance with § 425.314(b). In addition to these record retention proposals, we expect any ACO that establishes a beneficiary incentive program to update its compliance plan (as required under § 425.300(b)(2)), to address any finalized regulations that address beneficiary incentive programs.

Furthermore, we propose that an ACO be required to fully fund the costs associated with operating a beneficiary incentive program, including the cost of any incentive payments. We further propose to prohibit ACOs from accepting or using funds furnished by an outside entity, including, but not limited to, an insurance company, pharmaceutical company, or any other entity outside of the ACO, to finance its beneficiary incentive program. We believe these requirements are necessary to reduce the likelihood of undue influence resulting in inappropriate steering of beneficiaries to specific products or providers/suppliers. We seek comments on this issue.

We also propose to incorporate language in section 1899(m)(2)(E) of the Act, which provides that ''[t]he Secretary shall not make any separate payment to an ACO for the costs, including incentive payments, of carrying out an ACO Beneficiary Incentive Program . . . Nothing in this subparagraph shall be construed as prohibiting an ACO from using shared savings received under this section to carry out an ACO Beneficiary Incentive Program.'' Specifically, we propose under § 425.304(a)(2) that the policy regarding use of shared savings apply with regard to both in-kind items and services furnished under § 425.304(b) and incentive payments furnished under § 425.304(c).

Further, we propose to prohibit ACOs from shifting the cost of establishing or operating a beneficiary incentive program to a Federal health care program, as defined at section 1128B(f) of the Act. Essentially, ACOs would not be permitted to bill the cost of an incentive payment to any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government. We believe this requirement is necessary because billing another Federal health care program for the cost of a beneficiary incentive program would potentially violate section 1899(m)(2)(E) of the Act which prohibits the Secretary from making any separate payment to an ACO for the costs of carrying out a beneficiary incentive program, including the costs of incentive payments. We seek comments on all of our proposed program integrity requirements.

In addition, we are proposing to implement the language in section 1899(m)(2)(F) of the Act that ''incentive payments made by an ACO . . . shall be disregarded for purposes of calculating benchmarks, estimated average per capita Medicare expenditures, and shared savings under this section.'' We are also proposing to disregard incentive payments made by an ACO for purposes of calculating shared losses under this section given that that shared savings would be disregarded.

Furthermore, we propose to implement the language set forth in section 1899(m)(3) of the Act, which provides that ''any payment made under an ACO Beneficiary Incentive Program . . . shall not be considered income or resources or otherwise taken into account for the purposes of determining eligibility for benefits or assistance (or the amount or extent of benefits or assistance) under any Federal program or any State or local program financed in whole or in part with Federal funds; or any Federal or state laws relating to taxation.'' We have included this proposal at § 425.304(c)(6).

With regard to termination of a beneficiary incentive program, section 1899(m)(2)(H) of the Act provides that the ''Secretary may terminate an ACO Beneficiary Incentive Program . . . at any time for reasons determined appropriate by the Secretary.'' We believe it would be appropriate for CMS to terminate an ACO's use of the beneficiary incentive program for failure to comply with the requirements of our finalized proposals at § 425.304, in whole or in part, and for the reasons set forth in § 425.218(b), and we are therefore proposing this policy at § 425.304(c)(7). We solicit comment on whether it would be appropriate for the Secretary to terminate a beneficiary

incentive program in other circumstances as well, or whether an ACO should have the ability to terminate its beneficiary incentive program early. In addition, we propose to require any ACO that wishes to reestablish a beneficiary incentive program after termination to reapply in accordance with the procedures established by CMS. We are also proposing to modify our regulations at § 425.800 to implement the language set forth in section 1899(g)(6) of the Act, which provides that there shall be no administrative or judicial review under section 1869 or 1878 of the Act or otherwise of the termination of an ACO beneficiary incentive program.

With regard to evaluation of beneficiary incentive programs, we note that section 50341(c) of the Bipartisan Budget Act requires that, no later than October 1, 2023, the Secretary evaluate and report to Congress an analysis of the impact of implementing beneficiary incentive programs on health expenditures and outcomes. We welcome comments on whether there might be information that we should require ACOs to maintain (in addition to the information that would be maintained as part of record retention requirements set forth at § 425.304(c)(4)(i)) to support such an evaluation of beneficiary incentive programs. We note, however, that we do not want to discourage participation by imposing overly burdensome data management requirements on ACOs. We therefore seek comment on reporting requirements for ACOs that are approved to establish a beneficiary incentive program.

In addition, we note that under the existing regulations for monitoring ACO compliance with program requirements, CMS may employ a range of methods to monitor and assess ACOs, ACO participants and ACO providers/suppliers to ensure that ACOs continue to satisfy Shared Savings Program eligibility and program requirements (§ 425.316). The scope of this provision would include monitoring ACO, ACO participant, and ACO provider/supplier compliance with the requirements for establishing and operating a beneficiary incentive program.

We are considering whether beneficiaries should be notified of the availability of a beneficiary incentive program. Because beneficiary incentives may be subject to abuse, we believe it is necessary, and we have proposed, to prohibit the advertisement of a beneficiary incentive program. We are considering, however, whether ACOs should be required to make beneficiaries aware of the incentive via approved outreach material from CMS. For example, under the program's existing regulations (§ 425.312(a)), including as revised by this proposed rule in section II.C.3.a., all ACO participants are required to notify beneficiaries that their ACO providers/suppliers are participating in the Shared Savings Program. We solicit comment on whether the notifications required under § 425.312(a) should include information regarding the availability of an ACO's beneficiary incentive program, and, if so, whether CMS should supply template language on the topic. We also seek comment on how and when an ACO might otherwise notify its beneficiaries that its beneficiary incentive program is available, without inappropriately steering beneficiaries to voluntarily align with the ACO or to seek care from specific ACO participants, and, whether it would be appropriate to impose restrictions regarding advertising a beneficiary incentive program. We note that we would expect any beneficiary notifications regarding incentive payments to be maintained and made available for inspection in accordance with § 425.314.

To ensure transparency and to meet the requirements of section 1899(m)(2)(G) of the Act requiring that an ACO ''conducting an ACO Beneficiary Incentive Program . . . shall, at such times and in such format as the Secretary may require, report to the Secretary such information . . . as the Secretary may require, including the amount and frequency of incentive payments made and the number of Medicare fee-for-service beneficiaries receiving such payments,'' we further propose to revise the program's public reporting requirements in § 425.308 to require any ACO that has been approved to implement a beneficiary incentive program to publicly report certain information about incentive payments on its public reporting web page. Specifically, we propose to require ACOs to publicly report, for each performance year, the total number of beneficiaries who receive an incentive payment, the total number of incentive payments furnished, HCPCS codes associated with any qualifying payment for which an incentive payment was furnished, the total value of all incentive payments furnished, and the total type of each incentive payment (for example, check or debit card) furnished. We note that this proposed policy would require reporting for the 6-month performance year that begins on July 1, 2019. We seek comment on whether information about a beneficiary incentive program should be publicly reported by the ACO or simply reported to CMS annually or upon request.

In summary, we are proposing to revise the regulation at § 425.304 to enable an ACO participating in Track 2, levels C, D, or E of the BASIC track, or the ENHANCED track, to establish a beneficiary incentive program to provide incentive payments to beneficiaries for qualifying primary care services in compliance with the requirements outlined in the revised regulations.

Our proposed policies concerning an ACO's ability to establish a beneficiary incentive program are summarized in Table 10.

TABLE 10—ABILITY OF ACOS TO ESTABLISH A PROPOSED BENEFICIARY INCENTIVE PROGRAM BY TRACK

Policy	Policy description	Track 1 (one-sided model; propose to discontinue)	Track 2 (two-sided model; propose to discontinue)	Track 1+ model (two-sided model)	BASIC track (proposed new track)	ENHANCED track (proposed; current track 3 financial model)
Beneficiary Incentive Program.	Requires ACOs that establish a beneficiary incentive program to provide an incentive payment to each assigned beneficiary (prospective or preliminary prospective) for each qualifying service received.	N/A	Proposed beginning July 1, 2019 and for subsequent performance years (preliminary prospective assignment).	N/A	Proposed beginning July 1, 2019 and for subsequent performance years for ACOs in Levels C, D or E (prospective or preliminary prospective assignment).	Proposed beginning July 1, 2019 and for subsequent performance years (prospective or preliminary prospective assignment).

d. Clarification of Existing Rules

We are also taking this opportunity to add regulation text at renumbered § 425.304(b)(3) to clarify that the in-kind items or services provided to a Medicare FFS beneficiary under § 425.304 must not include Medicare-covered items or services, meaning those items or services that would be covered under Title XVIII of the Act on the date the in-kind item or service is furnished to the beneficiary. It was always our intention that the in-kind items or services furnished under existing § 425.304(a) be non-Medicare-covered items and services so that CMS can accurately monitor the cost of medically necessary care in the Shared Savings Program and to minimize the potential for fraud and abuse. We also clarify that the provision of in-kind items and services is available to all Medicare FFS beneficiaries and is not limited solely to beneficiaries assigned to an ACO.

Finally, we propose a technical change to the title and structure of § 425.304. Specifically, we are proposing to replace the title of § 425.304 with ''Beneficiary incentives'' and to add a new section § 425.305, with a title ''Other program safeguards'', by redesignating paragraphs § 425.304(b) and (c) as § 425.305(a) and (b), and to make conforming changes to regulations that refer to section § 425.304. Specifically, we propose to make the following conforming changes: Amending § 425.118 in paragraph (b)(1)(iii) by removing ''§ 425.304(b)'' and adding in its place ''§ 425.305(a)''; amending § 425.224 in newly redesignated paragraph (b)(1)(v) by removing ''§ 425.304(b)'' and adding in its place ''§ 425.305(a)''; amending § 425.310 in paragraph (c)(3) by removing ''§ 425.304(a)'' and adding in its place ''§ 425.304''; and amending § 425.402 in paragraph (e)(3)(i) by removing ''§ 425.304(a)(2)'' and adding in its place ''§ 425.304(b)(1).''

3. Empowering Beneficiary Choice

a. Beneficiary Notifications

(1) Background on Beneficiary Notifications

To ensure full transparency between providers participating in Shared Savings Program ACOs and the beneficiaries they serve, the November 2011 final rule established requirements for how a Shared Savings Program ACO must notify Medicare FFS beneficiaries receiving primary care services at the point of care that the physician, hospital, or other provider is participating in a Shared Savings Program ACO (76 FR 67945 through 67946). Specifically, the November 2011 final rule established a requirement that ACO participants provide standardized written notices to beneficiaries of both their ACO provider/supplier's participation in the Shared Savings Program and the potential for CMS to share beneficiary identifiable data with the ACO.

We initially established the beneficiary notification requirements for ACOs to protect beneficiaries by ensuring patient engagement and transparency, including requirements related to beneficiary notification, since the statute does not mandate that ACOs provide information to beneficiaries about the Shared Savings Program (76 FR 67945 through 67946). The beneficiary information notices included information on whether a beneficiary was receiving services from an ACO participant or ACO provider/supplier, and whether the beneficiary's expenditure and quality data would be used to determine the ACO's eligibility to receive a shared savings payment.

In the June 2015 final rule, we amended the beneficiary notification requirement and sought comment on simplifying the process of disseminating the beneficiary information notice. We received numerous comments from ACOs that the beneficiary notification requirement was too burdensome and created some confusion amongst beneficiaries about the Shared Savings Program (80 FR 32739). As a result, we revised the rule so that ACO providers/suppliers would be required to provide the notification by simply posting signs in their facilities and by making the notice available to beneficiaries upon request.

We also amended our rule to streamline the beneficiary notification process by which beneficiaries may decline claims data sharing and finalized the requirement that ACO participants use CMS-approved template language to notify beneficiaries regarding participation in an ACO and the opportunity to decline data sharing. In order to streamline operations, reduce burden and cost on ACOs and their providers, and avoid creating beneficiary confusion, we also streamlined the process for beneficiaries to decline data sharing by consolidating the data opt out process through 1–800–MEDICARE in the June 2015 final rule (80 FR 32737 through 32743). Beneficiaries must contact 1–800–MEDICARE to decline sharing their Medicare claims data or to reverse that decision.

As previously discussed, under the program's current requirements, an ACO participant (for example physician practices and hospitals) must notify beneficiaries in writing of its participation in an ACO by posting signs in its facilities and, in settings in which beneficiaries receive primary care services, by making a standardized written notice (the ''Beneficiary Information Notice'') available to beneficiaries upon request (§ 425.312). We provide ACOs with templates, in English and Spanish, to share with their ACO participants for display or distribution. To summarize:

- The poster language template indicates the providers' participation in the Shared Savings Program; describes ACOs and what they mean for beneficiary care; highlights that a beneficiary's freedom to choose his or her doctors and hospitals is maintained; and indicates that beneficiaries have the option to decline to have their Medicare Part A, B, and D claims data shared with their ACO or other ACOs. The poster must be in a legible format for display and in a place where beneficiaries can view it.
- The Beneficiary Information Notice template covers the same topics and includes details on how beneficiaries can select their primary clinician via MyMedicare.gov and voluntarily align to the ACO.

In addition to these two templates, there are two other ways that beneficiaries can learn about ACOs and of their option to decline Medicare claims data sharing with ACOs:

- Medicare & You handbook. The language in the ACO section of the handbook (available at *https://www.medicare.gov/pubs/pdf/10050-Medicare-and-You.pdf*) describes ACOs and tells beneficiaries they will be notified at the point of care if their doctor participates in the Shared Savings Program. It explains what doctor participation in an ACO means for a beneficiary's care and that beneficiaries have the right to receive care from any doctor that accepts Medicare. The ACO section of the handbook also explains that beneficiaries must call 1–800–MEDICARE (1–800–633–4227) to decline sharing their health care information with ACOs or to reverse that decision.
- 1–800–MEDICARE. Customer service representatives are equipped with scripted language about the Shared Savings Program, including background about ACOs. The customer service representatives also can collect information from beneficiaries about declining or reinstating Medicare claims data sharing.

Further, beginning in July 2017, Medicare FFS beneficiaries can login to MyMedicare.gov and select the primary

clinician whom they believe is most responsible for their overall care coordination (a process we refer to as voluntary alignment). The instructions for selecting a primary clinician are also included in the Medicare & You handbook, issued by CMS annually to Medicare beneficiaries. The Shared Savings Program uses a beneficiary's selection of a primary clinician for assignment purposes, when applicable, for ACOs in all tracks beginning in performance year 2018 (§ 425.402(e)).

We have made information about the Shared Savings Program publicly available to educate ACOs, providers, beneficiaries and the general public, and to further program transparency. This includes fact sheets, program guidance and specifications, program announcements and data available through the Shared Savings Program website (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html*). This material includes resources designed to educate beneficiaries about the Shared Savings Program and ACOs,[21] and specifically on the voluntary alignment process.[22]

(2) Proposed Revisions

We are revisiting the program's existing requirements at § 425.312 to ensure beneficiaries have a sufficient opportunity to be informed about the program and how it may affect their care and their data. We have also proposed changes in response to section 50331 of the Bipartisan Budget Act of 2018, which amends section 1899(c) of the Act to require that the Secretary establish a process by which Medicare FFS beneficiaries are (1) ''notified of their ability'' to identify an ACO professional as their primary care provider (for purposes of assigning the beneficiary to an ACO, as described in § 425.402(e)) and (2) ''informed of the process by which they may make and change such identification.''

In addition, in proposing revisions to § 425.312 we considered how to make the notification a comprehensive resource that compiles certain information about the program and what participation in the program means for beneficiary care. While there are many sources of information on the program that are available to beneficiaries, we are concerned that the existing information exists in separate resources, which may be time consuming for beneficiaries to compile, and, as a result, may be underutilized.

We also considered methods of notification that would better ensure that beneficiaries receive the comprehensive notification at the point of care. The current regulations emphasize use of posted signs in facilities and, in settings where beneficiaries receive primary care services, standardized written notices as a means to notify beneficiaries at the point of care that ACO providers/suppliers are participating in the program and of the beneficiary's opportunity to decline data sharing. Although standardized written notices must be made available upon request, we are concerned that few beneficiaries, or others who accompany beneficiaries to their medical appointments, may initiate request for this information. In turn, beneficiaries may not have the information they need to make informed decisions about their health care and their data.

Finally, we considered how to minimize burden on the ACO providers/suppliers that would provide the notification. We seek to balance the requirements of the notification to beneficiaries with the increased burden on health care providers that could draw their attention away from patient care.

With these considerations in mind, and to further facilitate beneficiary access to information on the Shared Savings Program, we are proposing to modify § 425.312(a) to require additional content for beneficiary notices. We propose that, beginning July 1, 2019, the ACO participant must notify beneficiaries at the point of care about voluntary alignment in addition to notifying beneficiaries that its ACO providers/suppliers are participating in the Shared Savings Program and that the beneficiary has the opportunity to decline claims data sharing. Specifically, the ACO participant must notify the beneficiary of his or her ability to, and the process by which, he or she may identify or change identification of a primary care provider for purposes of voluntary alignment.

We propose to modify § 425.312(b) to require that, beginning July 1, 2019, ACO participants must provide the information specified in § 425.312(a) to each Medicare FFS beneficiary at the first primary care visit of each performance year. Under this proposal, an ACO participant would be required to provide this notice during a beneficiary's first primary care visit in the 6-month performance year from July 1, 2019 through December 31, 2019, as well as the first primary care visit in the 12-month performance year that begins on January 1, 2020 (and in all subsequent performance years). We propose that this notice would be in addition to the existing requirement that an ACO participant must post signs in its facilities and make standardized written notices available upon request.

To mitigate the burden of this additional notification, we propose to require ACO participants to use a template notice that we would prepare and make available to ACOs. The template notice would contain all of the information required to be disclosed under § 425.312(a), including information on voluntary alignment. With respect to voluntary alignment, the template notice would provide details regarding how a beneficiary may select his or her primary care provider on *MyMedicare.gov*, and the step-by-step process by which a beneficiary could designate an ACO professional as his or her primary care provider, and how the beneficiary could change such designation. The CMS-developed template notice would also encourage beneficiaries to check their ACO professional designation regularly and to update such designation when they change care providers or move to a new area. The template notice could be provided to beneficiaries at their first primary care visit during a performance year, and the same template notice could be furnished upon request in accordance with § 425.312(b)(2).

We believe this proposed approach would appropriately balance the factors we described and achieve our desired outcome of more consistently educating beneficiaries about the program while mitigating burden of additional notification on ACO participants. In addition, we believe this approach would provide detailed information on the program to beneficiaries more consistently at a point in time when they may be inclined to review the notice and have an opportunity to ask questions and address their concerns. Furthermore, we believe this approach would pose relatively little additional burden on ACO participants, since they are already required to provide written notices to beneficiaries upon request.

We seek comment as to alternative means of dissemination of the beneficiary notice, including the frequency with which and by whom the notice should be furnished. For example, we seek comment on whether a beneficiary should receive the written notice at the beneficiary's first primary care visit of the performance year, or

[21] Accountable Care Organizations & You, available at *https://www.medicare.gov/Pubs/pdf/11588-Accountable-Care-Organizations-FAQs.pdf.*

[22] Empowering Patients to Make Decisions About Their Healthcare: Register for MyMedicare.gov and Select Your Primary Clinician, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/vol-alignment-bene-fact-sheet.pdf.*

during the beneficiary's first visit of the performance year with any ACO participant. We also seek comment on whether there are alternative media for disseminating the beneficiary notice that may be less burdensome on ACOs, such as dissemination via email.

In addition, we solicit comment on whether the template notice should include other information outlining ACO activities that may be related to or affect a Medicare FFS beneficiary. Such activities may include: ACO quality reporting and improvement activities, ACO financial incentives to lower growth in expenditures, ACO care redesign processes (such as use of care coordinators), the ACO's use of payment rule waivers (such as the SNF 3-day rule waiver), and the availability of an ACO's beneficiary incentive program.

We also welcome feedback on the format, content, and frequency of this additional notice to beneficiaries about the Shared Savings Program, the benefits and drawbacks to requiring additional notification about the program at the point of care, and the degree of additional burden this notification activity may place on ACO participants. More specifically, we welcome feedback on the timing of providing the proposed annual notice to the beneficiary, particularly what would constitute the appropriate point of care for the beneficiary to receive the notice.

We are also taking this opportunity to add regulation text at renumbered § 425.312(a) to clarify our longstanding requirement that beneficiary notification obligations apply with regard to all Medicare FFS beneficiaries, not only to beneficiaries who have been assigned to an ACO (76 FR 67945 through 67946). We seek comment on whether an ACO that elects prospective assignment should be required to disseminate the beneficiary notice at the point of care only to beneficiaries who are prospectively assigned to the ACO, rather than to all Medicare FFS beneficiaries.

Finally, we are also proposing technical changes to the title and structure of § 425.312. For example, we are proposing to replace the title of § 425.312 with ''Beneficiary notifications.''

b. Beneficiary Opt-In Based Assignment Methodology

In the November 2011 final rule establishing the Shared Savings Program (76 FR 67865), we discussed comments that we had received in response to our proposed assignment methodology suggesting alternative beneficiary assignment methodologies in order to promote beneficiary free choice. For example, some commenters suggested that a beneficiary should be assigned to an ACO only if the beneficiary ''opted-in'' or enrolled in the ACO. We did not adopt an opt-in or enrollment requirement for several reasons, including our belief that such a prospective opt-in approach that allows beneficiaries to voluntarily elect to be assigned to an ACO would completely sever the connection between assignment and actual utilization of primary care services. A patient could choose to be assigned to an ACO from which he or she had received very few or no primary care services at all. However, more recently, some stakeholders have suggested that we reconsider whether it might be feasible to incorporate a beneficiary ''opt-in'' methodology under the Shared Savings Program. These stakeholders believe that under the current beneficiary assignment methodology, it can be difficult for an ACO to effectively manage a beneficiary's care when there is little or no incentive or requirement for the beneficiary to cooperate with the patient management practices of the ACO, such as making recommended lifestyle changes or taking medications as prescribed. The stakeholders noted that in some cases, an assigned beneficiary may receive relatively few primary care services from ACO professionals in the ACO and the beneficiary may be unaware that he or she has been assigned to the ACO. These stakeholders suggested we consider an alternative assignment methodology under which a beneficiary would be assigned to an ACO if the beneficiary ''opted-in'' to the ACO in order to reduce the reliance on the existing assignment methodology under subpart E and as a way to make the assignment methodology more patient-centered, and strengthen the engagement of beneficiaries in their health care. These stakeholders believe that using such an approach to assignment could empower beneficiaries to become better engaged and empowered in their health care decisions.

Although arguably beneficiaries ''opt-in'' to assignment to an ACO under the existing claims-based assignment methodology in the sense that claims-based assignment is based on each beneficiary's exercise of free choice in seeking primary care services from ACO providers/suppliers, we believe that incorporating an opt-in based assignment methodology, and de-emphasizing the claims-based assignment methodology, could have merit as a way to assign beneficiaries to ACOs. Therefore, we are exploring options for developing an opt-in based assignment methodology to further encourage and empower beneficiaries to become better engaged and empowered in their health care decisions. This approach to beneficiary assignment might also allow ACOs to better target their efforts to manage and coordinate care for those beneficiaries for whose care they will ultimately be held accountable. As discussed in section II.E.2, we have recently implemented a voluntary alignment process (which we are proposing to refine based on requirements in the Bipartisan Budget Act), which is an electronic process that allows beneficiaries to designate a primary clinician as responsible for coordinating their overall care. If a beneficiary designates an ACO professional as responsible for their overall care and the requirements for assignment under § 425.402(e) are met, the beneficiary will be prospectively assigned to that ACO. For 2018, the first year in which beneficiaries could be assigned to an ACO based on their designation of a primary clinician in the ACO as responsible for coordinating their care, 4,314 beneficiaries voluntarily aligned to 339 ACOs, and 338 beneficiaries were assigned to an ACO based solely on their voluntary alignment. Ninety-two percent of the beneficiaries who voluntarily aligned were already assigned to the same ACO under the claims-based assignment algorithm.

Voluntary alignment is based upon the relationship between the beneficiary and a single practitioner in the ACO. In contrast, an opt-in based assignment methodology would be based on an affirmative recognition of the relationship between the beneficiary and the ACO, itself. Under an opt-in based assignment methodology, a beneficiary would be assigned to an ACO if the beneficiary opted into assignment to the ACO. Therefore, under an opt-in approach, ACOs might have a stronger economic incentive to compete against other ACOs and healthcare providers not participating in an ACO because to the extent the ACO is able to increase quality and reduce expenditures for duplicative and other unnecessary care, it could attract a greater number of beneficiaries to opt-in to assignment the ACO. We believe there are a number of policy and operational issues, including the issues previously identified in the November 2011 final rule that would need to be addressed in order to implement an opt-in based methodology to assign beneficiaries to ACOs. These issues

include the process under which beneficiaries could opt-in to assignment to an ACO, ACO marketing guidelines, beneficiary communications, system infrastructure to communicate beneficiary opt-ins, and how to implement an opt-in based assignment methodology that responds to stakeholder requests while conforming with existing statutory and program requirements under the Shared Savings Program. These issues are addressed in the following discussion.

We believe under an opt-in based assignment methodology, it would be important for ACOs to manage notifying beneficiaries, collecting beneficiary opt-in data, and reporting the opt-in data to CMS. On an annual basis, ACOs would notify their beneficiary population about their participation in the Shared Savings Program and provide the beneficiaries a window during which time they could notify the ACO of their decision to opt-in and be assigned to the ACO, or to withdraw their opt-in to the ACO. Opting-in to a Shared Savings Program ACO could be similar to enrolling in a MA plan. MA election periods define when an individual may enroll or disenroll from a MA plan. An individual (or his/her legal representative) must complete an enrollment request (using an enrollment form approved by CMS, an online application mechanism, or through a telephone enrollment) to enroll in a MA plan and submit the request to the MA plan during a valid enrollment period. MA plans are required by 42 CFR 422.60 to submit a beneficiary's enrollment information to CMS within the timeframes specified by CMS, using a standard IT transaction system. Subsequently, CMS validates the beneficiary's eligibility, at which point the MA plan must meet the remainder of its enrollment-related processing requirements (for example, sending a notice to the beneficiary of the acceptance or rejection of the enrollment within the timeframes specified by CMS). Procedures have been established for disenrolling from a MA plan during MA election periods. (For additional details about the enrollment process under MA, see the CMS website at *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html,* and the Medicare Managed Care Manual, chapter 2, section 40 at *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2018_MA_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf*).

Because opting-in or withdrawing an opt-in to assignment to a Shared Savings Program ACO could be similar to enrolling or disenrolling in a MA plan, we would need to establish the ACO opt-in process and timing in a way to avoid beneficiary confusion as to the differences between the Shared Savings Program and MA, and whether the beneficiary is opting-in to assignment to an ACO or enrolling in a MA plan. We would also need to determine how frequently beneficiaries would be able to opt-in or withdraw an opt-in to an ACO, and whether there should be limits on the ability to change an opt-in after the end of the opt-in window, in order to reduce possible beneficiary assignment ''churn''. We note that beneficiaries opting-in to assignment to an ACO would still retain the freedom to choose to receive care from any Medicare-enrolled provider or supplier, including providers and suppliers outside the ACO. The ACO would be responsible for providing the list of beneficiaries who have opted-in to assignment to the ACO, along with each beneficiary's Medicare number, address, and certain other demographic information, to CMS in a form and manner specified by CMS. After we receive this information from the ACO, we would verify that each of the listed beneficiaries meets the beneficiary eligibility criteria set forth in § 425.401(a) before finalizing the ACO's assigned beneficiary population for the applicable performance year. To perform these important opt-in related functions, ACOs might need to acquire new information technology systems, along with additional support staff, to track, monitor and transmit opt-in data to CMS, including effective dates for beneficiaries who opt-in or withdraw an opt-in to the ACO. Furthermore, changes in an ACO's composition of ACO participants and ACO providers/suppliers could affect a beneficiary's interest in maintaining his or her alignment with the ACO through an opt-in approach. As a result, we believe it would also be critical for an ACO participating under opt-in based assignment to inform beneficiaries of their option to withdraw their opt-in to the ACO, generally, and specifically, in the event that an ACO participant or ACO provider/supplier, from which the beneficiary has received primary care services is no longer participating in the ACO.

MA has marketing guidelines and requirements that apply to enrollment activities to prevent selective marketing or discrimination based on health status. (See 42 CFR 422.2260 through 422.2276 and section 30.4 of the Medicare Marketing Guidelines located at *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html*.) If we were to adopt an opt-in process for the Shared Savings Program, we would impose similar requirements to ensure ACOs are providing complete and accurate information to beneficiaries to inform their decision-making regarding opting-in to assignment to an ACO, and not selectively marketing or discriminating based on health status or otherwise improperly influencing beneficiary choice. Additionally, ACOs would be required to establish a method for tracking the beneficiaries they have notified regarding the opportunity to opt-in to assignment to the ACO, and the responses they received. Under § 425.314, ACOs agree and must require their ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree that CMS has the right to audit, inspect, investigate, and evaluate records and other evidence that pertain to the ACO's compliance with the requirements of the Shared Savings Program. We believe this provision would authorize CMS to conduct oversight regarding ACOs' records documenting the beneficiaries who received such a notification and the beneficiary responses.

We are also considering how we would implement an opt-in based assignment methodology that addresses stakeholder requests, while conforming to existing program requirements. First, the requirement at section 1899(b)(2)(D) of the Act, that an ACO have at least 5,000 assigned beneficiaries, would continue to apply. Thus, under an opt-in based assignment methodology, an ACO still would be required to have at least 5,000 FFS beneficiaries, who meet our beneficiary eligibility criteria, assigned to the ACO at the time of application and for the entirety of the ACO's agreement period. We are concerned that using an opt-in based assignment methodology as the sole basis for assigning beneficiaries to an ACO could make it difficult for many ACOs to meet the 5,000 assigned beneficiary requirement under section 1899(b)(2)(D) of the Act. In particular, we are considering how an opt-in based assignment methodology would be implemented for new ACOs that have applied to the Shared Savings Program, but have not yet been approved by CMS to participate in the program. We believe it could be difficult for a new ACO to achieve 5,000 beneficiary opt-ins prior to the start of its first performance year under the program, as required by the statute in order to be

eligible for the program. It could also be difficult for certain established ACOs, such as ACOs located in rural areas, to achieve and maintain 5,000 beneficiary opt-ins. Smaller assigned beneficiary populations would also significantly increase the minimum savings rate and minimum loss rate (MSR and MLR) thresholds used to determine eligibility for shared savings and accountability for shared losses when these rates are based on the size of the ACO's assigned population as described in section II.6.b of this proposed rule. Smaller assigned beneficiary populations would also be a potential concern if ACOs and their ACO participants were to target care management to a small subset of patients at the expense of a more comprehensive transformation of care delivery with benefits that would have otherwise extended to a wider mix of patients regardless of whether they are assigned to the ACO.

Second, under an opt-in assignment approach, we could allow beneficiaries to opt-in before they have received a primary care service from a physician in the ACO, or any service from an ACO provider/supplier. This is similar to the situation that can sometimes occur under MA, where a beneficiary enrolls in a MA plan without having received services from any of the plan's providers. That means a beneficiary could be assigned to an ACO based on his or her opting-in to the ACO, and the ACO would be accountable for the total cost and quality of care provided to the opted-in beneficiary, including care from providers/suppliers that are not participating in the ACO. We note that section 1899(c) of the Act requires that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians in the ACO, or beginning January 1, 2019, services provided in FQHCs/RHCs. In order to meet this requirement under an opt-in based assignment methodology, we are considering whether we would need to continue to require that a beneficiary receive at least one primary care service from an ACO professional in the ACO who is a primary care physician or a physician with a specialty used in assignment (similar to our current requirement under § 425.402(b)(1)), in order for the beneficiary to be eligible to opt-in to assignment to the ACO.

Third, we are considering whether any changes would need to be made to our methodology for establishing an ACO's historical benchmark if we were to implement an opt-in based assignment methodology. Under the current assignment methodology used in the Shared Savings Program, we assign beneficiaries to ACOs for a performance year based upon either voluntary alignment or the claims-based assignment methodology. Because the vast majority of beneficiaries are assigned using the claims-based assignment methodology, we are able to use the same claims-based assignment methodology to assign beneficiaries for purposes of either a performance year or a benchmark year. The expenditures of the beneficiaries assigned to the ACO for a benchmark year are then used in the determination of the benchmark. However, the same approach would not be possible under an assignment methodology based solely on a beneficiary opt-in approach. If we were to adopt an entirely opt-in based assignment methodology, we would need to consider if any changes would need to be made to our methodology for establishing an ACO's historical benchmark to address selection bias and/or variation in expenditures because beneficiaries would not have opted-in to assignment to the ACO during the 3 prior years included in the historical benchmark under § 425.602, § 425.603, or proposed new § 425.601. Thus, under an entirely opt-in based assignment methodology there could be a large disconnect between the beneficiaries who have opted-in to assignment to the ACO for a performance year and the beneficiaries who are assigned to the ACO on the basis of claims for the historical benchmark years. An adjustment to the benchmark would be necessary to address these discrepancies. Alternatively, if we were to adopt a methodology under which we use expenditures from the 3 historical benchmark years only for beneficiaries who have opted-in to assignment to the ACO in the applicable performance year, it could create an imbalance because the expenditures for the years that comprise the historical benchmark would not include expenditures for decedents because beneficiaries necessarily would have survived through the baseline period in order to opt-in for the given performance year. A similar approach was initially applied in the Pioneer ACO Model, but it required complex adjustments to ACOs' benchmarks to account for significantly lower spending in historical base years for assigned beneficiaries, who necessarily survived for the one or more years between the given base year and the applicable performance year in which they were assigned to the ACO. It would likely be even more difficult and complex to consistently and accurately adjust the benchmark in the context of the proposed change to 5 year agreement periods (or a 6 year agreement period for agreement periods starting on July 1, 2019) because the historical benchmarks would eventually rely on an even smaller subset of base year claims available for beneficiaries who were enrolled in both Medicare Parts A and B during the base year and have survived long enough to cover the up to 7-year gap between the historical base year and the performance year for which they have opted-in to assignment to the ACO.

In light of these issues, we are considering implementing an opt-in based assignment methodology that would address stakeholder requests that we incorporate such an approach to make the assignment methodology more patient-centered, while also addressing statutory requirements and other Shared Savings Program requirements. Specifically, we believe it may be feasible to incorporate an opt-in based assignment methodology into the Shared Savings Program in the following manner. We would allow, but not require, ACOs to elect an opt-in based assignment methodology. Under this approach, at the time of application to enter or renew participation in the Shared Savings Program, an ACO could elect an opt-in based assignment methodology that would apply for the length of the agreement period. Under this approach, we would use the assignment methodology under subpart E, including the proposed revisions to provisions at §§ 425.400, 425.401, 425.402 and 425.404 as discussed in sections II.E.2 and II.E.3 of this proposed rule (herein referred to as the ''existing assignment methodology'' which would be comprised of a claims-based assignment methodology and voluntary alignment), to determine whether an ACO applicant meets the initial requirement under section 1899(b)(2)(D) of the Act to be eligible to participate in the program. We would use this approach because the ACO applicant would not be able to actively seek Medicare beneficiary opt-ins until the next opt-in window. That is, we would continue to determine an ACO's eligibility to participate in the program under the requirement that an ACO have at least 5,000 assigned beneficiaries using the program's existing assignment methodology. Therefore, an ACO that elects to participate under opt-in based assignment could be eligible to enter an agreement period under the program if we determine that it has at least 5,000 assigned beneficiaries in each of the 3 years prior to the start of the ACO's

agreement period, based on the claims-based assignment methodology and voluntarily aligned beneficiaries.

If an ACO chooses not to elect the opt-in based assignment methodology during the application or renewal process, then beneficiaries would continue to be assigned to the ACO based on the existing assignment methodology (claims-based assignment with voluntary alignment). As an alternative to allowing ACOs to voluntarily elect participation in an opt-in based assignment methodology we are also considering discontinuing the existing assignment methodology and applying an opt-in based assignment methodology program-wide (described herein as a hybrid assignment approach which includes beneficiary opt-in, modified claims-based assignment, and voluntary alignment). As described in this section, ACOs could face operational challenges in implementing opt-in based assignment, and this approach to assignment could affect the size and composition of the ACO's assigned population, specifically to narrow the populations served by ACO. In light of these factors, we believe it would be important to gain experience with opt-in based assignment as a voluntary participation option before modifying the program to allow only this participation option.

For ACOs electing to participate under an opt-in based assignment methodology, we would assign beneficiaries to the ACO using a hybrid approach that would be based on beneficiary opt-ins, supplemented by voluntary alignment and a modified claims-based methodology. Notwithstanding the assignment methodology under § 425.402(b), under this hybrid approach, a beneficiary would be prospectively assigned to an ACO that has elected the opt-in based assignment methodology if the beneficiary opted in to assignment to the ACO or voluntarily aligned with the ACO by designating an ACO professional as responsible for their overall care. If a beneficiary was not prospectively assigned to such an ACO based on either beneficiary opt-in or voluntary alignment, then the beneficiary would be assigned to such ACO only if the beneficiary received the plurality of his or her primary care services from the ACO and received at least seven primary care services from one or more ACO professionals in the ACO during the applicable assignment window. If a beneficiary did not receive at least seven primary care services from one or more ACO professionals in the ACO during the applicable assignment window, then the beneficiary would not be assigned to the ACO on the basis of claims even if the beneficiary received the plurality of their primary care services from the ACO. We note that this threshold of seven primary care services is consistent with the threshold established by an integrated healthcare system in a prior demonstration that targeted intervention on chronic care, high risk patients in need of better coordinated care due to their frequent utilization of health care services. A threshold for assignment of seven primary care services would mean that up to 25 percent of an ACO's beneficiaries who would have been assigned to the ACO under the existing assignment methodology under § 425.402(b) could continue to be assigned to the ACO based on claims. We believe it could be appropriate to establish such a minimum threshold of seven primary care services for assigning beneficiaries to ACOs electing an opt-in based assignment methodology because it would enable such ACOs to focus their care coordination activities on beneficiaries who have either opted-in to assignment to the ACO or voluntarily aligned with the ACO, or who are receiving a high number of primary care services from ACO professionals and may have complex conditions requiring care coordination. We seek comment on whether to use a higher or lower minimum threshold for determining beneficiaries assigned to the ACO under a modified claims-based assignment approach.

Under this hybrid approach to assignment, we would allow the ACO a choice of claims-based beneficiary assignment methodology as proposed in section II.A.4.c. of this proposed rule. Therefore, ACOs that elect to participate under opt-in based assignment for their agreement period would also have the opportunity to elect either prospective or preliminary prospective claims-based assignment prior to the start of their agreement period, and to elect to change this choice of assignment methodology annually.

More generally, we believe that the hybrid assignment methodology, which would incorporate claims-based and opt-in based assignment methods, as well as voluntary alignment, could be preferable to an opt-in only approach. A hybrid assignment methodology would increase the number of beneficiaries for whom the ACO would be accountable for quality and cost of care delivery and thereby provide stronger statistical confidence for shared savings or shared losses calculations and provide a stronger incentive for ACOs and their ACO participants and ACO providers/suppliers to improve care delivery for every FFS beneficiary rather than focusing only on beneficiaries who happen to have opted-in to assignment to the ACO.

For ACOs that enter an agreement period in the Shared Savings Program under an opt-in based assignment methodology, we would allow for a special election period during the first calendar year quarter of the ACO's first performance year for beneficiaries to opt-in to assignment to the ACO. For each subsequent performance year of an ACO's agreement period, the opt-in period would span the first three calendar year quarters (January through September) of the prior performance year. Beneficiaries that opt-in, and are determined eligible for assignment to the ACO, would be prospectively assigned to the ACO for the following performance year. Under this approach, there would be no floor or minimum number of opt-in beneficiaries required. Rather, we would consider whether, in total, the ACO's assigned beneficiary population (comprised of beneficiaries who opt-in, beneficiaries assigned under the modified claims-based assignment approach, and beneficiaries that have voluntarily aligned) meets the minimum population size of 5,000 assigned beneficiaries each performance year to comply with the requirements for continued participation in the program. To illustrate this hybrid assignment approach in determining performance year assignment: if an ACO has 2,500 beneficiaries assigned under the modified claims-based assignment approach who have not otherwise opted-in to assignment to the ACO, and 50 voluntarily aligned beneficiaries who have not otherwise opted-in to assignment to the ACO, then the ACO would be required to have at least 2,450 beneficiaries who have opted-in to assignment to remain in compliance with the program eligibility requirement to have at least 5,000 assigned beneficiaries.

Consistent with current program policy, ACOs electing the opt-in based assignment methodology with a performance year assigned population below the 5,000-minimum may be subject to the pre-termination actions in § 425.216 and termination of their participation agreement under § 425.218. Under the proposals for modifying the MSR/MLR to address small population sizes described in section II.A.6.3. of this proposed rule, if an ACO that elects an opt-in based assignment methodology has an assigned population below 5,000 beneficiaries, the ACO's MSR/MLR would be set at a level consistent with

the number of assigned beneficiaries to provide assurance that shared savings and shared losses represent meaningful changes in expenditures rather than normal variation.

As an alternative approach, we also considered requiring ACOs that have elected an opt-in based assignment methodology to maintain at least a minimum number of opt-in beneficiaries assigned in each performance year of its agreement period. We believe that any minimum population requirement should be proportional to the size of ACO's population, to recognize differences in the population sizes of ACOs across the program. We also considered whether we should require incremental increases in the size of the ACO's opt-in assigned population over the course of the ACO's agreement period, recognizing that it may take time for ACOs to implement the opt-in approach and for beneficiaries to opt-in. Another factor we considered is the possibility that the size of an ACO's population, and therefore the proportion of opt-in beneficiaries, could be affected by ACO participant list changes, and changes in the ACO providers/suppliers billing through ACO participant TINs, which could affect claims-based assignment, and the size of the ACO's voluntarily aligned population. Changes in the size of the ACO's claims-based assigned and voluntarily aligned populations could cause the ACO to fall out of compliance with a required proportion of opt-in assigned beneficiaries, even if there has been no reduction in the number of opt-in assigned beneficiaries.

Under opt-in based assignment, we anticipate that we would not establish restrictions on the geographic locations of the ACOs from which a beneficiary could select. This would be consistent with the program's voluntary alignment process, under which a beneficiary could chose to designate a primary clinician as being responsible for his or her care even if this clinician is geographically distant from the beneficiary's place of residence. Also, currently under the program's existing claims-based assignment methodology, beneficiaries who receive care in different parts of the country during the assignment window can be assigned to an ACO that is geographically distant from the beneficiary's place of residence. This approach also recognizes that a beneficiary could be assigned to a geographically distant ACO as a result of his or her individual circumstances, such as a beneficiary's change in place of residence, beneficiary spends time in and receives care in different parts of the country during the year (sometimes referred to as being a ''snowbird''), or the beneficiary receives care from a tertiary care facility that is geographically distant from his or her home. Further, this approach is in line with the expanded telehealth policies discussed in section II.B of this proposed rule under which certain geographic and other restrictions would be removed. We welcome comment on whether to establish geographic limitations on opt-in based assignment such that a beneficiary's choice of ACOs for opt-in would be limited to ACOs located near the beneficiary's place of residence, or where the beneficiary receives his or her care, or a combination of both.

When considering the options for incorporating an opt-in based assignment methodology, we considered if such a change in assignment methodology would also require changes to the proposed benchmarking methodology under § 425.601. A hybrid assignment approach could potentially require modifications to the benchmarking methodology to account for factors such as: Differences in beneficiary characteristics, including health status, between beneficiaries who may be amenable to opting-in to assignment to an ACO, beneficiaries who voluntarily align, and beneficiaries assigned under a modified claims-based assignment methodology who must have received at least seven primary care services from the ACO; differences between the existing claims-based assignment methodology and the alternative claims-based approach under which a minimum of seven primary care services would be required for assignment; and discrepancies caused by the use of the existing claims-based assignment methodology to perform assignment for historical benchmark years and the use of a hybrid assignment methodology for performance years. For simplicity, we prefer an approach that would use, to the greatest extent possible, the program's benchmarking methodology, as proposed to be modified as discussed in section II.D. of this proposed rule. This would allow us to more rapidly implement an opt-in based assignment approach, and may be easier to understand for ACOs and other program stakeholders experienced with the program's benchmarking methodology. We considered the following approach to establishing and adjusting the historical benchmark for ACOs that elect an opt-in based assignment methodology.

In establishing the historical benchmark for ACOs electing an opt-in based beneficiary assignment methodology, we would follow the benchmarking approach described in the provisions of the proposed new regulation at § 425.601. In particular, we would continue to determine benchmark year assignment based on the population of beneficiaries that would have been assigned to the ACO under the program's existing assignment methodology in each of the 3 most recent years prior to the start of the ACO's agreement period. However, we would take a different approach to annually risk adjusting the historical benchmark expenditures than what is proposed in section II.D and in the proposed provisions at §§ 425.605(a)(1) and 425.610(a)(2).

In risk adjusting the historical benchmark for each performance year, we would maintain the current approach of categorizing beneficiaries by Medicare enrollment type; however, we would further stratify the benchmark year 3 and performance year assigned populations into groups that we anticipate would have comparable expenditures and risk score trends. That is, we would further stratify the performance year population into two categories: (1) Beneficiaries who are assigned using the modified claims-based assignment methodology and must have received seven or more primary care services from ACO professionals and who have not also opted-in to assignment to the ACO; and (2) beneficiaries who opt-in and beneficiaries who voluntarily align. A beneficiary who has opted-in to assignment to the ACO would continue to be stratified in the opted in population throughout the agreement period regardless of whether the beneficiary would have been assigned using the modified claims-based assignment methodology because the beneficiary received seven or more primary care services from the ACO.

We would also further stratify the BY3 population, determined using the existing assignment methodology, into two categories: (1) Beneficiaries who received seven or more primary care services from the ACO; and (2) beneficiaries who received six or fewer primary care services from the ACO.

We anticipate that beneficiaries who opt-in would likely be a subset of beneficiaries who would have been assigned under the existing claims-based assignment methodology. As previously described, 92 percent of voluntarily aligned beneficiaries were already assigned to the same ACO using the existing claims-based assignment methodology. Further, based on our experience with the program about 75 percent of ACOs' assigned beneficiaries receive six or fewer primary care service

visits annually. Similar to the trend we observed with voluntarily aligned beneficiaries, we believe the opt-in beneficiaries would tend to resemble in health status and acuity a subset of the ACO's typical claims-based assigned population; that is, we anticipate opt-in beneficiaries, as with voluntarily aligned beneficiaries, would resemble the population of beneficiaries assigned in the benchmark year that received six or fewer primary care services.

We would determine ratios of risk scores for the comparable populations of performance year and BY3 assigned beneficiaries. We would calculate these risk ratios by comparing the risk scores for the BY3 population with seven or more primary care services with the risk scores for the performance year population with seven or more primary care services who have not otherwise opted-in or voluntarily aligned. We would also calculate risk ratios for the remaining beneficiary population by comparing risk scores for the BY3 population with six or fewer primary care services with the risk scores for the performance year population of opt-in and voluntarily aligned beneficiaries. We would use these ratios to risk adjust the historical benchmark expenditures not only by Medicare enrollment type, but also by these stratifications. That is, for each Medicare enrollment type, we would apply risk ratios comparing the risk scores of the BY3 population with seven or more primary care services and the risk scores of the performance year population with seven or more primary care services to adjust the historical benchmark expenditures for the population with seven or more primary care services in the benchmark period. Similarly, we would apply risk ratios comparing the risk scores of the BY3 population with six or fewer primary care services and the risk scores of the performance year opt-in or voluntarily aligned population to adjust the historical benchmark expenditures for the population with six or fewer primary care services in the benchmark period. We presume this is a reasonable approach based on our expectation that opt-in beneficiaries will resemble the population of beneficiaries, assigned under the existing claims-based assignment methodology, who have 6 or fewer primary care services with the ACO annually. This is supported by the assumptions that ACOs may selectively market opt-in to lower cost beneficiaries, and beneficiaries that require less intensive and frequent care may be more inclined to opt-in. However, since we lack experience with an opt-in based assignment approach, we would monitor the effects of this policy to determine if it is effective in addressing the differences in characteristics between the population assigned for establishing the ACO's benchmark under the existing assignment methodology and the population assigned for the performance year under the hybrid assignment approach, and if further adjustments may be warranted such as additional adjustments to the historical benchmark to account for such differences.

In rebasing the ACO's benchmark, which occurs at the start of each new agreement period, we would include in the benchmark year assigned population beneficiaries who were opted in to the ACO in a prior performance year that equates to a benchmark year for the ACO's new agreement period. For example if an ACO elected opt-in for a 5-year agreement period beginning January 1, 2020 and concluding December 31, 2024, and a beneficiary opted in and was assigned for 2023 and remained opted in and assigned for 2024, we would include this beneficiary in the benchmark year assigned population for BY2 (2023) and BY3 (2024) when we rebase the ACO for its next agreement period beginning January 1, 2025. We considered that the health status of an opt-in beneficiary may continue to change over time as the beneficiary ages, which would be accounted for in our use of full CMS–HCC risk scores in risk adjusting the rebased historical benchmark. We considered approaches to further adapt the rebasing methodology to account for the characteristics of the ACO's opt-in beneficiaries, and the ACO's experience with participating in an opt-in based assignment methodology.

We considered an approach under which we could determine the assigned population for the ACO's rebased benchmark using the program's existing assignment methodology and incorporate opt-in assigned beneficiaries in the benchmark population. In risk adjusting the ACO's rebased benchmark each performance year, we could use a stratification approach similar to the approach previously described in this discussion. That is we would stratify the BY3 population into two categories: (1) Beneficiaries who received seven or more primary care services from the ACO; and (2) beneficiaries who received six or fewer primary care services from the ACO. We would categorize opt-in beneficiaries, assigned in BY3, into either one of these categories based on the number of primary care services they received from ACO during BY3. We could continue to stratify the performance year population assigned under the hybrid assignment methodology into two categories: (1) Beneficiaries who are assigned using the modified claims-based assignment methodology and must have received seven or more primary care services from ACO professionals and who have not also opted-in to assignment to the ACO; and (2) beneficiaries who opt-in and beneficiaries who voluntarily align. We would apply risk ratios comparing the risk scores of the BY3 population with seven or more primary care services and the risk scores of the performance year population with seven or more primary care services to adjust the historical benchmark expenditures for the population with seven or more primary care services in the benchmark period. Similarly, we would apply risk ratios comparing the risk scores of the BY3 population with six or fewer primary care services and the risk scores of the performance year opt-in or voluntarily aligned population to adjust the historical benchmark expenditures for the population with six or fewer primary care services in the benchmark period.

An alternative approach to rebasing the benchmark for an ACO that elected opt-in assignment in their most recent prior agreement period and continues their participation in an opt-in based assignment methodology in their new agreement period, would be to use the hybrid assignment approach to determine benchmark year assignment. To risk adjust the benchmark each performance year we could then stratify the BY3 and the performance year assigned populations into two categories: (1) Beneficiaries assigned through the modified claims-based assignment methodology who received seven or more primary care services from the ACO; or (2) beneficiaries who opt-in and beneficiaries who voluntarily align. This approach would move ACOs to participation under a purely hybrid assignment approach since we would no longer use the existing assignment methodology in establishing the benchmark. However, this approach could result in smaller benchmark year assigned populations compared to populations determined based on the more inclusive, existing assignment methodology. In turn, this approach could result in ACOs that were successful at opting-in beneficiaries being ineligible to continue their participation in the program under an opt-in assignment methodology because they do not meet the program's eligibility requirement to have at least 5,000 beneficiaries assigned in each benchmark year.

In section II.D. of this proposed rule, we propose that annual adjustments in prospective CMS–HCC risk scores would be subject to a symmetrical cap of positive or negative 3 percent that would apply for the agreement period, such that the adjustment between BY3 and any performance year in the agreement period would never be more than 3 percent in either direction. We are considering whether a modified approach to applying these caps would be necessary for ACOs that elect opt-in based assignment methodology. For example, for the first performance year an opted-in beneficiary is assigned to an ACO, we could allow for full upward or downward CMS–HCC risk adjustment, thereby excluding these beneficiaries from the symmetrical risk score caps. This would allow us to account for newly opted-in beneficiaries' full CMS–HCC scores in risk adjusting the benchmark. In each subsequent performance year, the opted-in beneficiaries remain aligned to the ACO, we could use an asymmetrical approach to capping increases and decreases in risk scores. We would cap increases in the opt-in beneficiaries' CMS–HCC risk scores to guard against changes in coding intensity, but we would apply no cap to decreases in their CMS–HCC risk scores. That is, the risk scores for these opt-in beneficiaries would be subject to the positive 3 percent cap, but not the negative 3 percent cap. We believe this approach would safeguard against ACOs trying to enroll healthy beneficiaries, who would likely be less expensive than their benchmark population, in order to benefit from having a limit on downward risk adjustment. Beneficiaries who have not otherwise opted-in who are assigned to the ACO based on the modified claims-based assignment methodology and those that voluntarily align would be subject to the proposed symmetrical 3 percent cap. We note that we do not apply caps to risk scores when we rebase an ACO's historical benchmark, which allows the historical benchmark to reflect the current health status of the beneficiary populations assigned for the benchmark years.

As indicated in the alternatives considered section of the Regulatory Impact Analysis (see section IV.D of this proposed rule), there is limited information presently available to model the behavioral response to an opt-in based assignment methodology, for example in terms of ACOs' willingness to elect such an approach and beneficiaries' willingness to opt-in. Although for some policies we can draw upon our initial experience with implementing voluntary alignment. We believe the approach to adjusting benchmarks to address an opt-in based assignment methodology, as discussed in this proposed rule, could address our concerns about the comparability of benchmark and performance year populations. If such a policy were finalized we would monitor the impact of these adjustments on ACOs' benchmarks, and we would also monitor to determine ACOs' and beneficiaries' response to the opt-in based assignment participation option, characteristics of opt-in beneficiaries and the ACOs they are assigned to, and the cost and quality trends of opt-in beneficiaries to determine if further development to the program's financial methodology would be necessary to account for this approach.

If we were to establish an opt-in based assignment methodology, we anticipate that we would also need to establish program integrity requirements similar to the program integrity requirements with respect to voluntary alignment at § 425.402(e)(3). The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities would be prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements to influence their decision to opt-in to assignment to the ACO. The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities would also be prohibited from directly or indirectly, committing any act or omission, or adopting any policy that coerces or otherwise influences a Medicare beneficiary's decision to opt-in to assignment to an ACO. Offering anything of value to a Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to opt-in (or not opt-in) to assignment to the ACO would not be considered to have a reasonable connection to the medical care of the beneficiary, as required under the proposed provision at § 425.304(b)(1).

Finally, we would emphasize that, as is the case for all FFS beneficiaries currently assigned to an ACO on the basis of claims or voluntary alignment, under an opt-in based assignment methodology, beneficiaries who opt-in to assignment to an ACO would retain their right to seek care from any Medicare-enrolled provider or supplier of their choosing, including providers and suppliers outside the ACO.

We are soliciting comment on whether we should offer ACOs an opportunity to voluntarily choose an alternative beneficiary assignment methodology under which an ACO could elect to have beneficiaries assigned to the ACO based on a beneficiary opt-in methodology supplemented by voluntary alignment and a modified claims-based assignment methodology. We welcome comments as to whether it would be appropriate to establish a minimum threshold number of primary care services, such as seven primary care services, for purposes of using claims to assign beneficiaries to ACOs electing an opt-in based assignment methodology to enable these ACOs to focus their care coordination efforts on those beneficiaries who have either opted-in to assignment to or voluntarily aligned with the ACO, or who are receiving a high number of primary care services from ACO professionals, and may have complex conditions requiring a significant amount of care coordination. We seek comment on whether this minimum threshold for use in determining modified claims-based assignment should be set at a higher or lower. We also welcome comments on an appropriate methodology for establishing and adjusting an ACO's historical benchmark under an opt-in based assignment methodology. Further, we seek comment on how to treat opt-in beneficiaries when rebasing the historical benchmark for renewing ACOs. Additionally, we welcome comments on any other considerations that might be relevant to adopting a methodology under which beneficiaries may opt-in to assignment to an ACO, including ways to minimize burden on beneficiaries, ACOs, ACO participants, and ACO providers/suppliers and avoid beneficiary confusion.

We have envisioned that if we were to incorporate such an opt-in based assignment methodology, the election by ACOs would be entirely voluntary. ACOs that did not elect this beneficiary assignment option would continue to have their beneficiaries assigned using the existing claims-based assignment methodology with voluntary alignment under § 425.402. However, we also seek comment on whether we should discontinue the existing assignment methodology under subpart E and instead assign beneficiaries to all ACOs using a hybrid assignment methodology, which would incorporate opt-in based assignment and the modified claims-based assignment methodology, as well as voluntary alignment. Under such an approach, the use of a modified

benchmarking methodology could help to ensure that an appropriate weight would be placed on the risk-adjusted expenditures of the ACO's opt-in population as this population increases in size.

D. Benchmarking Methodology Refinements

1. Background

An ACO's historical benchmark is calculated based on expenditures for beneficiaries that would have been assigned to the ACO in each of the 3 calendar years prior to the start of the agreement period (§§ 425.602(a), 425.603(b) and (c)). For ACOs that have continued their participation for a second or subsequent agreement period, the benchmark years for their current agreement period are the 3 calendar years of their previous agreement period.

There are currently differences between the methodology used to establish the ACO's first agreement period historical benchmark (§ 425.602) and the methodology for establishing the ACO's rebased historical benchmark in its second or subsequent agreement period (§ 425.603). We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991). For example, in resetting (or rebasing) an ACO's historical benchmark, we replace the national trend factor (used in in the first agreement period methodology) with regional trend factors, and we use a phased approach to adjust the rebased benchmark to reflect a percentage of the difference between the ACO's historical expenditures and FFS expenditures in the ACO's regional service area. This rebasing methodology incorporating factors based on regional FFS expenditures was finalized in the June 2016 final rule and is used to establish the benchmark for ACOs beginning a second or subsequent agreement period in 2017 and later years. An interim approach was established in the June 2015 final rule under which we adjusted the rebased benchmarks for ACOs that entered a second agreement period beginning in 2016 to account for savings generated in their first agreement period (§ 425.603(b)(2)).

In developing the June 2016 final rule, we considered the weight that should be applied in calculating the regional adjustment to an ACO's historical expenditures. We finalized a phased approach to transition to a higher weight in calculating the regional adjustment, where we determine the weight used in the calculation depending on whether the ACO is found to have lower or higher spending compared to its regional service area (§ 425.603(c)(9)). For ACOs that have higher spending compared to their regional service area, the weight placed on the regional adjustment is reduced to 25 percent (compared to 35 percent) in the first agreement period in which the regional adjustment is applied, and 50 percent (compared to 70 percent) in the second agreement period in which the adjustment is applied. Ultimately a weight of 70 percent will be applied in calculating the regional adjustment for all ACOs beginning no later than the third agreement period in which the ACO's benchmark is rebased using this methodology, unless the Secretary determines that a lower weight should be applied.

The annual update to the ACO's historical benchmark also differs for ACOs in their first versus second or subsequent agreement periods. In an ACO's first agreement period, the benchmark is updated each performance year based solely on the absolute amount of projected growth in national FFS spending for assignable beneficiaries (§ 425.602(b)). Although section 1899(d)(1)(B)(ii) of the Act requires us to update the benchmark using the projected absolute amount of growth in national per capita expenditures for Medicare Parts A and B services, we used our authority under section 1899(i)(3) of the Act to adopt an alternate policy under which we calculate the national update based on assignable beneficiaries, a subset of the Medicare FFS population as defined under § 425.20. For ACOs in a second or subsequent agreement period (beginning in 2017 and later years), we update the rebased benchmark annually to account for changes in FFS spending for assignable beneficiaries in the ACO's regional service area (§ 425.603(d)). We also used our authority under section 1899(i)(3) of the Act to adopt this alternate update factor based on regional FFS expenditures.

For all ACOs, at the time of reconciliation for each performance year, we further adjust the benchmark to account for changes in the health status and demographic factors of the ACO's performance year assigned beneficiary population (§§ 425.602(a)(9), 425.603(c)(10)). We use separate methodologies to risk-adjust the benchmark for populations of newly assigned and continuously assigned beneficiaries. For newly assigned beneficiaries, we use CMS–HCC prospective risk scores to adjust for changes in severity and case mix. We use demographic factors to adjust for changes in the health status of beneficiaries continuously assigned to the ACO. However, if the CMS–HCC prospective risk scores for the ACO's continuously assigned population decline, CMS will adjust the benchmark to reflect changes in severity and case mix for this population using the lower CMS–HCC prospective risk score. CMS–HCC prospective risk scores are based on diagnoses from the prior calendar year, as well as demographic factors.

2. Risk Adjustment Methodology for Adjusting Historical Benchmark Each Performance Year

a. Background

When establishing the historical benchmark, we use the CMS–HCC prospective risk adjustment model to calculate beneficiary risk scores to adjust for changes in the health status of the population assigned to the ACO. The effect of this policy is to apply full CMS–HCC risk adjustment to account for changes in case mix in the assigned beneficiary population between the first and third benchmark years and between the second and third benchmark years. For consistency, this approach is also used in adjusting the historical benchmark to account for changes to the ACO's certified ACO participant list for performance years within an agreement period and when resetting the ACO's historical benchmark for its second or subsequent agreement period. See §§ 425.602(a)(3) and (8), 425.603(c)(3) and (8); see also Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (May 2018, version 6) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.html.* Further, we use full CMS–HCC risk adjustment when risk adjusting county level FFS expenditures and to account for differences between the health status of the ACO's assigned population and the assignable beneficiary population in the ACO's regional service area as part of the methodology for adjusting the ACO's rebased historical benchmark to reflect regional FFS expenditures in the ACO's regional service area (see § 425.603(c)(9)(i)(C), (e)).

To account for changes in beneficiary health status between the historical benchmark period and the performance year, we perform risk adjustment using a methodology that differentiates

between newly assigned and continuously assigned beneficiaries, as defined in § 425.20. As specified under §§ 425.604(a), 425.606(a), and 425.610(a), we use CMS–HCC prospective risk scores to account for changes in severity and case mix for newly assigned beneficiaries between the third benchmark year (BY3) and the performance year. We use demographic factors to adjust for these changes in continuously assigned beneficiaries. However, if the CMS–HCC prospective risk scores for the continuously assigned population are lower in the performance year, we use the lower CMS–HCC prospective risk scores to adjust for changes in severity and case mix in this population. As we described in earlier rulemaking, this approach provides a balance between accounting for actual changes in the health status of an ACO's population while limiting the risk due to coding intensity shifts—that is, efforts by ACOs, ACO participants and/or ACO providers/suppliers to find and report additional beneficiary diagnoses so as to increase risk scores—that would artificially inflate ACO benchmarks (see for example, 81 FR 38008).

As described in the Shared Savings and Losses and Assignment Methodology specifications referenced previously in this section, all CMS–HCC and demographic beneficiary risk scores used in financial calculations for the Shared Savings Program are renormalized to ensure that the mean risk score among assignable beneficiaries in the national FFS population is equal to one. Renormalization helps to ensure consistency in risk scores from year to year, given changes made to the underlying risk score models. All risk adjustment calculations for the Shared Savings Program, including risk score renormalization, are performed separately for each Medicare enrollment type (ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid).

In practice, to risk adjust expenditures from one year to another, we multiply the expenditures that are to be adjusted by the quotient of two renormalized risk scores, known as the risk ratio. For example, to risk adjust the expenditures for an ACO's assigned beneficiary population from the first benchmark year to the third, we multiply benchmark year 1 (BY1) expenditures, by a risk ratio equal to the mean renormalized risk score among the ACO's assigned beneficiaries in benchmark year 3 (BY3) divided by the mean renormalized risk score among the ACO's assigned beneficiaries in BY1. One percent growth in renormalized risk scores between 2 years would be expressed by a risk ratio of 1.010. This ratio reflects growth in risk for the ACO's assigned beneficiary population relative to that of the national assignable population.

ACOs and other program stakeholders have expressed various concerns about the methodology for risk adjusting an ACO's benchmark each performance year, as described in comments on previous rulemaking (see 76 FR 67916 through 67919, 80 FR 32777 through 32778, 81 FR 37962 through 37968). We refer readers to these earlier rules for more detailed discussions of the issues raised by stakeholders. A common concern raised is that the current risk adjustment methodology does not adequately adjust for changes in health status among continuously assigned beneficiaries between the benchmark and performance years. Commenters have argued that the lack of upward CMS–HCC risk adjustment in response to increased patient acuity makes it harder for ACOs to realize savings and serves as a barrier to more ACOs taking on performance-based risk.

Stakeholders have also raised concerns that the current methodology, under which risk adjustment is performed separately for newly and continuously assigned beneficiaries, creates uncertainty around benchmarks. One commenter in prior rulemaking described the policy as rendering the role of risk scores ''opaque'', making it difficult for ACOs to anticipate how risk scores may affect their financial performance (81 FR 37968). We have attempted to increase transparency around the program's risk adjustment process by providing beneficiary-level risk score information in quarterly and annual reports, as well as by providing detailed explanations of the risk adjustment calculations to ACOs through webinars. However, despite these efforts, concerns about transparency remain, as evidenced by the many requests for technical assistance from ACOs related to risk adjustment.

b. Proposed Revisions

We appreciate the concerns regarding our current risk adjustment methodology raised by stakeholders, who have indicated that the current approach may not adequately recognize negative changes in health status that occur at the individual beneficiary level, particularly among continuously assigned beneficiaries who have experienced an acute event, such as a heart attack, stroke, or hip fracture, between the third benchmark year and the applicable performance year. We recognize that such acute events, which almost always require a hospitalization, are likely to have an upward impact on CMS–HCC risk scores that is not attributable to provider coding initiatives.

At the same time, we remain concerned that CMS–HCC risk scores, in general, are susceptible to increased diagnostic coding efforts. As noted previously, we employ full CMS–HCC risk adjustment when establishing an ACO's historical benchmark for its first agreement period, when adjusting the benchmark to account for participant list changes within an agreement period, and when resetting the benchmark for a second or subsequent agreement period, as we believe that doing so improves the accuracy of the benchmark. We have observed evidence of a modest increase in diagnostic coding completeness in the benchmark period for ACOs in their second agreement period (rebased ACOs). Simulation results suggest that rebased ACOs were more likely to benefit from full CMS–HCC risk adjustment in the benchmark period than were ACOs in a first agreement period. For rebased ACOs, the benchmark period coincides with their first agreement period in the Shared Savings Program, a time when these ACOs and their ACO participants and ACO providers/suppliers had an incentive to engage in increased coding so as to maximize their performance year risk scores, as well as their rebased benchmark in the next agreement period. ACOs in a first agreement period would have had less incentive to encourage their ACO participants and ACO providers/suppliers to engage in coding initiatives during the benchmark period as it took place before they entered the program. We recognize, however, that increased coding by ACO participants and ACO providers/suppliers may also reflect efforts to facilitate care coordination, quality improvement, and population management activities which require more complete clinical information at the point of care.

We also acknowledge that our current approach to risk adjustment for the performance year makes it difficult for ACOs to predict how their financial performance may be affected by risk adjustment. The current approach involves multiple steps including identifying newly and continuously assigned beneficiaries for each ACO for both the performance year and BY3, computing mean CMS–HCC risk scores for both populations and mean demographic risk scores for the continuously assigned beneficiary

population by Medicare enrollment type, conducting a test to determine whether an ACO will receive CMS–HCC or demographic risk adjustment for its continuously assigned population, and determining and applying the risk ratios used to adjust benchmark expenditures for the performance year. Although we have made efforts to explain these steps in detail through our program specifications, report documentation, and webinars, and have made beneficiary-level risk score data available, we frequently receive requests for technical assistance in this area suggesting that the methodology is still not entirely clear to ACOs.

To balance these competing concerns, we considered policies that would allow for some upward growth in CMS–HCC risk scores between the benchmark period and the performance year, while still limiting the impact of ACO coding initiatives, and also provide greater clarity for ACOs than the current methodology. In contemplating alternative policies, we also considered lessons learned from other CMS initiatives, including models tested by the Innovation Center. Finally, as we wish to encourage ACOs to take on higher levels of risk, we considered the importance of adopting a balanced risk adjustment methodology that provides ACOs with some protection against decreases in risk scores.

Our preferred approach would eliminate the distinction between newly and continuously assigned beneficiaries. We would use full CMS–HCC risk adjustment for all assigned beneficiaries between the benchmark period and the performance year, subject to a symmetrical cap of positive or negative 3 percent for the agreement period, which would apply such that the adjustment between BY3 and any performance year in the agreement period would never be more than 3 percent in either direction. In other words, the risk ratios applied to historical benchmark expenditures to capture changes in health status between BY3 and the performance year would never fall below 0.970 nor be higher than 1.030 for any performance year over the course of the agreement period. As is the case under the current policy, risk adjustment calculations would still be carried out separately for each of the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) and CMS–HCC prospective risk scores for each enrollment type would still be renormalized to the national assignable beneficiary population for that enrollment type before the cap is applied. Table 11 provides an illustrative example of how the cap would be applied to the risk ratio used to adjust historical benchmark expenditures to reflect changes in health status between BY3 and the performance year, for any performance year in the agreement period:

TABLE 11—HYPOTHETICAL DATA ON APPLICATION OF AGREEMENT PERIOD CAP ON PY TO BY3 RISK RATIO

Medicare enrollment type	BY3 renormalized CMS–HCC risk score	PY renormalized CMS–HCC risk score	Risk ratio before applying cap	Final risk ratio
ESRD	1.031	1.054	1.022	1.022
Disabled	1.123	1.074	0.956	0.970
Aged/dual eligible	0.987	1.046	1.060	1.030
Aged/non-dual eligible	1.025	1.001	0.977	0.977

In the example, the decrease in the disabled risk score and the increase in the aged/dual risk score would both be subject to the positive or negative 3 percent cap. Changes in the ESRD and aged/non-dual risk scores would not be affected by the cap; the ACO would receive full upward and downward adjustment, respectively, for these enrollment types.

This approach would provide full CMS–HCC risk adjustment for ACOs with changes in CMS–HCC risk below the cap, and a partial adjustment for ACOs with changes in CMS–HCC risk above the cap. Initial modeling suggests that among the 239 ACOs that received demographic risk adjustment for their continuously assigned population under the current policy in PY 2016 (55 percent of the 432 total ACOs reconciled), around 86 percent would have received a larger positive adjustment to their benchmark had this policy been in place. Therefore, we believe this approach would more consistently account for worsening health status of beneficiaries compared to the current policy. This could reduce the incentive for ACOs to avoid complex patients and potentially lead more ACOs to accept higher levels of performance-based risk. However, because of the cap on the increase in CMS–HCC risk, we believe that this policy would continue to provide protection to the Medicare Trust Funds against unwarranted increases in CMS–HCC prospective risk scores that are due to increased coding intensity, by limiting the impact of such increases on ACO benchmarks.

By instituting a symmetrical cap, this preferred approach would also limit large decreases in CMS–HCC prospective risk scores across all assigned beneficiaries. We believe that such a balanced approach would provide ACOs with a greater incentive to assume performance-based risk than under the current methodology, which provides ACOs with no protection from risk score decreases. Among the 193 ACOs that received CMS–HCC risk adjustment under the current policy for their continuously assigned population in PY 2016, 69 percent would have received a smaller negative adjustment with the symmetrical 3 percent cap. We also believe that this approach, which mirrors one of the risk adjustment methodologies tested in the Next Generation ACO Model, has a significant advantage over the current Shared Savings Program policy in that it is more straightforward, making it easier for ACOs to understand and determine the impact of risk adjustment on their benchmark. ACOs would be subject to risk adjustment within a clearly defined range, allowing them to more easily predict their performance.

Our choice of 3 percent as the preferred level for the symmetrical cap is influenced by program experience. A review of CMS–HCC risk score trends among Shared Savings Program ACOs found that a 3 percent cap on changes in aged/non-dual CMS–HCC risk scores (the enrollment category that represents the majority of assigned beneficiaries for most ACOs) would limit positive risk adjustment for less than 30 percent of ACOs, even when there is a 5-year lapse between BY3 and the performance year, which would be the case in the final year of a 5 year agreement period under

the proposal discussed in section II.A.2 of this proposed rule (or a 6-year lapse for the final performance year of the agreement period for ACOs that start a new agreement period on July 1, 2019, under the proposal discussed in section II.A.7). A 3 percent symmetrical cap was also advocated by some commenters on the 2016 proposed rule, who encouraged the Shared Savings Program to adopt a risk adjustment model similar to the one being used by the Next Generation ACO Model (see 81 FR 37968). Although we believe that a 3 percent cap on changes in CMS–HCC risk scores is reasonable and appropriate, we also considered alternate levels for a cap or allowing full CMS–HCC risk adjustment with no cap at all. However, we are concerned that a lower cap would not offer enough ACOs meaningfully greater protection against health status changes relative to the current approach. At the same time, we are concerned that adopting a higher cap, or allowing for full, uncapped risk adjustment would not provide sufficient protection against potential coding initiatives.

After consideration of these alternatives, we are proposing to change the program's risk adjustment methodology to use CMS–HCC prospective risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a symmetrical cap of positive or negative 3 percent for the agreement period for agreement periods beginning on July 1, 2019, and in subsequent years. The cap would reflect the maximum change in risk scores allowed in an agreement period between BY3 and any performance year in the agreement period. For ACOs participating in a 5 year and 6-month agreement period beginning on July 1, 2019, as discussed in section II.A.7 of this proposed rule, the cap would represent the maximum change in risk scores for the agreement period between BY3 and calendar year 2019 in the context of determining financial performance for the 6-month performance year from July 1, 2019 through December 31, 2019, as well as the maximum change in risk scores between BY3 and any of the subsequent five performance years of the agreement period. We would apply this approach to ACOs participating under the proposed BASIC track, as reflected in the proposed new section of the regulations at § 425.605, and to ACOs participating under the proposed ENHANCED track, as reflected in the proposed modifications to § 425.610. We seek comment on this proposal, including the level of the cap.

3. Use of Regional Factors When Establishing and Resetting ACOs' Benchmarks

a. Background

As described in the background for this section, we apply a regional adjustment to the rebased historical benchmark for ACOs entering a second or subsequent agreement period in 2017 or later years. This adjustment reflects a percentage of the difference between the regional FFS expenditures in the ACO's regional service area and the ACO's historical expenditures. The percentage used in calculating the adjustment is phased in over time, ultimately reaching 70 percent, unless the Secretary determines a lower weight should be applied and such lower weight is specified through additional notice and comment rulemaking.

In the June 2016 final rule, we laid out the steps used to calculate and apply the regional adjustment (see 81 FR 37963). These steps are recapped here:

- First, we calculate the ACO's rebased historical benchmark and regional average expenditures for the most recent benchmark year for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible), resulting in average per capita expenditure values for each of the Medicare enrollment types. The regional average expenditure amounts are adjusted for differences between the health status of the ACO's assigned beneficiary population and that of the assignable population in the ACO's regional service area.
- For each Medicare enrollment type, we then determine the difference between the average per capita regional amount and the average per capita amount of the ACO's rebased historical benchmark. These values may be positive or negative. For example, the difference between these values for a particular Medicare enrollment type will be expressed as a negative number if the value of the ACO's rebased historical benchmark expenditure for that Medicare enrollment type is greater than the regional average amount.
- Next, we multiply the resulting difference for each Medicare enrollment type by the applicable percentage weight used to calculate the amount of the regional adjustment for that agreement period. The products (one for each Medicare enrollment type) resulting from this step are the amounts of the regional adjustments that will be applied to the ACO's historical benchmark.
- We then apply the adjustment to the ACO's rebased historical benchmark by adding the adjustment amount for the Medicare enrollment type to the ACO's rebased historical benchmark expenditure for the same Medicare enrollment type.
- We next multiply the regionally-adjusted value of the ACO's rebased historical benchmark for each Medicare enrollment type by the proportion of the ACO's assigned beneficiary population for that Medicare enrollment type, based on the ACO's assigned beneficiary population for benchmark year 3.
- Finally, we sum expenditures across the four Medicare enrollment types to determine the ACO's regionally-adjusted rebased historical benchmark.

In the June 2016 final rule, we also detailed how the percentage weight used to calculate the regional adjustment will be phased in over time (see 81 FR 37971 through 37974). For the first agreement period in which this methodology applies, ACOs for which the weighted average adjustment across the enrollment types is positive (net positive adjustment) will receive a weight of 35 percent for all enrollment types (including individual enrollment types for which the adjustment is negative) and ACOs for which the weighted average adjustment is negative (net negative adjustment) will receive a weight of 25 percent for all enrollment types (including individual enrollment types for which the adjustment is positive). For the second agreement period in which the methodology applies, ACOs with a net positive adjustment will receive a weight of 70 percent for all enrollment types and ACOs with a net negative adjustment will receive a weight of 50 percent for all enrollment types. By the third agreement period in which the methodology applies, ACOs with either a net positive or a net negative adjustment will receive a weight of 70 percent for all enrollment types, unless the Secretary determines that a lower weight should be applied.

This regional adjustment is one of three ways in which regional expenditures are currently incorporated into the program's methodology for resetting the historical benchmark for an ACO's second or subsequent agreement period. We also use regional, instead of national, trend factors for each enrollment type to restate BY1 and BY2 expenditures in BY3 terms when calculating the rebased benchmark, and we use regional update factors to update the regionally-adjusted rebased

historical benchmark to the performance year at the time of financial reconciliation. As described in the June 2016 final rule (81 FR 37977 through 37981), we used our statutory authority under section 1899(i)(3) of the Act to adopt a policy under which we update the benchmark using regional factors in lieu of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act.

The regional trend factors used to calculate an ACO's rebased benchmark and the regional update factors used to update the benchmark to the performance year represent growth rates in risk-adjusted FFS expenditures among assignable beneficiaries in the ACO's regional service area, including beneficiaries assigned to the ACO. An ACO's regional service area is defined at § 425.20 as all counties in which at least one of the ACO's assigned beneficiaries resides. To calculate expenditures used in determining the regional adjustment and the trend and update factors, we first calculate risk-adjusted FFS expenditures among assignable beneficiaries for each county in the ACO's regional service area and then weight these amounts by the proportion of the ACO's assigned beneficiaries residing in each county, with all calculations performed separately by Medicare enrollment type (ESRD, disabled, aged/dual, aged/non-dual).

In the June 2016 final rule, we discussed the benefits that we believe to be associated with incorporating regional expenditures into ACO benchmarks. We explained, for example, that the incorporation of regional expenditures provides an ACO with a benchmark that is more reflective of FFS spending in the ACO's region than a benchmark based solely on the ACO's own historical expenditures (see 81 FR 37955). We believe that this approach creates stronger financial incentives for ACOs that have been successful in reducing expenditures to remain in the program, thus improving program sustainability. Many commenters expressed support for the approach, citing it as an improvement over the existing rebasing methodology (see 81 FR 37956). In the June 2016 final rule, we also discussed how using regional trend and update factors would allow us to better capture the cost experience in the ACO's region, the health status and socio-economic dynamics of the regional population, and location-specific Medicare payments when compared to using national FFS expenditures (see 81 FR 37976 through 37977). In that rule, we stated our intention to explore the possibility of incorporating regional expenditures, including the regional adjustment and regional trend and update factors, in the benchmark established for an ACO's first agreement period (see 81 FR 37973). In section II.D.3.b of this proposed rule, we discuss our proposals for incorporating regional expenditures into the benchmarks for ACOs in their first agreement period under the program.

We also acknowledged in the June 2016 final rule that the incorporation of regional expenditures into ACO benchmarks can have differential effects depending on an ACO's individual circumstances (see 81 FR 37955). For example, ACOs with low historical expenditures relative to their regional service area will see their rebased historical benchmark increase due to the regional adjustment, whereas the benchmarks for higher spending ACOs will be reduced. One concern is that, as the higher weights for the regional adjustment are phased in over time, the benchmarks for low-spending ACOs may become overly inflated to the point where these organizations need to do little to maintain or change their practices to generate savings. For higher-spending ACOs, there is the concern that a negative regional adjustment will discourage program participation or discourage these ACOs from caring for complex, high-cost patients. There is also concern about the longer-term effects on participation resulting from lower trend and update factors among ACOs that have had past success in reducing expenditures and that serve a high proportion of the beneficiaries within certain counties in their regional service area. In sections II.D.3.c and II.D.3.d of this proposed rule, we discuss proposals designed to mitigate these concerns.

b. Proposals To Apply Regional Expenditures in Determining the Benchmark for an ACO's First Agreement Period

A number of stakeholders offering comments on the February 2016 proposed rule advocated for extending the policies incorporating regional expenditures proposed for determining the rebased benchmarks for ACOs entering a second or subsequent agreement period under the program to the methodology for establishing the benchmarks for ACOs in their first agreement period under the program (see 81 FR 37971). While we declined to modify the methodology used to establish benchmarks for ACOs in a first agreement period to incorporate regional expenditures as part of the June 2016 final rule, we did signal our intention to explore this matter further after gaining experience with the new rebasing methodology (see 81 FR 37973).

Since the publication of the June 2016 final rule we have employed the new methodology to determine rebased benchmarks for ACOs starting second agreement periods in 2017 and 2018. This experience has reinforced our belief that a benchmarking methodology that incorporates regional expenditures, in addition to an ACO's own historical expenditures, is important for the sustainability of the program. For agreement periods starting in 2017, for example, we found that around 80 percent of ACOs receiving a rebased benchmark benefitted from receiving a regional adjustment. Having observed variation across ACO regional service areas, we also maintain that the incorporation of regional expenditure trends can lead to more accurate benchmarks that better reflect experience in ACOs' individual regions than benchmarks computed solely using national factors. We believe that introducing regional expenditures into the benchmarking methodology for ACOs in a first agreement period, as has been recommended by stakeholders, would serve to further strengthen the incentives under the program, improve program sustainability, and increase the accuracy of benchmark calculations for new ACOs by making their benchmarks more reflective of the regional environment in which these organizations operate. We also believe that adopting a more consistent benchmarking methodology would provide greater simplicity and more predictability for ACOs. Under this approach, ACOs entering the program would only be required to familiarize themselves with a single benchmarking methodology that would apply for all agreement periods under the program.

For the above reasons, we are proposing to incorporate regional expenditures into the benchmarking methodology for ACOs in a first agreement period for all ACOs entering the program beginning on July 1, 2019 and in subsequent years. Under this proposal, we would use almost the same methodology for determining the historical benchmarks for ACOs in their first agreement period as will apply for ACOs in their second or subsequent agreement period, including all policies proposed in this proposed rule, should they be finalized, regarding establishing the historical benchmark at the start of the agreement period, adjusting the historical benchmark for each

performance year within an agreement period, and updating the benchmark for each performance year (or for calendar year 2019 in the context of determining the financial performance of ACOs during the 6-month performance year from July 1, 2019 through December 31, 2019, as proposed in section II.A.7 of this proposed rule). The only distinction between the methodology that would be used to determine the historical benchmark for ACOs in their first agreement period and those in a second or subsequent agreement period would be the weights that are applied to the 3 benchmark years. Under this proposal we would continue to use weights of 10 percent, 30 percent, and 60 percent to weight the 3 benchmark years, respectively, when calculating the historical benchmark for an ACO in its first agreement period, rather than the equal weights that are used in resetting the benchmark for ACOs entering a second or subsequent agreement period. As described in the June 2015 final rule (80 FR 32787 through 32788), the use of equal weights when calculating the rebased benchmark was motivated by the concern that placing higher weights on the later benchmark years would reduce the incentive for ACOs that generate savings or that are trending positive in their first agreement period to participate in the program over the longer run, or reduce incentives for ACOs to achieve savings in the final year of their first agreement period. This concern is not relevant for ACOs in a first agreement period. Therefore, for these ACOs, we favor maintaining the existing weights, which we believe are more accurate because they capture the ACO's most recent experience in the benchmark period.

We propose to add a new provision at § 425.601 to the regulations that will describe how we will establish, adjust, update and reset historical benchmarks using factors based on regional FFS expenditures for all ACOs for agreement periods beginning on July 1, 2019 and in subsequent years. We seek comment on this proposal.

c. Proposals for Modifying the Regional Adjustment

In finalizing the phase-in structure for the original regional adjustment in the June 2016 final rule, we acknowledged that it might be necessary to reevaluate the effects of the regional adjustment on the Shared Savings Program and, if warranted, to modify the adjustment through additional rulemaking. Therefore, we adopted a policy under which the maximum weight to be applied to the adjustment would be 70 percent, unless the Secretary determines that a lower weight should be applied, as specified through future rulemaking (see 81 FR 37969 through 32974). Relevant considerations in determining the appropriate weight to be applied to the adjustment include, but are not limited to, effects on net program costs; the extent of participation in the program; and the efficiency and quality of care received by beneficiaries.

We have revaluated the effects of the regional adjustment as part of the regulatory impact analysis required for this proposed rule (see section IV) and have also taken into consideration our experience in applying the regional adjustment under the policies established in the June 2016 final rule. While we continue to believe that it is necessary to employ a benchmarking methodology that incorporates expenditures in an ACO's regional service area in addition to the ACO's own historical expenditures in order to maintain or improve program sustainability, we are concerned that, if unaltered, the regional adjustment will have unintended consequences and adverse effects on ACO incentives as discussed in the Regulatory Impact Analysis (section IV).

By design, the regional adjustment results in more generous benchmarks for ACOs that spend below their regions. As noted in section II.D.3.b of this proposed rule, our initial experience with the regional adjustment found that 80 percent of ACOs that renewed for a second agreement period starting in 2017 received a positive adjustment. These ACOs saw their benchmarks increase by 1.8 percent, on average, when the adjustment was applied with the 35 percent weight, with several ACOs seeing increases of over 5 percent, and one over 7 percent. Preliminary results for ACOs that renewed for a second agreement period starting in 2018 show a similar share of ACOs receiving a positive adjustment and one ACO seeing an adjustment of over 10 percent. As the weight applied to the regional adjustment increases, we are concerned that the benchmarks for the ACOs with the lowest spending relative to their region will become overly inflated to the point where they will need to do little to change their care practices to generate savings, which could reduce incentives for these ACOs to improve the efficiency of care provided to beneficiaries.

On the other hand, the regional adjustment reduces benchmarks for ACOs with higher spending compared to their region. Among 14 ACOs that received a net negative regional adjustment to their benchmark in 2017, the average reduction was 1.6 percent, with one ACO seeing a reduction of over 7 percent. These adjustments were calculated using only a 25 percent weight. Although preliminary results for ACOs that started a second agreement period in 2018 show slightly smaller negative adjustments, on average, we are concerned that the ACOs with the highest relative costs, some of which have targeted specific beneficiary populations that are inherently more complex and costly than the regional average, will find little value in remaining in the Shared Savings Program when faced with a significantly reduced benchmark as the weight applied to the adjustment increases.

To reduce the likelihood that the regional adjustment will have these undesired effects, we are proposing policies that would limit the magnitude of the adjustment by reducing the weight that is applied to the adjustment and imposing an absolute dollar limit on the adjustment. We believe that moderating the regional adjustment would lower potential windfall gains to lower-cost ACOs and could help to improve the incentive for higher-cost ACOs to continue to participate in the program.

First, we are proposing to amend the schedule of weights used to phase in the regional adjustment. Consistent with our current policy, the first time that an ACO is subject to a regional adjustment, we would apply a weight of 35 percent if the ACO's historical spending was lower than its region and a weight of 25 percent if the ACO's historical spending was higher than its region. The second time that an ACO is subject to a regional adjustment, we would apply a weight of 50 percent if the ACO's historical spending was lower than its region and 35 percent if the ACO's historical spending was higher than its region. The third or subsequent time that an ACO is subject to a regional adjustment we would apply a weight of 50 percent in all cases.

We wish to make two points related to the proposed schedule of weights clear. First, consistent with our current policy under § 425.603(c)(8) for determining the adjusted benchmark for the second or subsequent performance year of an ACO's agreement period, in calculating an adjusted benchmark for an ACO that makes changes to its ACO participant list or assignment methodology, we would use the same set of weights as was used for the first performance year in the agreement period. For example, an ACO that is subject to a weight of 25 percent in its first performance year of an agreement period would continue to be subject to a weight of either 35 or 25 percent,

depending on whether the ACO's historical expenditures, as adjusted, are higher or lower than its region, for any subsequent years in the same agreement period.

Second, for renewing or re-entering ACOs (see section II.A.5.c of this proposed rule) that previously received a rebased historical benchmark under the current benchmarking methodology adopted in the June 2016 final rule, we would consider the agreement period the ACO is entering upon renewal or re-entry in combination with the weight previously applied to calculate the regional adjustment to the ACO's benchmark in the ACO's most recent prior agreement period to determine the weight that would apply in the new agreement period. For example, an ACO that was subject to a weight of 35 or 25 percent in its second agreement period in the Shared Savings Program under the current benchmarking methodology that enters its third agreement period upon renewal would be subject to a weight of 50 or 35 percent. By contrast, if the same ACO had terminated during its second agreement period and subsequently re-enters the program, the ACO would continue to face a weight of 35 or 25 percent until the start of its subsequent agreement period. For a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO, we would consider the weight most recently applied to calculate the regional adjustment to the benchmark for the ACO in which the majority of the new ACO's participants were participating previously.

The weights included in the proposed new schedule were chosen in part to maintain consistency with the current schedule which already includes the 25, 35, and 50 percent values. Furthermore, we believe that using 50 percent as the maximum weight is appropriate because it strikes an even balance between rewarding an ACO for attainment (efficiencies already demonstrated at the start of the agreement period) versus improvement during the agreement period over its past historical performance.

We also wish to note that while this proposal would reduce the maximum regional adjustment as compared to current regulations, our proposal to extend the regional adjustment to ACOs in their first agreement period in the program would increase the number of years that an ACO would be subject to the adjustment. Thus, the lower maximum weight in later years would be balanced to some extent by an earlier phase-in.

Based on the magnitude of regional adjustments observed in the first 2 years under the new rebasing methodology, which were calculated using the lowest weights under the current phase-in schedule, we are concerned that reducing the maximum weight on the adjustment may not be sufficient to guard against the undesired effects of large positive or negative regional adjustments on incentives faced by individual ACOs. Therefore, to complement the proposed changes to the schedule of weights used to phase-in the regional adjustment, we also considered options for imposing a cap on the dollar amount of the regional adjustment. We believe that limiting regional adjustments for ACOs that are particularly low- or high-cost relative to their regions, will better align incentives for these ACOs with program goals, while continuing to reward ACOs that have already attained efficiency relative to their regional service areas.

We are thus also proposing to cap the regional adjustment amount using a flat dollar amount equal to 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS OACT. The cap would be calculated and applied by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) and would apply for both positive and negative adjustments.

We believe that defining the cap based on national per capita expenditures offers simplicity and transparency in that, for each enrollment type, a single value would be applicable for all ACOs with the same agreement start date. When selecting the level of the proposed cap, we aimed to choose a level that would only constrain the adjustment for the most extreme ACOs. When looking at the distribution of observed final regional adjustments among the 73 ACOs that received a rebased benchmark in 2017, we found that the amount of the regional adjustment calculated for around 95 percent of these ACOs would fall under a symmetrical cap equal to 5 percent of national FFS expenditures. We believe that capping the amount of the regional adjustment at this level would continue to provide a meaningful reward for ACOs that are efficient relative to their region, while reducing windfall gains for the ACOs with the lowest relative costs. Similarly, we believe capping the amount of a negative regional adjustment at this level would continue to impose a penalty on ACOs that are less efficient relative to their region, but by guarding against extremely high negative adjustments, should increase the program's ability to retain ACOs that serve complex patients and that may need some additional time to lower costs.

To implement the cap, we would continue to calculate the difference between the average per capita regional amount and the per capita rebased benchmark amount for each Medicare enrollment type. We would continue to multiply the difference for each enrollment type by the appropriate weight (determined using the schedule described previously) in order to determine the uncapped adjustment for each Medicare enrollment type. For positive adjustments, the final adjustment amount for a particular enrollment type would be set equal to the lesser of the uncapped adjustment or a dollar amount equal to 5 percent of the national per capita FFS expenditures for assignable beneficiaries in that enrollment type for BY3. For negative adjustments, the final adjustment amount for a particular enrollment type would be set equal to the greater (that is, the smaller negative value) of either the uncapped adjustment or the negative of 5 percent of the national per capita FFS expenditures for assignable beneficiaries in that enrollment type for BY3. We would then apply the final adjustment for each enrollment type to the benchmark expenditure for that enrollment type in the same manner that we currently apply the uncapped regional adjustment. Table 12 provides an illustrative example of how the final adjustment would be determined.

TABLE 12—HYPOTHETICAL DATA ON APPLICATION OF CAP TO REGIONAL ADJUSTMENT AMOUNT

Medicare enrollment type	Uncapped adjustment	National assignable FFS expenditure	5 percent of national assignable FFS expenditure	Final adjustment
ESRD	$4,214	$81,384	$4,069	$4,069
Disabled	−600	11,128	556	−556
Aged/dual eligible	788	16,571	829	788
Aged/non-dual eligible	−367	9,942	497	−367

In this example, the ACO's positive adjustment for ESRD would be constrained by the cap because the uncapped adjustment amount exceeds 5 percent of the national assignable FFS expenditure for the ESRD population. Likewise, the ACO's negative adjustment for the disabled population would also be reduced by the cap. The adjustments for aged/dual and aged/non-dual eligible populations would not be affected.

We also considered an alternative approach under which the cap would be applied at the aggregate level rather than at the Medicare enrollment type level. Under this approach, we would calculate regional adjustments by Medicare enrollment type as we do currently and then determine the weighted average of these adjustments, using the enrollment distribution in the ACO's BY3 assigned beneficiary population, to arrive at a single aggregate regional adjustment. We would then determine a weighted average of national per capita FFS expenditures for assignable beneficiaries across the four enrollment types, again using the enrollment distribution in the ACO's BY3 assigned beneficiary population, to arrive at a single aggregate national expenditure value. We would calculate a symmetrical aggregate cap equal to positive or negative 5 percent of the aggregate national expenditure value and compare this cap to the uncapped aggregate regional adjustment amount to determine the final aggregate regional adjustment. Specifically, if the uncapped aggregate regional adjustment amount is above the aggregate cap, then the final aggregate regional adjustment would equal the cap. However, if the uncapped aggregate regional adjustment amount is below the aggregate cap, then the final aggregate regional adjustment would equal the uncapped regional adjustment amount. The regional adjustment calculated for each Medicare enrollment type would then be multiplied by the ratio of the final aggregate regional adjustment to the uncapped aggregate regional adjustment. If the uncapped aggregate regional adjustment exceeds the aggregate cap, this ratio will be less than one and the regional adjustment for each Medicare enrollment type would be reduced by the same percentage. If the uncapped aggregate regional adjustment is less than or equal to the aggregate cap, the ratio will equal one and the regional adjustment would not be reduced for any Medicare enrollment type.

For example, if the uncapped aggregate regional adjustment amount was $550 and the aggregate cap was $500, the final aggregate regional adjustment would be $500. The regional adjustment for each Medicare enrollment type would be multiplied by a ratio of $500 to $550 or 0.909. This is equivalent to reducing the adjustment for each enrollment type by 9.1 percent. As another example, if the uncapped aggregate regional adjustment was $450 and the aggregate cap remained at $500, the final aggregate regional adjustment would be $450 because it is less than the aggregate cap. The regional adjustment for each Medicare enrollment type would be multiplied by a ratio equal to 1, and thus would not be reduced.

Initial modeling found the two methods to be comparable for most ACOs but suggested that our proposed approach (capping the regional adjustment at the Medicare enrollment type level) is somewhat more effective at limiting larger upside or downside adjustments. This is likely because the aggregate approach smooths out variation in adjustments across individual enrollment types. For example, for some ACOs, large positive adjustments in one enrollment type may be offset by smaller positive adjustments, or negative adjustments in other enrollment types under the aggregate approach. The proposed approach also aligns with our current benchmark calculations, which are done by Medicare enrollment type, and provides greater accuracy and transparency. Under this approach, the cap will only reduce the magnitude of the adjustment for a particular enrollment type if the original uncapped value of the adjustment is relatively large. This is not necessarily the case under the aggregate approach, where adjustments for all enrollment types, large or small, will be reduced if the aggregate regional adjustment exceeds the aggregate cap.

We believe that imposing a cap on the magnitude of the adjustment, coupled with the proposed changes to the schedule of weights used in applying the regional adjustment, will help to reduce windfall gains to low-spending ACOs and will also help to reduce the incentive for higher spending ACOs to leave the program by limiting the negative adjustments these ACOs will experience. We anticipate that the proposed cap on the regional adjustment will provide stronger incentives for higher spending ACOs to remain in the program (by reducing the magnitude of the benchmark decrease associated with negative regional adjustments) than disincentives for lower spending ACOs. We expect this latter group would still be sufficiently rewarded by the regional adjustment under the proposed approach to encourage their continued participation in the program. However, we also believe that by reducing the windfall gains for these ACOs, the proposed constraints on the regional adjustment would lead to greater incentives for these ACOs to further reduce spending in order to increase their shared savings payments.

In summary, we are proposing both to modify the schedule of weights used to phase in the regional adjustment and to impose a cap on the dollar amount of the adjustment. For the first agreement period that an ACO is subject to the regional adjustment, we are proposing to apply a weight of 35 percent if the ACO's historical spending was lower than its region and a weight of 25 percent if the ACO's historical spending was higher than its region. For the second agreement period, we are proposing to apply weights of 50 percent and 35 percent for lower and

higher spending ACOs, respectively. For the third or subsequent agreement period, we are proposing to apply a weight of 50 percent for all ACOs. Additionally, we would impose a symmetrical cap on the regional adjustment equal to positive or negative 5 percent of the national per capita FFS expenditures for assignable beneficiaries for each enrollment type. We are proposing to apply the modified schedule of weights and the cap on the regional adjustment for agreement periods beginning on July 1, 2019, and in subsequent years. The policies proposed in this section are included in the proposed new provision at § 425.601, which will govern the determination of historical benchmarks for all ACOs for agreement periods starting on July 1, 2019, and in subsequent years. We are seeking comment on these proposals, as well as the alternative capping methodology considered. We are also seeking comment on the proposed timeline for application of these proposals.

d. Proposals for Modifying the Methodology for Calculating Growth Rates Used in Establishing, Resetting, and Updating the Benchmark

As discussed previously, we believe that using regional expenditures to trend forward BY1 and BY2 to BY3 in the calculation of the historical benchmark and to update the benchmark to the performance year has the advantage of producing more accurate benchmarks. Regional trend and update factors allow us to better capture the cost experience in the ACO's region, the health status and socio-economic dynamics of the regional population, and location-specific Medicare payments when compared to using national FFS expenditures. However, we acknowledge the concern raised by stakeholders that the use of regional trend or update factors may affect ACOs' incentives to reduce spending growth or to continue participation in the program, particularly in circumstances where an ACO serves a high proportion of beneficiaries in select counties making up its regional service area. For such an ACO, a purely regional trend will be more influenced by the ACO's own expenditure patterns, making it more difficult for the ACO to outperform its benchmark and conflicting with our goal to move ACOs away from benchmarks based solely on their own historical costs. We therefore considered options that would continue to incorporate regional expenditures into trend and update factors while still protecting incentives for ACOs that serve a high proportion of the Medicare FFS beneficiaries in their regional service area.

One approach, supported by a number of stakeholders commenting on the 2016 proposed rule, would be to exclude an ACO's own assigned beneficiaries from the population used to compute regional expenditures. However, as we explained in the June 2016 final rule (see 81 FR 37959 through 37960), we believe that such an approach would create potential bias due to the potential for small sample sizes and differences in the spending and utilization patterns between ACO-assigned and non-assigned beneficiaries. The latter could occur, for example, if an ACO tends to focus on a specialized beneficiary population. We are also concerned that excluding an ACO's own assigned beneficiaries from the population could provide ACOs with an incentive to influence the assignment process by seeking to provide more care to healthy beneficiaries and less care to more costly beneficiaries. Given these concerns, we chose to focus on alternative options that would address stakeholder concerns by using a combination of national and regional factors.

The first approach we considered would use a blend of national and regional growth rates to trend forward BY1 and BY2 to BY3 when establishing or resetting an ACO's historical benchmark (referred to as the national-regional blend). By incorporating a national trend factor that is more independent of an ACO's own performance, we believe that the national-regional blend would reduce the influence of the ACO's assigned beneficiaries on the ultimate trend factor applied. It would also lead to greater symmetry between the Shared Savings Program and MA which, among other adjustments, applies a national projected trend to update county-level expenditures

Under this approach, the national-regional blend would be calculated as a weighted average of national FFS and regional trend factors, where the weight assigned to the national component would represent the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO, calculated as described in this section of the proposed rule. The weight assigned to the regional component would be equal to 1 minus the national weight. As an ACO's penetration in its region increases, a higher weight would be placed on the national component of the national-regional blend and a lower weight on the regional component, reducing the extent to which the trend factors reflect the ACO's own expenditure history.

The national component of the national-regional blend would be trend factors computed for each Medicare enrollment type using per capita FFS expenditures for the national assignable beneficiary population. These trend factors would be calculated in the same manner as the national trend factors used to trend benchmark year expenditures for ACOs in a first agreement period under the current regulations. For example, the national trend factor for the aged/non-dual population for BY1 would be equal to BY3 per capita FFS expenditures among the national aged/non-dual assignable population divided by BY1 per capita FFS expenditures among the national aged/non-dual assignable population. Consistent with our current approach, the per capita FFS expenditures used in these calculations would not be explicitly risk-adjusted. By using risk ratios based on risk scores renormalized to the national assignable population, as described in section II.D.2 of this proposed rule, we are already controlling for changes in risk in the national assignable population elsewhere in the benchmark calculations, rendering further risk adjustment of the national trend factors unnecessary.

The regional component of the national-regional blend would be trend factors computed for each Medicare enrollment type based on the weighted average of risk-adjusted county FFS expenditures for assignable beneficiaries, including assigned beneficiaries, in the ACO's regional service area. These trend factors would be computed in the same manner as the regional trend factors used to trend benchmark year expenditures for ACOs that enter a second or subsequent agreement period in 2017 or later years under the current regulations. The regional trend factors reflect changes in expenditures within given counties over time, as well shifts in the geographic distribution of an ACO's assigned beneficiary population. This is because regional expenditures for each year are calculated as the weighted average of county-level expenditures for that year where the weight for a given county is the proportion of the ACO's assigned beneficiaries residing in that county in that year.

The weights used to blend the national and regional components would be calculated separately for each Medicare enrollment type using data for BY3. To calculate the national weights, we would first calculate for each enrollment type the share of assignable

beneficiaries that are assigned to the ACO in each county in the ACO's regional service area. We would then weight each county's share by the proportion of the ACO's total assigned beneficiary population in that enrollment type residing in that county to obtain the regional share. This weighting approach mirrors the methodology used to calculate regional expenditures, as it gives higher precedence to counties where more of the ACO's assigned beneficiaries reside when determining the ACO's overall penetration in its region.

As an example, assume an ACO has 11,000 assigned beneficiaries with aged/non-dual eligible enrollment status and the ACO's regional service area consists of two counties, County A and County B. There were 10,000 assignable aged/non-dual beneficiaries residing in County A in BY3, with 9,000 assigned to the ACO in that year. There were 12,000 assignable aged/non-dual beneficiaries residing in County B with 2,000 assigned to the ACO. The weight for the national component of the blended trend factor for the aged/non-dual enrollment type would be: [(Assigned Beneficiaries in County A/Assignable Beneficiaries in County A) × (Assigned Beneficiaries in County A/Total Assigned Beneficiaries)] + [(Assigned Beneficiaries in County B/Assignable Beneficiaries in County B) × (Assigned Beneficiaries in County B/Total Assigned Beneficiaries)] or [(9,000/10,000) × (9,000/11,000)] + [(2,000/12,000) × (2,000/11,000)], or 76.7 percent. The weight given to the regional component of the blended trend factor for aged/non-dual enrollment type in this example would be 23.3 percent. Because this hypothetical ACO has high penetration in its regional service area, the national component of the blended trend factor would receive a much higher weight than the regional component.

Initial modeling among 73 ACOs that renewed for a second agreement period in 2017 found that the weighted average share of assignable beneficiaries in an ACO's regional service area that are assigned to the ACO ranged from under 1 percent to around 60 percent, when looking at all four enrollment types combined, with a median of 12.3 percent and a mean of 15.1 percent. Among the 73 ACOs, 8 (11 percent) had regional shares above 30 percent. We found similar distributions when looking at the four enrollment types individually. Among ACOs with overall regional shares above 30 percent, the simulated use of blended trend factors caused changes in benchmarks (relative to current policy) of −0.8 percent to 0.3 percent, with half seeing a slight negative impact and the other half seeing a slight positive impact. Based on these statistics, it appears that most ACOs currently do not have significant penetration in their regional service areas. As a result, we would expect that for most ACOs the regional component of the blended trend factor would receive a higher weight than the national component and that the overall impact of the national-regional blend on benchmarks relative to current policy would be small. Should penetration patterns change over time, the blended formula would automatically shift more weight to the national component of the trend factor.

We would also use a national-regional blend when updating the historical benchmark for each performance year. That is, we would multiply historical benchmark expenditures for each Medicare enrollment type by an update factor that blends national and regional expenditure growth rates between BY3 and the performance year. The national component for each update factor would equal performance year per capita FFS expenditures for the national assignable beneficiary population for that enrollment type divided by BY3 per capita FFS expenditures for the national assignable beneficiary population for that enrollment type. As described above, the FFS expenditures for the national population would not be risk-adjusted. The regional component for each update factor would equal the weighted average of risk-adjusted county FFS expenditures among assignable beneficiaries, including the ACO's assigned beneficiaries, in the ACO's regional service area in the performance year divided by the weighted average of risk-adjusted county FFS expenditures among assignable beneficiaries, including the ACO's assigned beneficiaries, in the ACO's regional service area in BY3. This regional component would be computed in the same manner as the regional updates used to update the rebased benchmark for ACOs that enter a second or subsequent agreement period in 2017 or later years under the current regulations. The weights used to blend the national and regional components of the update factor would be calculated in the same manner as the weights that we are proposing to use in calculating the blended trend factors for the historical benchmark, except they would be based on performance year rather than BY3 data. That is, the weight assigned to the national component would represent the share of assignable beneficiaries in ACO's regional service area that are assigned to the ACO (based on a weighted average of county-level shares) in the performance year and the weight assigned to the regional component would be equal to 1 minus that share.

In addition to the national-regional blend, we considered an alternate approach that would incorporate national trends at the county level instead of at the regional service area level (national-county blend). Under this alternative, for each county that is in an ACO's regional service area in BY3, we would calculate trend factors to capture growth in county-level risk-adjusted expenditures for assignable beneficiaries from BY1 to BY3 and from BY2 to BY3. Each county-level trend factor would be blended with the national trend factor. The blended trend factor for each county would be a weighted average of the national and county-level trends where the weight applied to the national component would be the share of assignable beneficiaries in the county that are assigned to the ACO in BY3. The weight applied to the county component of the blend would be 1 minus the national weight.

After computing the blended trend factor for each county, we would determine the weighted average across all counties in the ACO's regional service area in BY3, using the proportion of assigned beneficiaries residing in each county in BY3 as weights to obtain an overall blended trend factor. We would then apply this overall blended trend factor to the expenditures for the ACO's assigned beneficiary population for the relevant benchmark year. All calculations would be done separately for each Medicare enrollment type. A similar approach would be used to compute update factors between BY3 and the performance year, but using weights based on share of assignable beneficiaries in each county that are assigned to the ACO in the performance year.

Returning to the hypothetical ACO from above, under the national-county blend we would calculate separate blended trend factors for County A and County B. For County A, the national component would receive a weight of 90.0 percent (9,000/10,000) and the county component would receive a weight of 1 minus 90.0 percent, or 10.0 percent. For County B, the national component would receive a weight of 16.7 percent (2,000/12,000) and the county component would receive a weight of 1 minus 16.7 percent, or 83.3 percent. After computing the blended trend factor for each county, we would take the weighted average across the two

counties, with County A's blended trend factor receiving a weight of 81.8 percent (9,000/11,000) and County B's blended trend factor receiving a weight of 18.2 percent (2,000/11,000).

Our modeling suggests that, for most ACOs, applying the blend at the county-level would yield similar results to the national-regional blend. However, for ACOs that have experienced shifts in the geographic distribution of their assigned beneficiaries over time, we found the two methods to diverge. This is because the national-regional blend reflects not only changes in expenditures within specific counties over time, but also changes in the geographic distribution of the ACO's own assigned beneficiaries. The national-county blend, by contrast, holds the geographic distribution of an ACO's assigned beneficiaries fixed at the BY3 distribution (for trend factors) or at the performance year distribution (for update factors), potentially reducing accuracy.

We are also concerned that calculating trends at the county rather than regional level, in addition to being less accurate, would be less transparent to ACOs. While national and regional trends are both used under our current benchmarking policies, and are thus familiar to ACOs, county-level trends would present a new concept. For these reasons, we favor the approach that incorporates national trends at the regional rather than county level.

Finally, we considered yet another approach that would simply replace regional trend and update factors with national factors for ACOs above a certain threshold of penetration in their regional service area. Specifically, if the share of assignable beneficiaries in an ACO's regional service area that are assigned to that ACO (computed as described above as a weighted average of county-level shares) is above the 90th percentile among all currently active ACOs for a given enrollment type in BY3, we would use national trend factors to trend forward BY1 and BY2 expenditures to BY3. For ACOs that are below the 90th percentile for a given enrollment type, we would continue to use regional factors as we do under the current policy. We would use a similar approach for the update factors, except the threshold would be based on the share of assignable beneficiaries that are assigned to the ACO in the performance year rather than BY3. Among the 73 ACOs that entered a second agreement period in 2017, the 90th percentile for the four enrollment types ranged between 25 and 30 percent of assignable beneficiaries in the ACO's regional service area. One drawback of this approach relative to the blended approaches previously described is that it treats ACOs that are just below the threshold and just above the threshold very differently, even though they may be similarly influencing expenditure trends in their regional service areas.

As we have previously indicated with respect to regional trends (see, for example, 81 FR 37976) and as suggested by our modeling, the national-regional blend, as well as the other options considered, would have mixed effects on ACOs depending on how the expenditure trends in an ACO's regional service area differ from the national trend. ACOs that have high penetration in their regional service area and that have helped to drive lower growth in their region relative to the national trend would benefit from this policy. ACOs that have contributed to higher growth in their regions would likely have lower benchmarks as a result of this policy than under current policy, helping to protect the Medicare Trust Fund and providing increased incentives for these ACOs to lower costs.

Based on the considerations previously discussed, we propose to use a blend of national and regional trend factors (that is, the national-regional blend) to trend forward BY1 and BY2 to BY3 when determining the historical benchmark. We also propose to use a blend of national and regional update factors, computed as described in this section, to update the historical benchmark to the performance year (or to calendar year 2019 in the context of determining the financial performance of ACOs for the 6-month performance year from July 1, 2019 through December 31, 2019, as proposed in section II.A.7 of this proposed rule). The blended trend and update factors would apply to determine the historical benchmark for all agreement periods starting on July 1, 2019 or in subsequent years, regardless of whether it is an ACO's first, second, or subsequent agreement period. We also wish to make clear that in the event an ACO makes changes to its certified ACO participant list for a given performance year or its assignment methodology selection, should our proposal in section II.A.4.c be finalized, the weight that is applied to the national and regional components of the blended trend and update factors would be recomputed to reflect changes in the composition of the ACO's assigned beneficiary population in BY3.

Because the proposed blended update factor would be used in place of an update factor based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program as called for in section 1899(d)(1)(B)(ii) of the Act, this proposal would require us to use our authority under section 1899(i)(3) of the Act. This provision grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under this title and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

By combining a national component that is more independent of an ACO's own experience with a regional component that captures location-specific trends, we believe that the proposed blended update factor would mitigate concerns about ACO influence on regional trend factors, improving the accuracy of the benchmark update and potentially protecting incentives for ACOs that may have high penetration in their regional service areas. As such, we believe that this proposed change to the statutory benchmarking methodology would improve the quality and efficiency of the program. As discussed in the Regulatory Impact Analysis (section IV. of this proposed rule), we project that this proposed approach, in combination with other changes to the statutory payment model proposed elsewhere in this proposed rule, as well as current policies established using the authority of section 1899(i)(3) of the Act, would not increase program expenditures relative to those under the statutory payment model.

In summary, we propose to use a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark and a blend of national and regional update factors to update the historical benchmark to the performance year (or to calendar year 2019 in the context of determining the financial performance of ACOs for the 6-month performance year from July 1, 2019 through December 31, 2019, as proposed in section II.A.7 of this proposed rule). The national component of the blended trend and update factors would receive a weight equal to the share of assignable beneficiaries in the regional service area that are assigned to the ACO, computed as described in this section by taking a weighted average of county-level shares. The regional component of the blended trend and update factors would receive a weight equal to 1 minus the national weight. The proposed blended trend and update factors would apply to all

agreement periods starting on July 1, 2019 or in subsequent years, regardless of whether it is an ACO's first, second, or subsequent agreement period. These proposed policies are included in the proposed new provision at § 425.601, which would govern the determination of historical benchmarks for all ACOs. We seek comment on these proposals, as well as the alternatives considered, including incorporating national trends at the county rather than regional level or using national trend factors for ACOs with penetration in their regional service area exceeding a certain threshold.

4. Technical Changes To Incorporate References to Benchmark Rebasing Policies

We are also proposing to make certain technical, conforming changes to the following provisions to reflect our proposal to add a new section of the regulations at § 425.601 to govern the calculation of the historical benchmark for all agreement periods starting on July 1, 2019, and in subsequent years. We are also proposing to make conforming changes to these provisions to incorporate the policies on resetting, adjusting, and updating the benchmark that were adopted in the June 2016 final rule, and codified in the regulations at § 425.603.

- Under subpart C, which governs application procedures, add references to §§ 425.601 and 425.603 in § 425.204(g);
- Under subpart D, which governs the calculation of shared savings and losses, add references to § 425.603 in §§ 425.604 (Track 1) and 425.606 (Track 2); and add references to §§ 425.601 and 425.603 in § 425.610 (ENHANCED track);
- As part of the modifications to § 425.610, make a wording change to the paragraph currently numerated as (a)(2)(ii) that could not be completed with the June 2016 final rule due to a typographical error. In this paragraph, we would remove the phase ''adjusts for changes'', and in its place add the phrase ''CMS adjusts the benchmark for changes''; and
- Under subpart I, which governs the reconsideration review process, add references to §§ 425.601 and 425.603 to § 425.800(a)(4). In addition, as previously described, we have used our authority under section 1899(i)(3) of the Act to modify certain aspects of the statutory payment and benchmarking methodology under section 1899(d) of the Act. Accordingly, we also propose to amend § 425.800(a)(4) to clarify that the preclusion of administrative and judicial review applies only to the extent that a specific calculation is performed in accordance with section 1899(d) of the Act.

E. Updating Program Policies

1. Overview

This section addresses various proposed revisions to the Shared Savings Program designed to update program policies. We propose to revise our regulations governing the assignment process in order to align our voluntary alignment policies with the requirements of section 50331 of the Bipartisan Budget Act of 2018 and to update the definition of primary care services. We also propose to extend the policies that we recently adopted for ACOs impacted by extreme and uncontrollable circumstances during 2017 to 2018 and subsequent performance years. We also solicit comment on considerations related to supporting ACOs' activities to address the national opioid crisis and the agency's meaningful measures initiative. We propose to discontinue use of the quality performance measure that assesses an ACO's eligible clinicians' level of adoption of CEHRT and propose instead that ACOs annually certify that the percentage of eligible clinicians participating in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds certain thresholds. Lastly, we seek comment on how Medicare ACOs and Part D sponsors could be encouraged to collaborate so as to improve the coordination of pharmacy care for Medicare FFS beneficiaries.

2. Revisions to Policies on Voluntary Alignment

a. Background

Section 50331 of the Bipartisan Budget Act of 2018 amended section 1899(c) of the Act (42 U.S.C. 1395jjj(c)) to add a new paragraph (2)(B) that requires the Secretary, for performance year 2018 and each subsequent performance year, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as the primary care provider of the beneficiary for purposes of assigning such beneficiary to an ACO, if a system is available for electronic designation. A voluntary identification by a Medicare FFS beneficiary under this provision supersedes any claims-based assignment otherwise determined by the Secretary. Section 50331 also requires the Secretary to establish a process under which a Medicare FFS beneficiary is notified of his or her ability to designate a primary care provider or subsequently to change this designation. An ACO professional is defined under section 1899(h) of the Act as a physician as defined in section 1861(r)(1) of the Act and a practitioner described in section 1842(b)(18)(C)(i) of the Act.

We believe that section 50331 requires certain revisions to our current beneficiary voluntary alignment policies in § 425.402(e). Prior to enactment of the Bipartisan Budget Act of 2018, section 1899(c) of the Act required that beneficiaries be assigned to an ACO based on their use of primary care services furnished by a physician as defined in section 1861(r)(1) of the Act, and beginning January 1, 2019, services provided in RHCs/FQHCs. In order to satisfy this statutory requirement, we currently require that a beneficiary receive at least one primary care service during the beneficiary assignment window from an ACO professional in the ACO who is a physician with a specialty used in assignment in order to be assigned to the ACO (see § 425.402(b)(1)). As currently provided in § 425.404(b), for performance year 2019 and subsequent performance years, for purposes of the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician. After identifying the beneficiaries who have received a primary care service from a physician in the ACO, we use a two-step, claims-based methodology to assign beneficiaries to a particular ACO for a calendar year (see § 425.402(b)(2) through (4)). In the CY 2017 PFS final rule (81 FR 80501 through 80510), we augmented this claims-based beneficiary assignment methodology by finalizing a policy under which beneficiaries, beginning in 2017 for assignment for performance year 2018, may voluntarily align with an ACO by designating a ''primary clinician'' they believe is responsible for coordinating their overall care using MyMedicare.gov, a secure online patient portal. MyMedicare.gov contains a list of all of the Medicare-enrolled practitioners who appear on the Physician Compare website and beneficiaries may choose any practitioner present on Physician Compare as their primary clinician.

Notwithstanding the assignment methodology in § 425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at § 425.401(a) and is not excluded from assignment by the

criteria in § 425.401(b), and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or a physician with one of the primary specialty designations included in § 425.402(c) (see § 425.402(e)). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year, superseding any assignment that might have otherwise occurred under the claims-based methodology. Further, beneficiaries may change their designation at any time through *MyMedicare.gov;* the new choice will be incorporated when we perform assignment for the subsequent performance year. Beneficiaries who designate a provider or supplier outside an ACO, who is a primary care physician, a physician with a specialty designation that is considered in the assignment methodology, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care will not be added to an ACO's list of assigned beneficiaries, even if they would otherwise meet the criteria for claims-based assignment.

b. Proposals

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. Under our current methodology, a beneficiary may select any practitioner who has a record on the Physician Compare website as their primary clinician; however, we will only assign the beneficiary to an ACO if they have chosen a practitioner who is a primary care physician (as defined at § 425.20), a physician with one of the primary specialty designations included in § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. Therefore, we propose to modify our current voluntary alignment policies at § 425.402(e)(2)(iii) to provide that we will assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. Under this proposal, a beneficiary may select a practitioner with any specialty designation, for example, a specialty of allergy/immunology or surgery, as their primary care provider and be eligible for assignment to the ACO in which the practitioner is an ACO professional. Specifically, we propose to revise § 425.402(e)(2)(iii) to remove the requirement that the ACO professional designated by the beneficiary be a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. In addition, the provision at § 425.402(e)(2)(iv) addresses beneficiary designations of clinicians outside the ACO as their primary clinician. The current policy at § 425.402(e)(2)(iv) provides that a beneficiary will not be assigned to an ACO for a performance year if the beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist as their primary clinician responsible for coordinating their overall care. Consistent with the proposed revisions to § 425.402(e)(2)(iii) to incorporate the requirements of section 50331 of the Bipartisan Budget Act, we propose to revise § 425.402(e)(2)(iv) to indicate that if a beneficiary designates any provider or supplier outside the ACO as their primary clinician responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year.

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to allow a beneficiary to voluntarily align with an ACO, and does not impose any restriction with respect to whether the beneficiary has received any services from an ACO professional (see section 1899(c)(2)(B)(i) of the Act). We also believe the requirement in section 1899(c)(2)(B)(iii) of the Act that a beneficiary's voluntary identification shall supersede any claims-based alignment is consistent with eliminating the requirement that the beneficiary have received a service from an ACO professional in order to be eligible to be assigned an ACO. Therefore, we propose to remove the requirement at § 425.402(e)(2)(i) that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12 month assignment window in order to be assigned to the ACO. Under this proposal, a beneficiary who selects a primary clinician who is an ACO professional, but who does not receive any services from an ACO participant during the assignment window, will remain eligible for assignment to the ACO. We believe this approach reduces burden on beneficiaries and their practitioners by not requiring practitioners to provide unnecessary care during a specified period of time in order for a beneficiary to remain eligible for assignment to the ACO. Consistent with this proposal, we propose to remove § 425.402(e)(2)(i) in its entirety.

We note that, under this proposal, if a beneficiary does not change their primary clinician designation, the beneficiary will remain assigned to the ACO in which that practitioner participates during the ACO's entire agreement period and any subsequent agreement periods under the Shared Savings Program, even if the beneficiary no longer seeks care from any ACO professionals. Because a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care, this proposed change could also impact assignment under certain Innovation Center models in which overlapping beneficiary assignment is not permitted. Although we believe our proposed policy is consistent with the requirement under section 1899(c)(2)(B)(iii) of the Act that a voluntary identification by a beneficiary shall supersede any claims-based assignment, we also believe it could be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific Innovation Center models, such as the CEC Model. CMS implemented the CEC Model to test a new system of payment and service delivery that CMS believes will lead to better health outcomes for Medicare beneficiaries living with ESRD, while lowering costs to Medicare Parts A and B. Under the model, CMS is working with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals receive. We believe that an ESRD beneficiary, who is otherwise eligible for assignment to an entity participating in the CEC Model, could benefit from the focused attention on and increased care coordination for their ESRD available under the CEC Model. Such a beneficiary could be disadvantaged if they were unable to receive the type of specialized care for their ESRD that would be available from an entity participating in the CEC Model. Furthermore, we believe it could be difficult for the Innovation Center to conduct a viable test of a specialty or

disease-specific model, if we were to require that beneficiaries who have previously designated an ACO professional as their primary clinician remain assigned to the Shared Savings Program ACO under all circumstances. Currently, the CEC Model completes its annual PY prospective assignment lists prior to the Shared Savings Program in order to identify the beneficiaries who may benefit from receiving specialized care from an entity participating in the CEC Model. Additionally, on a quarterly basis, a beneficiary may be assigned to the CEC Model who was previously assigned to a Track 1 or Track 2 ACO.

As a result, we believe that in some instances it may be necessary for the Innovation Center to use its authority under section 1115A(d)(1) of the Act to waive the requirements of section 1899(c)(2)(B) of the Act solely as necessary for purposes of testing a particular model.

Therefore, we are proposing to create an exception to the general policy that a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care. Specifically, we propose that we would not assign such a beneficiary to the ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model. Under this proposal, if a beneficiary selects a primary clinician who is a Shared Savings Program ACO professional and the beneficiary is also eligible for alignment to a specialty care or disease specific model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination that a waiver of the requirement in section 1899(c)(2)(B) is necessary solely for purposes of testing the Model, the Innovation Center or its designee would notify the beneficiary of their alignment to an entity participating in the model. Additionally, although such a beneficiary may still voluntarily identify his or her primary clinician and may seek care from any clinician, the beneficiary would not be assigned to a Shared Savings Program ACO even if the designated primary clinician is a Shared Savings Program ACO professional.

We would include a list of any models that meet these criteria on the Shared Savings Program website, to supplement the information already included in the beneficiary assignment reports we currently provide to ACOs (as described under § 425.702(c)), so that ACOs can know why certain beneficiaries, who may have designated an ACO professional as their primary clinician, are not assigned to them. Similar information would also be shared with 1–800–MEDICARE to ensure that Medicare customer service representatives are able to help beneficiaries who may be confused as to why they are not aligned to the ACO in which their primary clinician is participating.

Section 1899(c)(2)(B)(ii) of the Act, as amended by section 50331 of the Bipartisan Budget Act, requires the Secretary to establish a process under the Shared Savings Program through which each Medicare FFS beneficiary is notified of the ability to identify an ACO professional as his or her primary care provider and informed of the process that may be used to make and change such identification. We intend to implement section 1899(c)(2)(B)(ii) of the Act under the beneficiary notification process at § 425.312. In addition, we plan to use the beneficiary notification process under § 425.312 to address the concern that beneficiary designations may become outdated. Specifically, we propose to require ACO participants to use a CMS-developed template notice that encourages beneficiaries to check their designation regularly and to update their designation when they change care providers or move to a new area. We discuss our beneficiary notification processes further in section II.C.3.a of this proposed rule.

We propose to apply these modifications to our policies under the Shared Savings Program regarding voluntary alignment beginning for performance years starting on January 1, 2019, and subsequent performance years. We propose to incorporate these new requirements in the regulations by redesignating § 425.402(e)(2)(i) through (iv) as § 425.402(e)(2)(i)(A) through (D), adding a paragraph heading for newly redesignated § 425.402(e)(2)(i), and including a new § 425.402(e)(2)(ii).

We note that as specified in § 425.402(e)(2)(ii) a beneficiary who has designated an ACO professional as their primary clinician must still be eligible for assignment to an ACO by meeting the criteria specified in § 425.401(a). These criteria establish the minimum requirements for a beneficiary to be eligible to be assigned to an ACO under our existing assignment methodology, and we believe it is appropriate to impose the same basic limitations on the assignment of beneficiaries on the basis of voluntary alignment. We do not believe it would be appropriate, for example, to assign a beneficiary to an ACO if the beneficiary does not reside in the United States, or if the other eligibility requirements are not met.

We request comments on our proposals to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. We also seek comment on our proposal to create a limited exception to our proposed policies on voluntary alignment to allow a beneficiary to be assigned to an entity participating in a model tested or expanded under section 1115A of the Act when certain criteria are met. In addition, we welcome comments on how we might increase beneficiary awareness and further improve the electronic process through which a beneficiary may voluntarily identify an ACO professional as their primary care provider through My.Medicare.gov for purposes of assignment to an ACO.

3. Revisions to the Definition of Primary Care Services Used in Beneficiary Assignment

a. Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician and all services furnished by RHCs and FQHCs. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment. We established the initial list of services that we considered to be primary care services in the November 2011 final rule (76 FR 67853). In that final rule, we indicated that we intended to monitor this issue and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS, as summarized in the CY 2018 PFS proposed rule (82

FR 34109 and 34110). Subsequently, in the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional chronic care management service codes, 99487, 99489, and G0506, and four behavioral health integration service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). These additions are effective for purposes of performing beneficiary assignment under § 425.402 for performance year 2019 and subsequent performance years.

Accounting for these recent changes, we define primary care services in § 425.400(c) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a Nursing Facility, excluding services furnished in a SNF which are reported on claims with place of service code 31).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the Annual Wellness Visits).

(3) G0463 (code for services furnished in electing teaching amendment hospitals).

(4) G0506 (code for chronic care management).

(5) G0502, G0503, G0504 and G0507 (codes for behavioral health integration).

As discussed in the CY 2018 PFS final rule, a commenter recommended that CMS consider including the advance care planning codes, CPT codes 99497 and 99498, in the definition of primary care services in future rulemaking (82 FR 53213). We indicated that we would consider whether CPT codes 99497 and 99498 or any additional existing HCPCS/CPT codes should be added to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program. In addition, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494, 99484 (82 FR 53078).

CPT codes 99304 through 99318 are used for reporting evaluation and management services furnished by physicians and other practitioners in a skilled nursing facility (reported on claims with POS code 31) or a nursing facility (reported on claims with POS code 32). Based on stakeholder input, we finalized a policy in the CY 2016 PFS final rule (80 FR 71271 through 71272) effective for performance year 2017 and subsequent performance years, to exclude services identified by CPT codes 99304 through 99318 from the definition of primary care services for purposes of the beneficiary assignment methodology when the claim includes the POS code 31 modifier designating the services as having been furnished in a SNF. We established this policy to recognize that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their true primary care needs. We continue to believe that it is appropriate for SNF patients to be assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the true primary care needs of these beneficiaries. ACOs serving special needs populations, including beneficiaries receiving long term care services, and other stakeholders have recently suggested that we consider an alternative method for determining operationally whether services identified by CPT codes 99304 through 99318 were furnished in a SNF. Instead of indirectly determining whether a beneficiary was a SNF patient when the services were furnished based on physician claims data, these stakeholders suggest we more directly determine whether a beneficiary was a SNF patient based on SNF facility claims data. These stakeholders have recommended that CMS use contemporaneous SNF Medicare facility claims to determine whether a professional service identified by CPT codes 99304 through 99318 was furnished in a SNF and thus should not be used for purposes of the beneficiary assignment methodology under § 425.402. Specifically, these stakeholders suggest that we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by determining whether the beneficiary also received SNF facility services on the same date of service.

In this rule we propose to make changes to the definition of primary care services in § 425.400(c) to add new codes and to revise how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF.

b. Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believe it would be appropriate to amend the definition of primary care services to include certain additional codes. Specifically, we propose to revise the definition of primary care services in § 425.400(c) to include the following HCPCS and CPT codes: (1) Advance care planning service codes, CPT codes 99497 and 99498, (2) administration of health risk assessment service codes, CPT codes 96160 and 96161, (3) prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure, CPT codes 99354 and 99355, (4) annual depression screening service code, HCPCS code G0444, (5) alcohol misuse screening service code, HCPCS code G0442, and (6) alcohol misuse counseling service code, HCPCS code G0443. In addition, in the recent CY 2019 PFS proposed rule (see 83 FR 35841 through 35844) CMS proposed to create three new HCPCS codes to reflect the additional resources involved in furnishing certain evaluation and management services: (1) GPC1X add-on code, for the visit complexity inherent to evaluation and management associated with certain primary care services, (2) GCG0X add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care, and (3) GPRO1, an additional add-on code for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure. We believe it would be appropriate to include these codes in the definition of primary care services under the Shared Savings Program because these codes are used to bill for services that are similar to services that are already included in the list of primary care codes at § 425.400(c). We

also expect that primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists frequently furnish these services as part of their overall management of a patient. As a result, we believe that including these codes would increase the accuracy of the assignment process by helping to ensure that beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary's care.

The following provides additional information about the HCPCS and CPT codes that we are proposing to add to the definition of primary care services:

Advance care planning (CPT codes 99497 and 99498): Effective January 1, 2016, CMS pays for voluntary advance care planning under the PFS (80 FR 70955 through 70959). See CMS, Medicare Learning Network, ''Advance Care Planning'' (ICN 909289, August 2016), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf.* Advance care planning enables Medicare beneficiaries to make important decisions that give them control over the type of care they receive and when they receive it. Medicare pays for advance care planning either as a separate Part B service when it is medically necessary or as an optional element of a beneficiary's Annual Wellness Visit. We believe it would be appropriate to include both Advance Care Planning codes 99497 and 99498 in the definition of primary care services under the Shared Savings Program because the services provided as part of advance care planning include counseling and other evaluation and management services similar to the services included in Annual Wellness Visits and other evaluation and management service codes that are already included in the list of primary care codes.

Administration of health risk assessment (CPT codes 96160 and 96161): In the CY 2017 PFS final rule (81 FR 80330 through 80331), CMS added two new CPT codes, 96160 and 96161, to the PFS, effective for CY 2017, to be used for payment for the administration of health risk assessment. These codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base code. For example, if a health risk assessment service were administered during a physician office visit, then the physician would bill for both the appropriate office visit code and the appropriate health risk assessment code. We believe it would be appropriate to include CPT codes 96160 and 96161 in the definition of primary care services because these add-on codes frequently represent additional practice expenses related to office visits for evaluation and management services that are already included in the definition of primary care services.

Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355): These two codes are also ''add-on codes'' that describe additional resource components of a broader service furnished in the office or other outpatient setting that are not accounted for in the valuation of the base codes. Code 99354 is listed on a claim to report the first hour of additional face-to-face time with a patient and code 99355 is listed separately for each additional 30 minutes of face-to-face time with a patient beyond the time reported under code 99354. Codes 99354 and 99355 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. (See Medicare Claims Processing Manual Chapter 12, Sections 30.6.15.1 Prolonged Services With Direct Face-to-Face Patient Contact Service (Codes 99354–99357) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf;* also see CMS, MLN Matters, Prolonged Services (Codes 99354–99359) (Article Number MM5972, Revised March 7, 2017), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5972.pdf.*) Although we do not currently include prolonged services codes CPT code 99354 and 99355 on our list of primary care services, based on further review we believe it would be appropriate to include them on our list of primary care services to more accurately assign beneficiaries to ACOs based on all the allowed charges for the primary care services furnished to beneficiaries. We note that the definitions of codes 99354 and 99355 also include prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services. Therefore, we propose to include the allowed charges for CPT code 99354 and 99355, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

Annual depression screening (HCPCS code G0444), alcohol misuse screening (HCPCS code G0442), and alcohol misuse counseling (HCPCS code G0443): Effective October 14, 2011, all Medicare beneficiaries are eligible for annual depression screening and alcohol misuse screening. (See CMS Manual System, Screening for Depression in Adults (Transmittal 2359, November 23, 2011) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2359CP.pdf* and see CMS, MLN Matters, Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (Article Number MM7633, Revised June 4, 2012), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm7633.pdf*). Although these three codes have been in use since before the implementation of the Shared Savings Program in 2012, based on further review of these services, we believe that it would be appropriate to consider these services in beneficiary assignment. Annual depression screening may be covered if it is furnished in a primary care setting that has staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up. Alcohol misuse screening and counseling are screening and behavioral counseling interventions in primary care to reduce alcohol misuse. All three of these codes include screening and counseling services similar to counseling and other evaluation and management services included in the codes already on the list of primary care codes.

In the recent CY 2019 PFS proposed rule (see 83 FR 35841 through 35844)), CMS proposed to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for services represented by CPT codes 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient). All three of these codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base codes.

HCPCS code GPC1X is intended to capture the additional resource costs, beyond those involved in the base evaluation and management codes, of providing face-to-face primary care services for established patients. HCPCS code GPC1X would be billed in addition to the base evaluation and management code for an established patient when the visit includes primary care services. In contrast, new HCPCS code GCG0X is an add-on code intended to reflect the

complexity inherent to evaluation and management services associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, and interventional pain management-centered care. We believe it would be appropriate to include both proposed new HCPCS codes GCG0X and GPC1X in our definition of primary care services because they represent services that are currently included in CPT codes 99201 through 99215, which are already included in the list of primary care codes in § 425.400(c).

Finally, proposed new HCPCS code GPRO1 (prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure, in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes) is modeled on CPT code 99354, a prolonged services code discussed earlier in this section which we are proposing to add to our list of primary care services. HCPCS code GPRO1 is intended to reflect prolonged evaluation and management or psychotherapy service(s) of 30 minutes duration beyond the typical service time of the primary or base service, whereas existing CPT code 99354 reflects prolonged services of 60 minutes duration. As is the case for code 99354, code GPRO1 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. We believe it would be appropriate to include proposed HCPCS code GPRO1 on our list of primary care services for the same reasons we are proposing to add CPT code 99354 to our list of primary care services. Because the proposed definition of HCPCS code GPRO1 also includes prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services, we propose to include the allowed charges for HCPCS code GPRO1, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

We propose to include these codes in the definition of primary care services when performing beneficiary assignment under § 425.402, for performance years starting on January 1, 2019, and subsequent years. We note, however, that our proposal to include the three proposed new ''add-on codes'', GPC1X, GCG0X, and GPRO1, is contingent on CMS finalizing its proposal to create these new codes for use starting in 2019.

As previously discussed in section II.E.3.a, ACOs and other stakeholders have expressed concerns regarding our current policy of identifying services billed under CPT codes 99304 through 99318 furnished in a SNF by using the POS modifier 31. We continue to believe it is appropriate to exclude from assignment services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. However, we agree with stakeholders that it might increase the accuracy of beneficiary assignment for these vulnerable and generally high cost beneficiaries if we were to revise our method for determining whether services identified by CPT codes 99304 through 99318 were furnished in a SNF to focus on whether the beneficiary also received SNF facility services on the same day. We believe it would be feasible for us to directly and more precisely determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by analyzing our facility claims data files rather than by using the POS modifier 31 in our professional claims data files. Operationally, we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service. Therefore, we propose to revise the regulation at § 425.400(c)(1)(iv)(A)(*2*), effective for performance years starting on January 1, 2019 and subsequent performance years, to remove the exclusion of claims including the POS code 31 and in its place indicate more generally that we would exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF.

Under our current process, if CMS's HCPCS committee or the American Medical Association's CPT Editorial Panel modifies or replaces any of the codes that we designate as primary care service codes in § 425.400(c), we must revise the primary care service codes listed in § 425.400(c) as appropriate through further rulemaking before the revised codes can be used for purposes of assignment. As noted previously, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494 and 99484. Therefore, consistent with our current process, we propose to revise the primary care service codes in § 425.400(c)(1)(iv) to replace HCPCS codes G0502, G0503, G0504 and G0507 with CPT codes 99492, 99493, 99494 and 99484 for performance years starting on January 1, 2019, and subsequent performance years.

We note that the regulations text at § 425.400(c)(1)(iv) includes brief descriptions for the HCPCS codes that we have designated as primary care service codes, but does not include such descriptions for the CPT codes that we have designated as primary care service codes. For consistency, we are proposing a technical change to the regulations at § 425.400(c)(1)(iv)(A) to also include descriptions for the CPT codes. We also note that one of the Chronic Care Management (CCM) codes, CPT code 99490, is inadvertently listed in the regulations text at § 425.400(c)(1)(iv)(A)(*6*) along with the codes for Transitional Care Management (TCM) services. We are proposing a technical change to the regulations to move CPT code 99490 up to § 425.400(c)(1)(iv)(A)(*5*) with the other CCM codes.

We welcome comments on the new codes we are proposing to add to the definition of primary care services used for purposes of assigning beneficiaries to Shared Savings Program ACOs. In addition, we seek comments on our proposal to revise our method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF. We also seek comments on the other proposed technical changes to § 425.400(c)(1)(iv). We also welcome comments on any additional existing HCPCS/CPT codes that we should consider adding to the definition of primary care services in future rulemaking.

4. Extreme and Uncontrollable Circumstances Policies for the Shared Savings Program

a. Background

Following the 2017 California wildfires and Hurricanes Harvey, Irma, Maria and Nate, stakeholders expressed concerns that the effects of these types of disasters on ACO participants, ACO providers/suppliers, and the assigned beneficiary population could undermine an ACO's ability to successfully meet the quality performance standards, and adversely affect financial performance, including, in the case of ACOs under performance-based risk, increasing shared losses. To address these concerns, we published an interim final rule with comment period titled Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017 (hereinafter referred to as the Shared Savings Program IFC) that appeared in the

Federal Register on December 26, 2017 (82 FR 60912). In the Shared Savings Program IFC, we established policies for addressing ACO quality performance scoring and the determination of the shared losses owed by ACOs participating under performance-based risk tracks for ACOs that were affected by extreme or uncontrollable circumstances during performance year 2017. The policies adopted in the Shared Savings Program IFC were effective for performance year 2017, including the applicable quality data reporting period for the performance year. We have considered the comments received to date on the Shared Savings Program IFC in developing the policies in this proposed rule for 2018 and subsequent years.

The extreme and uncontrollable circumstances policies established in the Shared Savings Program for performance year 2017 align with the policies established under the Quality Payment Program for the 2017 MIPS performance period and subsequent MIPS performance periods (see CY 2018 Quality Payment Program final rule with comment, 82 FR 53780 through 53783 and Quality Payment Program IFC, 82 FR 53895 through 53900). In particular, in the Shared Savings Program IFC (82 FR 60914), we indicated that we would determine whether an ACO has been affected by an extreme and uncontrollable circumstance by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in performance year 2017 as determined under the Quality Payment Program or the ACO's legal entity is located in such an area. In the Quality Payment Program IFC, we explained that we anticipated that the types of events that could trigger the extreme and uncontrollable circumstances policies would be events designated a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, although we indicated that we would review each situation on a case-by-case basis (82 FR 53897).

Because ACOs may face extreme and uncontrollable circumstances in 2018 and subsequent years, we believe it is appropriate to propose to extend the policies adopted in the Shared Savings Program IFC for addressing ACO quality performance scoring and the determination of the shared losses owed for ACOs affected by extreme or uncontrollable circumstances to performance year 2018 and subsequent performance years. In addition, in the Shared Savings Program IFC, we indicated that we planned to observe the impact of the 2017 hurricanes and wildfires on ACOs' expenditures for their assigned beneficiaries during performance year 2017, and might revisit the need to make adjustments to the methodology for calculating the benchmark in future rulemaking. We consider this issue further in the discussion that follows.

b. Proposed Revisions

The financial and quality performance of ACOs located in areas subject to extreme and uncontrollable circumstances could be significantly and adversely affected. Disasters may have several possible effects on ACO quality and financial performance. For instance, displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting, as well as, reduce the beneficiary response rate on survey measures. Further, for practices damaged by a disaster, the medical records needed for quality reporting may be inaccessible. We also believe that disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals. The effects of a disaster could include challenges in communication between the ACO and its participating providers and suppliers and in implementation of and participation in programmatic activities. Catastrophic events outside the ACO's control can also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO's benchmark in the subsequent agreement period. These factors could jeopardize ACOs' ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program.

Because widespread disruptions could occur during 2018 or subsequent performance years, we believe it is appropriate to have policies in place to change the way in which we assess the quality and financial performance of Shared Savings Program ACOs in any affected areas. Accordingly, we propose to extend the automatic extreme and uncontrollable circumstances policies under the Shared Savings Program that were established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we propose that the Shared Savings Program extreme and uncontrollable circumstances policies for performance year 2018 and subsequent performance years would apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. As we discussed in the Shared Savings Program IFC (82 FR 60914), we believe it is also appropriate to extend these policies to encompass the quality reporting period, unless the reporting period is extended, because if an ACO is unable to submit its quality data as a result of a disaster occurring during the quality data submission window, we would not have the quality data necessary to measure the ACO's quality performance for the performance year. For example, if an extreme and uncontrollable event were to occur in February 2019, which we anticipate would be during the quality data reporting period for performance year 2018, then the extreme and uncontrollable circumstances policies would apply for quality data reporting and quality performance scoring for performance year 2018, if the reporting period is not extended. We do not believe it is appropriate to extend this policy to encompass the quality data reporting period if the reporting period is extended because affected ACOs would have an additional opportunity to submit their quality data, enabling us to measure their quality performance in the applicable performance year. Accordingly, we also propose that the policies regarding quality reporting would apply with respect to the determination of the ACO's quality performance in the event that an extreme and uncontrollable event occurs during the applicable quality data reporting period for a performance year and the reporting period is not extended. However, we note that, because a disaster that occurs after the end of the performance year would have no impact on the determination of an ACO's financial performance for that performance year, we do not believe it would be appropriate to make an adjustment to shared losses in the event an extreme or uncontrollable event occurs during the quality data reporting period.

(1) Modification of Quality Performance Scores for all ACOs in Affected Areas

As we explained in the Shared Savings Program IFC (82 FR 60914 through 60916), ACOs and their ACO

participants and ACO providers/suppliers are frequently located across several different geographic regions or localities, serving a mix of beneficiaries who may be differentially impacted by hurricanes, wildfires, or other triggering events. Therefore, for 2017, we established a policy for determining when an ACO, which may have ACO participants and ACO providers/suppliers located in multiple geographic areas, would qualify for the automatic extreme and uncontrollable circumstance policies for the determination of quality performance. Specifically, we adopted a policy for performance year 2017 of determining whether an ACO has been affected by extreme and uncontrollable circumstances by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in the performance year, as determined under the Quality Payment Program as discussed in the Quality Payment Program IFC (82 FR 53898) or the ACO's legal entity is located in such an area. For 2017, we adopted a policy under which the location of an ACO's legal entity is determined based on the address on file for the ACO in CMS's ACO application and management system. We used 20 percent of the ACO's assigned beneficiary population as the minimum threshold to establish an ACO's eligibility for the policies regarding quality reporting and quality performance scoring for 2017 because, as we stated in the Shared Savings Program IFC, we believe the 20 percent threshold provides a reasonable way to identify ACOs whose quality performance may have been adversely affected by an extreme or uncontrollable circumstance, while excluding ACOs whose performance would not likely be significantly affected.

The 20 percent threshold was selected to account for the effect of an extreme or uncontrollable circumstance on an ACO that has the minimum number of assigned beneficiaries to be eligible for the program (5,000 beneficiaries), and in consideration of the average total number of unique beneficiaries for whom quality information is required to be reported in the combined CAHPS survey sample (860 beneficiaries) and the CMS web interface sample (approximately 3,500 beneficiaries). (There may be some overlap between the CAHPS sample and the CMS web interface sample.) Therefore, we estimated that an ACO with an assigned population of 5,000 beneficiaries typically would be required to report quality information on a total of 4,000 beneficiaries. Thus, we indicated that we believe the 20 percent threshold ensures that an ACO with the minimum number of assigned beneficiaries would have an adequate number of beneficiaries across the CAHPS and CMS web interface samples in order to fully report on these measures. However, we also noted that it is possible that some ACOs that have fewer than 20 percent of their assigned beneficiaries residing in affected areas may have a legal entity that is located in an emergency declared area. Consequently, their ability to quality report may be equally impacted because the ACO legal entity may be unable to collect the necessary information from the ACO participants or experience infrastructure issues related to capturing, organizing, and reporting the data to CMS. We stated that if less than 20 percent of the ACO's assigned beneficiaries reside in an affected area and the ACO's legal entity is not located in a county designated as an affected area, then we believe that there is unlikely to be a significant impact upon the ACO's ability to report or on the representativeness of the quality performance score that is determined for the ACO. For performance year 2017, we will determine what percentage of the ACO's performance year assigned population was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. Although beneficiaries are assigned to ACOs under Track 1 and Track 2 based on preliminary prospective assignment with retrospective reconciliation after the end of the performance year, these ACOs will be able to use their quarterly assignment lists, which include beneficiaries' counties of residence, for early insight into whether they are likely to meet the 20 percent threshold.

In the Shared Savings Program IFC, we modified the quality performance standard specified under § 425.502 by adding a new paragraph (f) to address potential adjustments to the quality performance score for performance year 2017 of ACOs determined to be affected by extreme and uncontrollable circumstances. We also modified § 425.502(e)(4) to specify that an ACO receiving the mean Shared Savings Program ACO quality score for performance year 2017 based on the extreme and uncontrollable circumstances policies is not eligible for bonus points awarded based on quality improvement in that year because quality data will not be available to determine if there was improvement from year to year.

In the Shared Savings Program IFC, we established policies with respect to quality reporting and quality performance scoring for the 2017 performance year. In anticipation of any future extreme and uncontrollable events, we believe it is appropriate to propose to extend these policies, with minor modifications, to subsequent performance years as well. In order to avoid confusion and reduce unnecessary burdens on affected ACOs, we propose to align our policies for 2018 and subsequent years with policies established for the Quality Payment Program in final rule with comment period, entitled CY 2018 Updates to the Quality Payment Program (82 FR 53568). Specifically, we propose to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the identification of the affected geographic areas and the applicable time periods. Generally, in line with the approach taken for 2017 in the Quality Payment Program IFC (82 FR 53897), we anticipate that the types of events that would be considered an automatic triggering event would be events designated as a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, but CMS will review each situation on a case-by-case basis. We also propose that CMS would have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity. Additionally, we propose to determine an ACO's legal entity location based on the address on file for the ACO in CMS's ACO application and management system.

In the Shared Savings Program IFC, we established a policy for performance year 2017 under which we will determine the percentage of the ACO's assigned population that was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. We begin producing the final list of assigned beneficiaries after allowing for 3 months of claims run out following the end of a performance year. However, the quality reporting period ends before the 3-month claims run out period ends. Therefore, we are concerned that if, for future performance years, we continue to calculate the percentage of affected beneficiaries based on the ACO's final

list of assigned beneficiaries, it would not be operationally feasible for us to notify an ACO as to whether it meets the 20 percent threshold prior to the end of the quality reporting period because the final list of assigned beneficiaries is not available until after the close of the quality reporting period. We now believe it would be appropriate to base this calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which would be available with the quarter three program reports, generally in November of the applicable performance year (or calendar year for the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019). Under this timeline, we would be able to notify ACOs earlier as to whether they exceed the 20 percent threshold, and ACOs could then use this information to decide whether to report quality data for the performance year. Therefore, for performance year 2018 and subsequent performance years, we are proposing to determine the percentage of an ACO's assigned beneficiaries that reside in an area affected by an extreme and uncontrollable circumstance using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample. We believe we can use this assignment list report regardless of the date(s) the natural disaster occurred. The assignment list report provides us with a list of beneficiaries who have received the plurality of their primary care services from ACO professionals in the ACO at a specific point in time. As this is the list that is used to determine the quality reporting sample, we believe it is appropriate to use the same list to determine how many of the ACO's beneficiaries reside in an area affected by a disaster, such that the ACO's ability to report quality data could be compromised. We propose to revise § 425.502(f) to reflect this proposal for performance year 2018 and subsequent years. We welcome comments on this proposal

In the Shared Savings Program IFC (82 FR 60916), we described the policies under the MIPS APM scoring standard that would apply for performance year 2017 for MIPS eligible clinicians in an ACO that did not completely report quality. The existing tracks of the Shared Savings Program (Track 1, Track 2 and Track 3), and the Track 1+ Model are MIPS APMs under the APM scoring standard.[23] If finalized, we expect the proposed BASIC track and ENHANCED track (based on Track 3) would similarly be considered MIPS APMs under the APM scoring standard. For purposes of the APM scoring standard, MIPS eligible clinicians in an ACO that has been affected by an extreme and uncontrollable circumstance and does not report quality for a performance year, and therefore, receives the mean ACO quality score under the Shared Savings Program, would have the MIPS quality performance category reweighted to zero percent resulting in MIPS performance category weighting of 75 percent for the Promoting Interoperability performance category and 25 percent for Improvement Activities performance category under the APM scoring standard per our policy at § 414.1370(h)(5)(i)(B). In the event an ACO that has been affected by an extreme and uncontrollable circumstance is able to completely and accurately report all quality measures for a performance year, and therefore receives the higher of the ACO's quality performance score or the mean quality performance score under the Shared Savings Program, we would not reweight the MIPS quality performance category to zero percent under the APM scoring standard. Additionally, unless otherwise excepted, the ACO participants will receive a Promoting Interoperability (PI) (formerly called Advancing Care Information (ACI)) performance category score under the APM scoring standard based on their reporting, which could further increase their final score under MIPS.

We propose to revise § 425.502(f) to extend the policies established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we propose that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, or that the ACO's legal entity is located in such an area, we would use the following approach to calculate the ACO's quality performance score instead of the methodology specified in § 425.502(a) through (e).

- The ACO's minimum quality score would be set to equal the mean quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we would use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO's quality performance score is used, the ACO would also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO would not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we would measure quality improvement based on a comparison between the ACO's performance in that year and in the most recently available prior performance year in which the ACO reported quality. Under this approach, the comparison will continue to be between consecutive years of quality reporting, but these years may not be consecutive calendar years.

Additionally, we propose to address the possibility that ACOs that have a 6-month performance year (or performance period) during 2019 may be affected by extreme and uncontrollable circumstances. As described in section II.A.7 of this proposed rule, we are proposing to use 12 months of data, based on the calendar year, to determine quality performance for the two 6-month performance years during 2019 (from January 2019 through June 2019, and from July 2019 through December 2019). We are also proposing to use this same approach to determine quality performance for ACOs that start a 12-month performance year on January 1, 2019, and then elect to voluntarily terminate their participation agreement with an effective termination date of June 30, 2019, and enter a new agreement period starting on July 1, 2019. Accordingly, we believe it is necessary to account for disasters occurring in any month(s) of calendar year 2019 for ACOs participating in a 6-month performance year (or performance period) during 2019 regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the

[23] See, for example Alternative Payment Models in the Quality Payment Program as of February 2018, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Comprehensive-List-of-APMs.pdf*.

disaster. Therefore, for ACOs affected by a disaster in any month of 2019, we would use the alternative scoring methodology specified in § 425.502(f) to determine the quality performance score for the 2019 quality reporting period, if the reporting period is not extended. For example, assume that an ACO participates in the Shared Savings Program for a 6-month performance year from January 1, 2019, through June 30, 2019, and does not continue its participation in the program for a new agreement period beginning July 1, 2019. Further assume that we determine that 20 percent or more of the ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, in September 2019. The ACO's quality performance score for the 2019 reporting period would be adjusted according to the policies in § 425.502(f).

We propose to specify the applicability of the alternative scoring methodology in § 425.502(f) to the 6-month performance years (or the 6-month performance period) within calendar year 2019 in the proposed new section of the regulations at § 425.609 that describes the methodology for determining an ACO's financial and quality performance for the two 6-month performance years (or the 6-month performance period) during 2019.

(2) Mitigating Shared Losses for ACOs Participating in a Performance-Based Risk Track

In the Shared Savings Program IFC (82 FR 60916) we modified the payment methodology for performance-based risk tracks for performance year 2017, established under the authority of section 1899(i) of the Act, to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances. Under this approach, we will reduce the ACO's shared losses, if any, determined to be owed for performance year 2017 under the existing methodology for calculating shared losses in the Shared Savings Program regulations at 42 CFR part 425 subpart G by an amount determined by multiplying the shared losses by two factors: (1) The percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. For performance year 2017, we will determine the percentage of the ACO's performance year assigned beneficiary population that was affected by the disaster based on the final list of beneficiaries assigned to the ACO for the performance year. For example, assume that an ACO is determined to owe shared losses of $100,000 for performance year 2017, a disaster was declared for October through December during the performance year, and 25 percent of the ACO's assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner: $\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750$. The policies for performance year 2017 are specified in paragraph (i) in § 425.606 for ACOs under Track 2 and § 425.610 for ACOs under Track 3.

We believe it is appropriate to continue to apply these policies in performance year 2018 and subsequent years to address stakeholders' concerns that ACOs participating under a performance-based risk track could be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given the increase in utilization, difficulty of coordinating care for patient populations leaving the impacted areas, and the use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare FFS rules. Absent this relief, we believe ACOs that are participating in performance-based risk tracks may reconsider whether they are able to continue their participation in the Shared Savings Program under a performance-based risk track. The approach we adopted for performance year 2017 in the Shared Savings Program IFC, and which we are proposing to continue for performance year 2018 and subsequent years, balances the need to offer relief to affected ACOs with the need to continue to hold those ACOs accountable for losses incurred during the months in which there was no applicable disaster declaration and for the portion of their final assigned beneficiary population that was outside the area affected by the disaster. Consistent with the policy adopted for performance year 2017 in the Shared Savings Program IFC, we believe it is appropriate to continue to use the final assignment list report for the performance year for purposes of this calculation. This final assignment list report will be available at the time we conduct final reconciliation and provides the most complete information regarding the extent to which an ACO's assigned beneficiary population was affected by a disaster.

Additionally, we propose to also address the possibility that ACOs that have a 6-month performance year during 2019 may be affected by extreme and uncontrollable circumstances. As described in section II.A.7 of this proposed rule, we are proposing to use 12 months of expenditure data, based on the calendar year, to perform financial reconciliation for the two 6-month performance years during 2019 (from January 2019 through June 2019, and from July 2019 through December 2019). Accordingly, for ACOs participating in a 6-month performance year during 2019, we believe it is necessary to account for disasters occurring in any month(s) of calendar year 2019, regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster. This proposal applies to ACOs participating under a 6-month performance year during calendar year 2019, that would be reconciled based on their financial performance during the entire 12-month calendar year 2019 (as described in section II.A.7 of this proposed rule and in the proposed provision at § 425.609). This proposal also applies to ACOs that start a 12-month performance year on January 1, 2019, and then elect to voluntarily terminate their participation agreement with an effective termination date of June 30, 2019, and enter a new agreement period starting on July 1, 2019. Consistent with § 425.221(b)(3)(i), we would reconcile these ACOs for the performance period from January 1, 2019, through June 30, 2019, based on their financial performance during the entire 12-month calendar year 2019, according to the methodology in the proposed provision at § 425.609.

For ACOs with a 6-month performance year (or performance period) that are affected by an extreme or uncontrollable circumstance during calendar year 2019, we propose to first determine shared losses for the ACO over the full calendar year, adjust the ACO's losses for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year (or performance period) according to the methodology proposed under § 425.609. For example, assume that: A disaster was declared for October 2019 through December 2019; an ACO is being reconciled for its participation during the performance year (or performance period) from January 1, 2019, through June 30, 2019; the ACO is determined to have shared losses of $100,000 for calendar year 2019; and 25 percent of

the ACO's assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner: $100,000 − ($100,000 × 0.25 × 0.25) = $100,000 − $6,250 = $93,750, then we would multiply these losses by the portion of the year the ACO participated = $93,750 × 0.5 = $46,875.

This proposed approach to mitigate shared losses for ACOs that may be affected by extreme and uncontrollable circumstances would also apply to ACOs that are liable for a pro-rated share of losses, determined based on their financial performance during the entire performance year, as a consequence of voluntary termination of a 12-month performance year after June 30 or involuntary termination by CMS (as described in section II.A.6 of this proposed rule and in the proposed revisions to § 425.221(b)(2)). We note that according to the proposed policies in section II.A.6.d of this proposed rule, an ACO under a two-sided model that voluntarily terminates its participation agreement under § 425.220 during a 6-month performance year with an effective date of termination prior to the last calendar day of the performance year is not liable for shared losses incurred during the performance year. For ACOs that are involuntarily terminated from a 6-month performance year, pro-rated shared losses for the 6-month performance year would be determined based on assigned beneficiary expenditures for the full calendar year 2019 (as described in section II.A.7 of this proposed rule) and then pro-rated to account for the partial year of participation prior to involuntary termination.

We acknowledge that it is possible that ACOs that either voluntarily terminate after June 30th of a 12-month performance year or are involuntarily terminated and will be reconciled to determine a pro-rated share of any shared losses may also be affected by extreme and uncontrollable circumstances. In this case, we propose that the amount of shared losses calculated for the calendar year would be adjusted to reflect the number of months and the percentage of the assigned beneficiary population affected by extreme and uncontrollable circumstances, before we calculate the pro-rated amount of shared losses for the portion of the year the ACO participated in the Shared Savings Program. For example, assume that: A disaster was declared for October 2019 through December 2019; an ACO had been involuntarily terminated on March 31, 2019 and will be reconciled for its participation during the portion of the performance year from January 1, 2019 through March 31, 2019. The ACO is determined to have shared losses of $100,000 for calendar year 2019; and 25 percent of the ACO's assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner: $100,000 − ($100,000 × 0.25 × 0.25) = $100,000 − $6,250 = $93,750, then we would multiply these losses by the portion of the year the ACO participated = $93,750 × 0.25 = $23,437.50.

Therefore, we propose to amend §§ 425.606(i) and 425.610(i) to extend the policies regarding extreme and uncontrollable circumstances that were established for performance year 2017 to performance year 2018 and subsequent years. In section II.A.3.a of this proposed rule, we discuss our proposal that these policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial performance would also apply to BASIC track ACOs under performance-based risk. These proposals are reflected in the proposed new provision at § 425.605(f). We also propose to specify in revisions to §§ 425.606(i) and 425.610(i), and in the proposed new provision for the BASIC track at § 425.605(f), that the policies regarding extreme and uncontrollable circumstances will also apply to ACOs that are reconciled for a partial year of performance under § 425.221(b)(2) as a result of voluntary or involuntary early termination. The proposed revisions to §§ 425.606(i) and 425.610(i) also address the applicability of these policies to a Track 2 or Track 3 ACO that starts a 12-month performance year on January 1, 2019, and then elects to voluntarily terminate its participation agreement with an effective termination date of June 30, 2019, and enters a new agreement period starting on July 1, 2019; these ACOs would be reconciled for the performance period from January 1, 2019 through June 30, 2019, consistent with the proposed new provision at § 425.221(b)(3)(i). In addition, we are proposing to include a provision at § 425.609(d) to provide that the policies on extreme and uncontrollable circumstances would apply to the determination of shared losses for ACOs participating in a 6-month performance year during 2019.

We note that to the extent that our proposal to extend the policies adopted in the Shared Savings Program IFC to 2018 and subsequent performance years constitutes a proposal to change the payment methodology for 2018 after the start of the performance year, we believe that consistent with section 1871(e)(1)(A)(ii) of the Act, and for the reasons discussed in this section of this proposed rule, it would be contrary to the public interest not to propose to establish a policy under which we would have the authority adjust the shared losses calculated for ACOs in Track 2 and Track 3 for performance year 2018 to reflect the impact of any extreme or uncontrollable circumstances that may occur during the year.

These proposed policies would not change the status of those payment models that meet the criteria to be Advanced APMs under the Quality Payment Program (see § 414.1415). Our proposed policies would reduce the amount of shared losses owed by ACOs affected by a disaster, but the overall financial risk under the payment model would not change and participating ACOs would still remain at risk for an amount of shared losses in excess of the Advanced APM generally applicable nominal amount standard. Additionally, these policies would not prevent an eligible clinician from satisfying the requirements to become a QP for purposes of the APM Incentive Payment (available for payment years through 2024) or higher physician fee schedule updates (for payment years beginning in 2026) under the Quality Payment Program.

We also want to emphasize that all ACOs would continue to be entitled to share in any savings they may achieve for a performance year. ACOs in all tracks of the program will continue to receive shared savings payments, if any, as determined under subpart G of the regulations. The calculation of savings and the determination of shared savings payment amounts for a performance year would not be affected by the proposed policies to address extreme and uncontrollable circumstances, except that the quality performance score for an affected ACO may be adjusted as described in this section of this proposed rule.

(3) Determination of Historical Benchmarks for ACOs in Affected Areas

In the Shared Savings Program IFC, we sought comment on how to address the impact of extreme and uncontrollable circumstances on the expenditures for an ACO's assigned beneficiary population for purposes of determining the benchmark (82 FR 60917). As we explained in the Shared Savings Program IFC (82 FR 60913), the impact of disasters on an ACO's financial performance could be unpredictable as a result of changes in utilization and cost of services furnished to the Medicare beneficiaries it serves. In some cases, ACO

participants might be unable to coordinate care because of migration of patient populations leaving the impacted areas. On the other hand, patient populations remaining in impacted areas might receive fewer services and have lower overall costs to the extent that healthcare providers are unable to reopen their offices because they lack power and water, or have limited access to fuel for operating alternate power generators. Significant changes in costs incurred, whether increased or decreased, as a result of an extreme or uncontrollable circumstance may impact the benchmark determined for the ACO's subsequent agreement period in the Shared Savings Program, as performance years of the current agreement period become the historical benchmark years for the subsequent agreement period. An increase in expenditures for a particular calendar year would result in a higher benchmark value when the same calendar year is used to determine the ACO's historical benchmark, and in calculating adjustments to the rebased benchmark based on regional FFS expenditures. Likewise, a decrease in expenditures for a particular calendar year would result in a lower benchmark value when the same calendar year is used to determine the ACO's historical benchmark.

While considering options for adjusting ACOs' historical benchmarks to account for disasters occurring during a benchmark year, we considered the effect that the proposed regional factors, that are discussed in section II.D.3 might have on the historical benchmarks for ACOs located in a disaster area. After review, we believe that when regional factors are applied to an ACO's historical benchmark, the regional factors would inherently adjust for variations in expenditures from year to year, and thus would also adjust for regional variations in expenditures related to extreme and uncontrollable circumstances. For example, assume that an ACO experienced a reduction in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, also assume expenditures returned to their previously higher level in 2018 and this ACO subsequently renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset (rebased), the expenditures for 2017 (now a historical benchmark year) would be subject to a higher regional trend factor because expenditures increased back to the expected level in 2018, which would increase the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark increased even further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark. In contrast, consider an ACO that experienced an increase in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, assume expenditures returned to their previously lower level in 2018 and this ACO renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset, the expenditures for 2017 would be subject to a lower regional trend factor because expenditures decreased back to the expected level in 2018, which would decrease the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark decreased further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark.

Our expectation that the proposed regional factors that would be used to establish an ACO's historical benchmark would also adjust for variations in expenditures related to extreme and uncontrollable circumstances is supported by a preliminary analysis of data for areas that were affected by the disasters that occurred in performance year 2017. Our analysis of the data showed that, as a result of the disasters in these areas, expenditure trends for the performance year appeared below projections. For these areas, the expenditures began to increase after the disaster incident period ended, but expenditures were still below expectations for the year. Based on the expenditure trends beginning to return to expected levels after the disaster period, it would be reasonable to expect that expenditures would continue to increase to expected levels in 2018. This difference between the lower than expected levels of expenditures in 2017 and a return to expected expenditures in 2018, would result in a higher regional trend factor being applied to 2017 expenditures when they are used to determine an ACO's historical benchmark.

In considering whether it might be necessary to make an additional adjustment to ACOs' historical benchmarks to account for expenditure variations related to extreme and uncontrollable circumstances, we considered an approach where we would adjust the historical benchmark by reducing the weight of expenditures for beneficiaries who resided in a disaster area during a disaster period and placing a correspondingly larger weight on expenditures for beneficiaries residing outside the disaster area during the disaster period. Such an approach would be expected to proportionally increase the historical benchmark for ACOs that experienced a decrease in expenditures, and conversely proportionally decrease the historical benchmark for ACOs that experienced an increase in expenditures for their assigned beneficiaries who were impacted by a disaster. Under this approach, for each of the historical benchmark years, we would identify each ACO's assigned beneficiaries who had resided in a disaster area during a disaster period. The portion of expenditures for these assigned beneficiaries that was impacted by the disaster would be removed from the applicable historical benchmark year(s). The removal of these expenditures from the historical benchmark year(s) would allow the historical benchmark calculations to include only expenditures that were not impacted by the disaster. We believe this methodology for calculating benchmark expenditures would adjust for expenditure increases or decreases that may occur as a result of impacts related to a disaster.

If we were to implement such an adjustment to the historical benchmark, we believe it would be appropriate to avoid making minor historical benchmark adjustments for an ACO that was not significantly affected by a disaster by establishing a minimum threshold for the percentage of an ACO's beneficiaries located in a disaster area. Based on data from 2017, quarter 3, over 80 percent of ACOs had less than 50 percent of their assigned beneficiaries residing in disaster counties, with over 75 percent having less than 10 percent of their assigned beneficiaries residing in disaster counties. Based on this data, we believe a minimum threshold of 50 percent of assigned beneficiaries residing in disaster counties could be an appropriate threshold for the adjustment to historical benchmarks because historical benchmarks are calculated based on the ACO's entire assigned beneficiary population in each benchmark year, rather than a sample as is used for quality reporting.

However, we are concerned that this methodology for calculating an adjustment might not be as accurate as the inherent adjustment that would result from applying regional factors when resetting the benchmark and may

impact other expected expenditure variations occurring in the impacted areas. For example, if an additional disaster adjustment were to be applied, it might have unintended impacts when expenditure truncation is applied, it might inappropriately weight and not account for expected variations in expenditures between areas that were and were not impacted by the disaster, and it might compound effects that have already been offset by the regional adjustment. In addition, the expenditures, as adjusted, may not be representative of the ACO's actual performance and aggregate assigned beneficiary population during the benchmark period.

In summary, we believe the regional factors that we are proposing to apply as part of the methodology for determining an ACO's historical benchmark would reduce the expenditures in a historical benchmark year when they are greater than expected (relative to other historical benchmark years) as a result of a disaster and conversely increase expenditures in a historical benchmark year when they are below the expected amount. For these reasons, we believe that the proposal in section II.D.3 of this proposed rule to apply regional factors when determining ACOs' historical benchmarks, starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years, would be sufficient to address any changes in expenditures during an ACO's historical benchmark years as a result of extreme and uncontrollable circumstances, and an additional adjustment, such as the method discussed previously in this section would not appear to be necessary. However, we will continue to evaluate the impact of the 2017 disasters on ACOs' assigned beneficiary expenditures, and we intend to continue to consider whether it might be appropriate to make an additional adjustment to the historical benchmark to account for expenditures that may have increased or decreased in a historical benchmark year as a result of an extreme or uncontrollable circumstance.

We welcome comments on these issues, including whether it is necessary to adjust ACOs' historical benchmarks to account for extreme and uncontrollable circumstances that might occur during a benchmark year, and appropriate methods for making such benchmark adjustments. We would also note that the proposal in section II.D.3 of this proposed rule to apply regional factors to determine ACOs' historical benchmarks would apply starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years and would therefore have no effect on benchmarks for ACOs in a first agreement period starting before July 1, 2019. Accordingly, we welcome comments on whether and how an adjustment should be made for ACOs whose benchmarks do not reflect these regional factors.

We invite comments on the policies being proposed for assessing the financial and quality performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years, including the applicable quality data reporting period for the performance year, unless the reporting period is extended. We believe these policies would reduce burden and financial uncertainty for ACOs, ACO participants, and ACO providers/suppliers affected by future catastrophes, and will also align with existing Medicare policies in the Quality Payment Program. We also invite comments on any additional areas where relief may be helpful or other ways to mitigate unexpected issues that may arise in the event of an extreme and uncontrollable circumstance.

5. Program Data and Quality Measures

In this section, we solicit comments on possible changes to the quality measure set and modifications to program data shared with ACOs to support CMS's Meaningful Measures initiative and respond to the nation's opioid misuse epidemic. As part of the Meaningful Measures initiative, we are focusing the agency's efforts on updating quality measures, reducing regulatory burden, and promoting innovation (see CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html).* Under the Meaningful Measures initiative, we are working towards assessing performance on only those core issues that are most vital to providing high-quality care and improving patient outcomes, with an emphasis on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. When we developed the quality reporting requirements under the Shared Savings Program, we considered the quality reporting requirements under other initiatives, such as the Physician Quality Reporting System (PQRS) and Million Hearts Initiative, and consulted with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden.

Since the Shared Savings Program was first established in 2012, we have not only updated the quality measure set to reduce reporting burden, but also to focus on more meaningful outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2017 PFS Final Rule (81 FR 80484 through 80489) to adopt the ACO measure recommendations made by the Core Quality Measures Collaborative, a multi-stakeholder group with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. Currently, more than half of the 31 Shared Savings Program quality measures are outcome-based, including:

- Patient-reported outcome measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience;
- Outcome measures supporting care coordination and effective communication, such as unplanned admission and readmission measures; and
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes and control of high blood pressure.

It is important that the quality reporting requirements under the Shared Savings Program align with the reporting requirements under other Medicare initiatives and those used by other payers in order to minimize the need for Shared Savings Program participants to devote excessive resources to understanding differences in measure specifications or engaging in duplicative reporting. We seek comment, including recommendations and input on meaningful measures, on how we may be able to further advance the quality measure set for ACO reporting, consistent with the requirement under section 1899(b)(3)(C) of the Act that the Secretary seek to improve the quality of care furnished by ACOs by specifying higher standards, new measures, or both.

One particular area of focus by the Department of Health and Human Services is the opioid misuse epidemic. The Centers for Disease Control and Prevention (CDC) reports that the number of people experiencing chronic pain lasting more than 3 months is estimated to include 11 percent of the adult population. According to a 2016

CDC publication, 2 million Americans had opioid use disorder (OUD) associated with prescription opioids in 2014 (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*). Since the implementation of Medicare Part D in 2006 to cover prescription medications, the Medicare program has become the largest payer for prescription opioids in the United States (Zhou et al, 2016; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4955937/*). Safe and effective opioid prescribing for older adults is of particular importance because misuse and abuse of opioids can lead to increased adverse events in this population (for example, increased falls, fractures, hospitalization, ER visits, mortality), especially given the high prevalence of polypharmacy in the elderly. Polypharmacy is the simultaneous use of multiple drugs by a single patient, for one or more conditions, which increases the risk of adverse events. For example, a study by MedPAC found that some beneficiaries who use opioids fill more than 50 prescriptions among 10 drug classes annually (*http://www.medpac.gov/docs/default-source/reports/chapter-5-polypharmacy-and-opioid-use-among-medicare-part-d-enrollees-june-2015-report-.pdf?sfvrsn=0,* MedPAC, 2015).

As part of a multifaceted response to address the growing problem of overuse and abuse of opioids in the Part D program, CMS adopted a policy in 2013 requiring Medicare Part D plan sponsors to implement enhanced drug utilization review. Between 2011 through 2014, there was a 26 percent decrease or 7,500 fewer Medicare Part D beneficiaries identified as potential opioid over-utilizers which may be due, at least in part, to these new policies. On January 5, 2017, CMS released its Opioid Misuse Strategy. This document outlines CMS's strategy and the array of actions underway to address the national opioid misuse epidemic and can be found at *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.*

We aim to align our policies under the Shared Savings Program with the priorities identified in the Opioid Misuse Strategy and to help ACOs and their participating providers and suppliers in responding to and managing opioid use, and are therefore considering several actions to improve alignment. Specifically, we are considering what information regarding opioid use, including information developed using aggregate Medicare Part D data, could be shared with ACOs. We are also considering the addition of one or more measures specific to opioid use to the ACO quality measures set. The potential benefits of such policies would be to focus ACOs on the appropriate use of opioids for their assigned beneficiaries and support their opioid misuse prevention efforts.

First, we are considering what information, including what aggregated Medicare Part D data, could be useful to ACOs to combat opioid misuse in their assigned beneficiary population. We recognize the importance of available and emerging resources regarding the opioid epidemic at the federal, state, and local level, and intend to work with our federal partners to make relevant resources available in a timely manner to support ACOs' goals and activities. We will also continue to share information with ACOs highlighting Federal opioid initiatives, such as the CDC Guideline for Prescribing Opioids for Chronic Pain (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*), which reviews the CDC's recommended approach to opioid prescribing, and the Surgeon General's report on Substance Use and Addiction, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, (*https://addiction.surgeongeneral.gov/*) which focuses on educating and mobilizing prescribers to take action to end the opioid epidemic by improving prescribing practices, informing patients about the risks of and resources for opioid addiction, and encouraging health care professionals to take a pledge to end the opioid crisis. We will also continue to highlight information about the opioid crisis and innovations for opioid treatment and prevention strategies in ACO learning system webinars. These webinars provide the forum for peer-to-peer sharing, such as the webinar held last year on Community Approaches to Preventing Opioid-Related Overdoses and Deaths, which included speakers from State and community organizations.

Although we recognize that not all beneficiaries assigned to Shared Savings Program ACOs have Part D coverage, we believe a sufficient number do have Part D coverage to make aggregate Part D data regarding opioid use helpful for the ACOs. As an example, we have found the following information for performance year 2016:

- Approximately 70 percent of beneficiaries assigned to ACOs participating in the Shared Savings Program had continuous Part D coverage.
- For assigned beneficiaries with continuous Part D enrollment, almost 37 percent had at least one opioid prescription. This percentage ranged from 10.6 percent to 58.3 percent across ACOs.
- The mean number of opioid medications filled per assigned beneficiary (with continuous Part D coverage) varied across ACOs, ranging from 0.3 to 4.5 prescriptions filled, with an average of 2.1 prescriptions filled.
- The number of opioid prescriptions filled for each assigned beneficiary with at least one opioid prescription filled varied across ACOs and ranged from 2.6 to 8.4 prescriptions, with an average of 5.5 opioid prescriptions filled.

ACOs currently receive as part of the monthly claims and claims line feed data Part D prescription drug event (PDE) data on prescribed opioids for their assigned beneficiaries who have not opted out of data sharing. We encourage ACOs to use this beneficiary-level data in their care delivery practices.

We also seek suggestions for other types of aggregate data related to opioid use that could be added for informational purposes to the aggregate quarterly and annual reports CMS provides to ACOs. The aim would be for ACOs to utilize this additional information to improve population health management for assigned beneficiaries, including prevention, identifying anomalies, and coordinating care. The type of aggregate data should be highly relevant for a population-based program at the national level and have demonstrated value in quality improvement initiatives. We are particularly interested in high impact aggregate data that would reflect gaps in quality of care, patient safety, multiple aspects of care, and drivers of cost. We aim to provide aggregate data that have validity for longitudinal analysis to enable both ACOs and the Shared Savings Program to trend performance across time and monitor for changes. Aggregate data on both processes and outcomes are appropriate, provided that the data are readily available. Types of aggregate data that we have begun to consider, based on the information available from prescription drug event records for assigned beneficiaries enrolled in Medicare Part D, include filled prescriptions for opioids (percentage of the ACO's assigned beneficiaries with any opioid prescription, number of opioid prescriptions per opioid user), number of beneficiaries with a concurrent prescription of opioids and benzodiazepines; and number of beneficiaries with opioid prescriptions above a certain daily Morphine Equivalent Dosage threshold. Second, we are seeking comments on measures

that can be added to the quality measure set for the purpose of addressing the opioid epidemic and addiction, more generally. We seek comment on measures related to various aspects of opioid use, such as prevention, pain management, or opioid use disorder treatment, and on measures related to addiction. In particular, we are considering the following relevant NQF-endorsed measures, with emphasis on Medicare individuals with Part D coverage who are 18 years or older without cancer or enrolled in hospice:

- NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer.
- NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
- NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

In addition, we seek input on potential measures for which data are readily available, such as measures that might be appropriately calculated using Part D data, and that capture performance on outcomes of appropriate opioid management. Comments on measures that are not already NQF endorsed should include descriptions of reliability, validity, benchmarking, the population in which the measure was tested, along with the data source that was used, and information on whether the measure is endorsed and by what organization. We recognize that measures of the various aspects of opioid use may involve concepts related to integrated, coordinated, and collaborative care, including as applicable for co-occurring and/or chronic conditions, as well as measures that reflect the impact of interventions on patient outcomes, including direct and indirect patient outcome measures. We also seek comment on opioid-related measures that would support effective measurement alignment of substance use disorders across programs, settings, and varying interventions.

6. Promoting Interoperability

Consistent with the call in the 21st Century Cures Act for interoperable access, exchange, and use of health information, the final rule entitled, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (2015 Edition final rule) (80 FR 62601) under 45 CFR part 170 [24] focuses on the 2015 Edition of health IT certification criteria that support patient care, patient participation in care delivery, and electronic exchange of interoperable health information. The 2015 Edition final rule, which was issued on October 16, 2015, is expected to improve interoperability by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information and to facilitate the accessibility and exchange of data by including enhanced data export, transitions of care, and application programming interface capabilities. These policies are relevant to assessing the use of CEHRT under the Quality Payment Program and other value based payment initiatives.

Under the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies. Consistent with the statute, ACOs participating in the Shared Savings Program are required to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers and to have a written plan to encourage and promote the use of enabling technologies for improving care coordination, including the use of electronic health records and electronic exchange of health information (§ 425.112(b)(4)). Additionally, since the inception of the program in 2012, CMS has assessed the level of CEHRT use by certain clinicians in the ACO as a double-weighted quality measure (Use of Certified EHR Technology, ACO–11) as part of the quality reporting requirements for each performance year. For the 2018 performance year, we will use data derived from the Quality Payment Program's Promoting Interoperability performance category to calculate the percentage of eligible clinicians participating in an ACO who successfully meet the Advancing Care Information Performance Category Base Score for purposes of ACO–11. Because the measure is used in determining an ACO's quality score and for determining shared savings or losses under the Shared Savings Program, all eligible clinicians participating in Shared Savings Program ACOs must submit data for the Quality Payment Program's Advancing Care Information performance category, including those eligible clinicians who are participating in Shared Savings Program tracks that have been designated as Advanced APMs and who have met the QP threshold or are otherwise not subject to the MIPS reporting requirements.

In contrast, some alternative payment models tested by the Innovation Center, require all participants to use CEHRT even though certain tracks within those Models do not meet the financial risk standard for designation as Advanced APMs, such as the Oncology Care Model (one-sided risk arrangement track) and the Comprehensive End-Stage Renal Disease Care (CEC) Model (non-LDO one-sided risk arrangement track).[25] The primary rationale for this requirement is to promote CEHRT use by eligible clinicians and organizations participating in APMs by requiring them to demonstrate a strong commitment to the exchange of health information, regardless of whether they are participating in an APM that meets the criteria to be designated as an Advanced APM. Additionally, under the Quality Payment Program, an incentive payment will be made to certain Qualifying APM Participants (QPs) participating in Advanced APMs. Beginning in 2017, an eligible clinician can become a QP for the year by participating sufficiently in an Advanced APM during the QP performance period. Eligible clinicians who are QPs for a year receive a lump sum APM incentive payment for payment years from 2019 through 2024, and are excluded from the MIPS reporting requirements for the performance year and the MIPS payment adjustment for the payment year. In the CY 2017 Quality Payment Program final rule (81 FR 77408) we finalized the criteria that define an

[24] For more information, see: *https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf.*

[25] See list of Alternative Payment Models in the Quality Payment Program as of February 2018, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Comprehensive-List-of-APMs.pdf.*

Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that, among other criteria, requires its participants to use CEHRT. In the CY 2017 Quality Payment Program final rule, we established that Advanced APMs meet this requirement if the APM either (1) requires at least 50 percent of eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers; or (2) for the Shared Savings Program, applies a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity (§ 414.1415(a)(1)(i) and (ii)). In the CY 2017 PFS final rule, we updated the title and specifications of EHR quality measure (ACO–11) to align with the Quality Payment Program criterion on CEHRT use in order to ensure that certain tracks under the Shared Savings Program could meet the criteria to be Advanced APMs. Specifically, we revised the ACO–11 measure to assess ACOs on the degree of CEHRT use by eligible clinicians participating in the ACO in order to align with the Quality Payment Program. Performance on the measure is determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Performance Category Base Score.

In light of our additional experience with the Shared Savings Program, our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center, as previously noted, we believe it would be appropriate to amend our regulations related to CEHRT use and the eligibility requirements for ACOs to participate in the Shared Savings Program. Specifically, we propose to add a requirement that all ACOs demonstrate a specified level of CEHRT use in order to be eligible to participate in the Shared Savings Program. Additionally, we propose that, as a condition of participation in a track, or a payment model within a track, that meets the financial risk standard to be an Advanced APM, ACOs must certify that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold required for Advanced APMs as defined under the Quality Payment Program (§ 414.1415(a)(1)(i)). In conjunction with this proposed new eligibility requirement, we propose to retire the EHR quality measure (ACO–11) related to CEHRT use, thereby reducing reporting burden, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years. In addition, consistent with our proposal to align with the Advanced APM criterion on use of CEHRT, we propose to apply the definition of CEHRT under the Quality Payment Program (§ 414.1305), including any subsequent updates to this definition, for purposes of the Shared Savings Program.

First, we are proposing that for performance years starting on January 1, 2019, and subsequent performance years ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must attest and certify upon application to participate in the Shared Savings Program, and subsequently, as part of the annual certification process, that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. ACOs would be required to submit this certification in the form and manner specified by CMS.

This proposed requirement aligns with the requirements regarding CEHRT use in many alternative payment models being tested by the Innovation Center (as previously noted). Additionally, we note that at the time of application, ACOs must have a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§ 425.112(b)(4)(i)(C)). Over the years, successful ACOs have impressed upon us the importance of ''hitting the ground running'' on the first day of their participation in the Shared Savings Program, rather than spending the first year or two developing their care processes. We believe that requiring ACOs that are entering a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM to certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT aligns with existing requirements under the Shared Saving Program and many Innovation Center alternative payment models and encourages participation by organizations that are more likely to meet the program goals. In addition, we believe such a requirement would also promote greater emphasis on the importance of CEHRT use for care coordination. Finally, we note that in the CY 2019 PFS proposed rule, we proposed to increase the threshold of CEHRT use required for APMs to meet criteria for designation as Advanced APMs under the Quality Payment Program to 75 percent (see 83 FR 35990). Given the proposals for updates and modifications to the Shared Savings Program tracks found elsewhere in this proposed rule, as well as the proposals under the Quality Payment Program, we believe it is important that only those ACOs that are likely to be able to meet or exceed the threshold designated for Advanced APMs should be eligible to enter and continue their participation in the Shared Savings Program. Because of this, and also our desire to align requirements as explained in more detail later in this section, we also considered whether to propose to require all Shared Savings Program ACOs, including ACOs in tracks or payment models within tracks that would not meet financial criteria to be designated as Advanced APMs, to meet the 75 percent threshold proposed under the Quality Payment Program.

We propose changes to the regulations at § 425.204(c) (to establish the new application requirement) and § 425.302(a)(3)(iii) (to establish the new annual certification requirement). We also propose to add a new provision at § 425.506(f)(1) to indicate that for performance years starting on January 1, 2019, and subsequent performance years, all ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of their eligible clinicians use CEHRT to document and communicate clinical care to their patients or other health care providers. We note that this proposal, if finalized, would not affect the previously-finalized provisions for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. In other words, MIPS eligible clinicians who are participating in ACOs would continue to report as usual on the Promoting Interoperability performance category. We welcome comment on these proposed changes. We also seek comment on whether the percentage of CEHRT use should be set at a level higher than 50 percent for ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM given

that average ACO performance on the Use of Certified EHR Technology measure (ACO–11) has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements,[26] suggesting that a higher threshold may be warranted now or in the future. Additionally, a higher threshold percentage (such as 75 percent) would align with the proposed changes to the CEHRT use requirement under the Quality Payment Program in the CY 2019 PFS proposed rule.

Further, for ACOs in tracks or models that meet the financial risk standard to be Advanced APMs under the Quality Payment Program, we propose to align the proposed CEHRT use threshold with the criterion on use of CEHRT established for Advanced APMs under the Quality Payment Program. Although we believe it would be ideal for all ACOs to meet the same CEHRT thresholds to be eligible for participation in the Shared Savings Program, we recognize that there may be reasons why it may be desirable for ACOs in tracks or payment models within a track that do not meet the financial risk standard for Advanced APMs to have a different threshold requirement for CEHRT use than more sophisticated ACOs that are participating in tracks or payment models that qualify as Advanced APMs under the Quality Payment Program. For example, we note that in order for an APM to meet the criteria to be an Advanced APM under the Quality Payment Program, it must currently require at least 50 percent of eligible clinicians in each participating APM entity to use CEHRT to document and communicate clinical care to their patients or other health care providers (in addition to certain other criteria). However, we have proposed to increase this threshold level under the Quality Payment Program to 75 percent of eligible clinicians in each participating Advanced APM entity, as part of the CY 2019 PFS proposed rule, as previously noted. Therefore, for performance years starting on January 1, 2019, and subsequent performance years for Shared Savings Program tracks (or payment models within tracks) that meet the financial risk standard to be an Advanced APM, we propose to align the CEHRT requirement with the Quality Payment Program Advanced APM CEHRT use criterion at § 414.1415(a)(1)(i). Specifically, we propose that such ACOs would be required to certify that they meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at § 414.1415(a)(1)(i). We believe that requiring these ACOs to meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs will ensure alignment of eligibility requirements across all Shared Savings Program ACOs, while also ensuring that if the CEHRT use criterion for Advanced APMs is higher than 50 percent, those Shared Savings Program tracks (or payment models within a track) that meet the financial risk standard to be an Advanced APM would also meet the CEHRT threshold established under the Quality Payment Program. We anticipate that for performance years starting on January 1, 2019, the tracks (or payment models within tracks) that would be required to meet the CEHRT threshold designated at § 414.1415(a)(1)(i) would include Track 2, Track 3, and the Track 1+ Model, and for performance years starting on July 1, 2019, they would include the BASIC track, Level E, and the ENHANCED track. ACOs in these tracks (or a payment model within such a track) would be required to attest and certify that the percentage of the eligible clinicians in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the level of CEHRT use specified under the Quality Payment Program regulation at § 414.1415(a)(1)(i). Although this proposal may cause Shared Savings Program ACOs in different tracks (or different payment models within the same track) to be held to different requirements regarding CEHRT use, we believe it is appropriate to ensure not only that ACOs that are still new to participation in the Shared Savings Program are not excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT, but also that eligible clinicians in ACOs further along the risk continuum have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program.

We propose to add a new provision to the regulations at § 425.506(f)(2) to establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or a payment model within a track that meets the financial risk standard to be an Advanced APM under the Quality Payment Program. These ACOs would be required to certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold for CEHRT use by Advanced APMs at § 414.1415(a)(1)(i). We seek comment on this proposal. We also seek comment on whether we should apply the same standard regarding CEHRT use across all Shared Savings Program ACOs, including ACOs participating in tracks or payment models within tracks that do not meet the financial risk standard to be designated as Advanced APMs, specifically Track 1 and the proposed BASIC track, Levels A through D, or maintain the proposed 50 percent requirement for these ACOs as they gain experience on the glide path to performance-based risk.

As a part of these proposals to require ACOs to certify that a specified percentage of their eligible clinicians use CEHRT, CMS reserves the right to monitor, assess, and/or audit an ACO's compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§ 425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§ 425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds. Additionally, we propose to adopt for purposes of the Shared Savings Program the same definition of ''CEHRT'' as is used under the Quality Payment Program. We propose to amend § 425.20 to incorporate a definition of CEHRT consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition. Consistent with this proposal and to ensure alignment with the requirements regarding CEHRT use under the Quality Payment Program, we also propose to amend § 425.20 to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program.

Additionally, if the proposal to introduce a specified threshold of CEHRT use as an eligibility requirement for participation in the Shared Savings

[26] This estimate is based on calculations of primary care physician CEHRT use prior to the changes made to ACO–11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.

Program is finalized, we believe this new requirement should replace the current ACO quality measure that assesses the Use of Certified EHR Technology (ACO–11). The proposed new eligibility requirement, which would be assessed through the application process and annual certification, would help to meet the goals of the program and align with the approach used in other MIPS APMs. Moreover, the proposed new requirement would render reporting on the Use of Certified EHR Technology quality measure unnecessary in order for otherwise eligible tracks (and payments models within tracks) to meet the Advanced APM criterion regarding required use of CEHRT under § 414.1415(a)(1)(i). As a result, continuing to require ACOs to report on this measure would introduce undue reporting burden on eligible clinicians that meet the QP threshold and would otherwise not be required to report the Promoting Interoperability performance category for purposes of the Quality Payment Program. Therefore, we are proposing to remove the Use of Certified EHR Technology measure (ACO–11) from the Shared Savings Program quality measure set, effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We propose corresponding changes to the regulation at § 425.506. As previously noted, the removal of the Use of Certified EHR Technology measure (ACO–11) from the quality measure set used under the Shared Savings Program, if finalized, would not affect policies under MIPS for reporting on the Promoting Interoperability performance category and scoring under the APM Scoring Standard for MIPS eligible clinicians in MIPS APMs. In other words, eligible clinicians subject to MIPS (such as eligible clinicians in BASIC track, Levels A through D, Track 1, and other MIPS eligible clinicians who are required to report on the Promoting Interoperability performance category for purposes of the Quality Payment Program) would continue to report as usual on the Promoting Interoperability performance category. However, data reported for purposes of the Promoting Interoperability performance category under MIPS would not be used to assess the ACO's quality performance under the Shared Savings Program. We welcome public comment on the proposal to remove the quality measure on Use of Certified EHR Technology (ACO–11) from the Medicare Shared Savings Program measure set, effective for quality reporting for performance years starting on January 1, 2019, and subsequent years.

Finally, as discussed previously in this section, in the CY 2017 Quality Payment Program final rule, CMS finalized a separate Advanced APM CEHRT use criterion that applies for the Shared Savings Program at § 414.1415(a)(1)(ii). To meet the Advanced APM CEHRT use criterion under the Shared Savings Program, a penalty or reward must be applied to an APM Entity based upon the degree of CEHRT use among its eligible clinicians. We believed that this alternative criterion was appropriate to assess the Advanced APM CEHRT use requirement under the Shared Savings Program because at the time a specific level of CEHRT use was not required for participation in the program (81 FR 77412).

We now believe that that our proposal to impose specific CEHRT use requirements on ACOs participating in the Shared Savings Program would eliminate the need for the separate CEHRT use criterion applicable to the Shared Savings Program APMs found at § 414.1415(a)(1)(ii). If the previously described proposals are finalized, ACOs seeking to participate in a Shared Savings Program track (or payment model within a track) that meets the financial risk standard to be an Advanced APM would be required to demonstrate that the percentage of eligible clinicians in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the percentage specified in the CEHRT use criterion for Advanced APMs at § 414.1415(a)(1)(i). As a result, a separate CEHRT use criterion for APMs under the Shared Savings Program would no longer be necessary.

We therefore propose to revise the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019. We seek comment on this proposal.

7. Coordination of Pharmacy Care for ACO Beneficiaries

Medicare ACOs and other stakeholders have indicated an interest in collaborating to enhance the coordination of pharmacy care for Medicare FFS beneficiaries to reduce the risk of adverse events and improve medication adherence. For example, areas where ACOs and the sponsors of stand-alone Part D PDPs might collaborate to enhance pharmacy care coordination include establishing innovative approaches to increase clinician formulary compliance (when clinically appropriate) and medication compliance; providing pharmacy counseling services from pharmacists; and implementing medication therapy management. Part D sponsors may be able to play a greater role in coordinating the care of their enrolled Medicare FFS beneficiaries and having greater accountability for their overall health outcomes, such as for beneficiaries with chronic diseases where treatment and outcome are highly dependent on appropriate medication use and adherence. Increased collaboration between ACOs and Part D sponsors may facilitate better and more affordable drug treatment options for beneficiaries by encouraging the use of generic prescription medications, where clinically appropriate, or reducing medical errors through better coordination between providers and Part D sponsors.

We believe that Medicare ACOs and Part D sponsors may be able to enter into appropriate business arrangements to support improved pharmacy care coordination, provided such arrangements comply with all applicable laws and regulations. However, challenges may exist in forming these arrangements. Under the Pioneer ACO Model, an average of 54 percent of the beneficiaries assigned to Pioneer ACOs in 2012 were also enrolled in a PDP in that year, with the median ACO having at most only 13 percent of its assigned beneficiaries enrolled in a plan offered by the same PDP parent organization. For performance year 2016, we found that approximately 70 percent of the beneficiaries assigned to Shared Savings Program ACOs had continuous Part D coverage.

We believe timely access to data could improve pharmacy care coordination. Although CMS already provides Medicare ACOs with certain Part D prescription drug event data, it may be useful for both Medicare ACOs and Part D sponsors to share certain clinical data and pharmacy data with each other to support coordination of pharmacy care. Any data sharing arrangements between ACOs and Part D sponsors should comply with all applicable legal requirements regarding the privacy and confidentiality of such data, including the Health Insurance Portability and Accountability Act (HIPAA).

We seek comment on how Medicare ACOs, and specifically Shared Savings Program ACOs, and Part D sponsors

could work together and be encouraged to improve the coordination of pharmacy care for Medicare FFS beneficiaries to achieve better health outcomes, better health care, and lower per-capita expenditures for Medicare beneficiaries. In addition, we seek comment on what kind of support would be useful for Medicare ACOs and Part D sponsors in establishing new, innovative business arrangements to promote pharmacy care coordination to improve overall health outcomes for Medicare beneficiaries. We also seek comment on issues related to how CMS, Medicare ACOs and Part D sponsors might structure the financial terms of these arrangements to reward Part D sponsors' contributions towards achieving program goals, including improving the beneficiary's coordination of care. Lastly, we seek comment on whether ACOs are currently partnering with Part D sponsors, if there are any barriers to developing these relationships (including, but not limited to, data and information sharing), and if there are any recommendations for how CMS can assist, as appropriate, with reducing barriers and enabling more robust data sharing.

F. Applicability of Proposed Policies to Track 1+ Model ACOs

1. Background

The Track 1+ Model was established under the Innovation Center's authority at section 1115A of the Act, to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. We have previously noted that 55 Shared Savings Program Track 1 ACOs entered into the Track 1+ Model beginning January 1, 2018. This includes 35 ACOs that entered the model within their current agreement period (to complete the remainder of their agreement period under the Model) and 20 ACOs that entered a 3-year agreement in the Model.

To enter the model, ACOs approved to participate are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement. See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.* Track 1+ Model ACOs are also required to have been approved to participate in the Shared Savings Program (Track 1) and to have executed a Shared Savings Program Participation Agreement. As indicated in the Track 1+ Model Participation Agreement, in accordance with its authority under section 1115A(d)(1) of the Act, CMS has waived certain provisions of law that otherwise would be applicable to ACOs participating in Track 1 of the Shared Savings Program, as necessary for purposes of testing the Track 1+ Model, and established alternative requirements for the ACOs participating in the Track 1+ Model.

Unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the Shared Savings Program under 42 CFR part 425 continue to apply. Consistent with § 425.212, Track 1+ Model ACOs are subject to all applicable regulatory changes, including but not limited to, changes to the regulatory provisions referenced within the Track 1+ Model Participation Agreement that become effective during the term of the ACO's Shared Savings Program Participation Agreement and Track 1+ Model Participation Agreement, unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement. We note that the terms of the Track 1+ Model Participation Agreement permit the parties (CMS and the ACO) to amend the agreement at any time by mutual written agreement.

2. Unavailability of Application Cycles for Entry Into the Track 1+ Model in 2019 and 2020

An ACO's opportunity to join the Track 1+ Model aligns with the Shared Savings Program's application cycle. The original design of the Track 1+ Model included 3 application cycles for ACOs to apply to enter or renew their participation in the Track 1+ Model for an agreement period start date of 2018, 2019, or 2020. The 2018 application cycle is closed, and as discussed elsewhere in this proposed rule, 55 ACOs began participating in the Track 1+ Model on January 1, 2018. As discussed in section II.A.7 of this proposed rule, we are not offering an application cycle for a January 1, 2019 start date for new agreement periods under the Shared Savings Program. Therefore, we would similarly not offer a start date of January 1, 2019, for participation in the Track 1+ Model.

In addition, we have also re-evaluated the need for continuing the Track 1+ Model as a participation option for 2019 and 2020 in light of the proposal to offer the BASIC track (including a glide path for eligible ACOs) as a participation option beginning in 2019. Like the Track 1+ Model, the BASIC track would offer relatively lower levels of risk and potential reward than Track 2 and the ENHANCED track. The BASIC track's glide path would allow the flexibility for eligible ACOs to enter a one-sided model and to automatically progress through levels of risk and reward that end at a comparable level of risk and reward (Level E) as offered in the Track 1+ Model and to also qualify as participating in an Advanced APM. ACOs in the glide path could also elect to more quickly enter higher levels of risk and reward within the BASIC track. If the proposed approach to adding the BASIC track is finalized and made available for agreement periods beginning in 2019 and subsequent years, we would discontinue future application cycles for the Track 1+ Model. In that case, the Track 1+ Model would not accept new model participants for start dates of July 1, 2019, or January 1, 2020, or in subsequent years.

Existing Track 1+ Model ACOs would be able to complete the remainder of their current agreement period in the model, or terminate their current participation agreements (for the Track 1+ Model and the Shared Savings Program) and apply to enter a new Shared Savings Program agreement period under either the BASIC track (Level E) or the ENHANCED track, depending upon whether the ACO is low revenue or high revenue (as described in section II.A.5 of this proposed rule). Additionally, as discussed in section II.A.7.c.1 of this proposed rule, ACOs would not have the opportunity to apply to use a SNF 3-day rule waiver starting on January 1, 2019, under our decision to forgo an annual application cycle for a January 1, 2019 start date in the Shared Savings Program and the proposal that the next available application cycle would occur in advance of a July 1, 2019 start date in the Shared Savings Program. An exception to the January 1 start date for use of a SNF 3-day rule waiver would similarly be made to allow for a July 1, 2019 start date for eligible Track 1+ Model ACOs that apply for and are approved to use a SNF 3-day rule waiver.

In making this decision to discontinue future application cycles for the Track 1+ Model, we considered the high level of participation in the Track 1+ Model in its first performance year. This high level of interest in the model indicates a positive response to its design, and therefore we believe we have met an important goal of testing the Track 1+ Model. As we previously described in section II.A.1 of this proposed rule, the availability of the Track 1+ Model

significantly increased the number of ACOs participating under a two-sided risk model in connection with their participation in the Shared Savings Program, with over half of the 101 Shared Savings Program ACOs that have elected to take on performance-based risk opting to participate in the Track 1+ Model starting in 2018, the Model's first year. We will evaluate the quality and financial performance of Track 1+ Model ACOs and consider the results of this evaluation in the development of future policies for the Shared Saving Program.

Further, as discussed in section II.A of this proposed rule, we have incorporated lessons learned from our initial experience with the Track 1+ Model into the design of the proposed BASIC track. This includes offering a payment model within the BASIC track (Level E) that includes the same level of risk and potential reward as available under the Track 1+ Model. We have also proposed a repayment mechanism estimation methodology based on our experience with the Track 1+ Model, to allow for potentially lower, and therefore less burdensome, repayment mechanism amounts for ACOs with relatively lower estimated ACO participant Medicare FFS revenue compared to estimated benchmark expenditures for their assigned Medicare FFS beneficiary population. We believe offering both the BASIC track and the Track 1+ Model would create unnecessary redundancy in participation options within CMS's Medicare ACO initiatives.

3. Applicability of Proposed Policies to Track 1+ Model ACOs Through Revised Program Regulations or Revisions to Track 1+ Model Participation Agreements

We believe a comprehensive discussion of the applicability of the proposed policies to Track 1+ Model ACOs would allow these ACOs to better prepare for their future years of participation in the program and the Track 1+ Model. There are two ways in which the proposed policies would become applicable to Track 1+ Model ACOs: (1) Through revisions to existing regulations that currently apply to Track 1+ Model ACOs, and (2) through revisions to the ACO's Track 1+ Model Participation Agreement.

Unless specified otherwise, the proposed changes to the program's regulations that are applicable to Shared Savings Program ACOs within a current agreement period would apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or Track 3 have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, any proposed changes to those regulations would also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or Track 3. For example, the following proposed policies would apply to Track 1+ Model ACOs, if finalized:

- Changes to the repayment mechanism requirements (other than the proposed provisions regarding calculation of the repayment mechanism amount at § 425.204(f)(4)), which would be applicable with the effective date of the final rule (section II.A.6.c). We believe these proposed requirements are similar to the requirements under which Track 1+ Model ACOs established their repayment mechanisms, such that no revision to these arrangements would be required, in the event the proposed policies are finalized. Further, consistent with the proposed changes to the repayment mechanism requirements, we note that Track 1+ Model ACOs that seek to renew their Shared Savings Program agreement would be permitted to use their existing repayment mechanism arrangement to support their continued participation in the Shared Savings Program under a two-sided model in their next agreement period, provided that the amount and duration of the repayment mechanism arrangement are updated as specified by CMS.
- The requirement to notify beneficiaries regarding voluntary alignment and to provide a standardized written notice at the first primary care visit of each performance year (section II.C.3.a.2). If finalized, the proposed policy would be applicable for the performance year beginning on July 1, 2019, and subsequent performance years.
- Revisions to voluntary alignment policies (section II.E.2). If finalized, the proposed policies would be applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Revisions to the definition of primary care services used in beneficiary assignment (section II.E.3.b). If finalized, the proposed policy would be applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Discontinuation of quality measure ACO–11; requirement to attest at the time of application and as part of the annual certification that a specified percentage of the ACO's eligible clinicians use CEHRT (section II.E.6). If finalized, the proposed policy would be applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

We would also seek to apply the following proposed policies to Track 1+ Model ACOs, although to do so would require an amendment to the Track 1+ Model Participation Agreement executed by CMS and the ACO:

- Monitoring for and consequences of poor financial performance (section II.A.5.d).
- Revising the MSR/MLR to address small population sizes (section II.A.6.b.3).
- Payment consequences of early termination for ACOs under performance-based risk (section II.A.6.d).
- Annual certification that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold established under § 414.1415(a)(1)(i) (section II.E.6). This certification would be required to ensure the Track 1+ Model continues to meet the CEHRT criterion for qualification as an Advanced APM for purposes of the Quality Payment Program.
- For ACOs that started a first or second Shared Savings Program participation agreement on January 1, 2016, and entered the Track 1+ Model on January 1, 2018, and that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019 (as described in section II.A.7 of this proposed rule):

++ Consistent with the policy proposed in section II.A.7.c.3 and § 425.204(f)(6), the ACO would be required to extend its repayment mechanism so that it ends 24 months after the end of the agreement period (June 30, 2021).

++ We would determine performance for the 6-month performance year from January 1, 2019 through June 30, 2019, according to the approach specified in a proposed new section of the regulations at § 425.609(b), applying the financial methodology for calculating shared losses specified in the ACO's Track 1+ Model Participation Agreement.

++ We would continue to share aggregate report data with the ACO for the entire calendar year 2019, consistent with the proposed approach described in section II.A.7.c.9, and the terms of the

ACO's Track 1+ Model Participation Agreement.

- Extreme and uncontrollable circumstances policies for determining shared losses for performance years 2018 and subsequent years, consistent with the policies specified in §§ 425.610(i) (section II.E.4) and 425.609(d) (section II.A.7.c.5) for ACOs that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019.
- Certain requirements related to the use of telehealth services beginning on January 1, 2020, as provided under section 1899(l) of the Act (section II.B.2.b.2). As previously described, the Bipartisan Budget Act of 2018 provides for coverage of certain telehealth services furnished by physicians and practitioners in ACOs participating in a model tested or expanded under section 1115A of the Act that operate under a two-sided model and for which beneficiaries are assigned to the ACO using a prospective assignment method. ACOs participating in the Track 1+ Model meet these criteria. We believe it would be appropriate to apply the same requirements under the Track 1+ Model with respect to the use of telehealth services that would apply to other Shared Savings Program ACOs that are applicable ACOs for purposes of section 1899(l) of the Act. This would ensure consistency across program operations, payments, and beneficiary protection requirements for Track 1+ Model ACOs and other Shared Savings Program ACOs with respect to the use of telehealth services.

We seek comment on these considerations, and any other issues that we may not have discussed related to the effect of the proposed policies on ACOs that entered the Track 1+ Model beginning in 2018. We note that these ACOs will complete their participation in the Track 1+ Model by no later than December 31, 2020 (for ACOs that entered the model at the start of a 3-year agreement period), or sooner in the case of ACOs that entered the model at the start of their second or third performance year within their current 3-year agreement period.

G. Summary of Proposed Timing of Applicability

Applicability or implementation dates may vary, depending on the policy, and the timing specified in the final rule. Unless otherwise noted, the proposed changes would be effective 60 days after publication of the final rule. Table 13 lists the anticipated applicability date of key changes in this proposed rule. By indicating that a provision is applicable to a performance year (PY) or agreement period, activities related to implementation of the policy may precede the start of the performance year or agreement period.

TABLE 13—APPLICABILITY DATES OF SELECT PROVISIONS OF THE PROPOSED RULE

Preamble section	Section title/description	Applicability date
II.A.2	Availability of an additional participation option under a new BASIC track (including glide path) under an agreement period of at least 5 years; Availability of Track 3 as the ENHANCED track under an agreement period of at least 5 years.	Agreement periods starting on or after July 1, 2019.
II.A.2	Discontinuing Track 1 and Track 2	No longer available for applicants for agreement periods starting in 2019 and subsequent years.
II.A.2	Discontinuing deferred renewal option	No longer available for renewal applicants for agreement periods starting in 2019 and subsequent years.
II.A.4.b	Permitting annual election of differing levels of risk and potential reward within the BASIC track's glide path.	Performance year beginning on July 1, 2019, and subsequent years for eligible ACOs.
II.A.4.c	Permitting annual election of beneficiary assignment methodology for ACOs in BASIC track or ENHANCED track.	Performance year beginning on July 1, 2019, and subsequent years.
II.A.5.c	Evaluation criteria for determining participation options based on ACO participants' Medicare FFS revenue, ACO legal entity and ACO participant experience with performance-based risk Medicare ACO initiatives, and prior performance (if applicable).	Agreement periods starting on or after July 1, 2019.
II.A.5.d.2	Monitoring for financial performance	Performance years beginning in 2019 and subsequent years.
II.A.6.b.2	Timing of election of MSR/MLR	Agreement periods starting on or after July 1, 2019.
II.A.6.b.3	Modifying the MSR/MLR to address small population sizes	Performance years beginning in 2019 and subsequent years.
II.A.6.c.3	Annual recalculation of repayment mechanism amounts	Agreement periods starting on or after July 1, 2019.
II.A.6.d	Payment consequences of early termination for ACOs under performance-based risk.	Performance years beginning in 2019 and subsequent years.
II.A.7	Participation options for agreement periods beginning in 2019	January 1, 2019 effective date for extension of existing agreement period for a 6-month fourth performance year, if elected by ACOs that started a first or second agreement period on January 1, 2016. One-time, July 1, 2019 agreement start date; 6-month first performance year.
II.B.2.a	Availability of the SNF 3-day rule waiver for eligible ACOs under performance-based risk under either prospective assignment or preliminary prospective assignment.	July 1, 2019 and subsequent performance years, for eligible ACOs applying for, or currently approved for, a SNF 3-day rule waiver. Not available to Track 2 ACOs.
II.B.2.a	Eligible CAHs and hospitals operating under a swing-bed agreements permitted to partner with eligible ACOs as SNF affiliates.	July 1, 2019, and subsequent performance years.

TABLE 13—APPLICABILITY DATES OF SELECT PROVISIONS OF THE PROPOSED RULE—Continued

Preamble section	Section title/description	Applicability date
II.B.2.b	Telehealth services furnished under section 1899(l)	Performance year 2020 and subsequent years for services furnished by physicians and practitioners billing through the TIN of an ACO participant in an applicable ACO.
II.C.2	Implementation of approved beneficiary incentive programs	July 1, 2019, and subsequent performance years.
II.C.3.a.2	New content and timing for beneficiary notifications	Performance year beginning on July 1, 2019, and subsequent years.
II.D.2.b	Benchmarking Methodology Refinements: Risk adjustment methodology for adjusting historical benchmark each performance year.	Agreement periods starting on or after July 1, 2019.
II.D.3.b	Benchmarking Methodology Refinements: Application of regional factors to determine the benchmark for an ACO's first agreement period.	Agreement periods starting on or after July 1, 2019.
II.D.3.c	Benchmarking Methodology Refinements: Modifying the regional adjustment..	Agreement periods starting on or after July 1, 2019.
II.D.3.d	Benchmarking Methodology Refinements: Modifying the methodology for calculating growth rates used in establishing, resetting, and updating the benchmark.	Agreement periods starting on or after July 1, 2019.
II.E.2	Modifications to voluntary alignment requirements	Performance years beginning in 2019 and subsequent years.
II.E.3	Revisions to the definition of primary care services used in beneficiary assignment.	Performance years beginning in 2019 and subsequent years.
II.E.4	Extreme and uncontrollable circumstances policies for the Shared Savings Program.	Performance year 2018 and subsequent years.
II.E.6	Addition of an interoperability criterion (use of CEHRT) to determine eligibility for program participation.	Performance years beginning in 2019 and subsequent years.
II.E.6	Discontinued use of quality measure ACO–11	Performance years beginning in 2019 and subsequent years.

III. Collection of Information Requirements

As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. Consequently, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make certain payment and policy changes to the Medicare Shared Savings Program established under section 1899 of the Act. The Shared Savings Program promotes accountability for a patient population, fosters the coordination of items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

The need for the proposed policies is summarized in the statement of the rule's purpose in section I of this proposed rule and described in greater detail throughout the discussion of the proposed policies in section II of this proposed rule. As we have previously explained in this proposed rule, ACOs in two-sided models have shown significant savings to the Medicare program and are advancing quality. However, the majority of ACOs remain under a one-sided model. Some of these ACOs are generating losses (and therefore increasing Medicare spending) while receiving waivers of certain federal requirements in connection with their participation in the program. These ACOs may also be encouraging consolidation in the market place and reducing competition and choice for Medicare FFS beneficiaries. Under the proposed redesign of the Shared Savings Program, ACOs of different compositions, and levels of experience with the accountable care model could continue to participate in the program, but the proposals included in this proposed rule would put the program on a path towards achieving a more measureable move to value and achieve savings for the Medicare program, while promoting a competitive and accountable marketplace.

In summary, this proposed rule would redesign the participation options, including the payment models, available to Shared Savings Program ACOs to encourage their transition to performance-based risk. As part of this approach, CMS proposes to extend the length of ACOs' agreement periods from 3 to 5 years as well as to make changes to the program's benchmarking methodology to allow for benchmarks that better reflect the ACO's regional service area expenditures beginning with its first agreement period, while mitigating the effects of factors based on regional FFS expenditures on ACO benchmarks more generally. These proposed policies are necessary to improve the value proposition of the program for currently participating ACOs considering continuing their participation, as well as for organizations considering entering the program. Further, these changes are timely as large cohorts of the program's early entrants, the vast majority of which are currently participating in the program's one-sided model (Track 1), face a required transition to performance-based risk at the start of their next agreement period under the program's current regulations.

Other key changes to the program's regulations are also necessary, including to implement new requirements established by the Bipartisan Budget Act, which generally allow for additional flexibilities in payment and program policies for ACOs and their participating providers and suppliers. Specifically, we are proposing policies to implement provisions of the Bipartisan Budget Act that allow certain ACOs to establish CMS-approved beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying primary care services; permit payment for expanded use of telehealth services furnished by physicians or other practitioners participating in an applicable ACO that is subject to a prospective assignment methodology;

provide greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under a retrospective beneficiary assignment methodology a choice of prospective assignment for the agreement period; and offer the opportunity for Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider with such a voluntary identification superseding claims-based assignment. Additionally, this proposed rule would expand the availability of the program's existing SNF 3-day rule waiver to all ACOs participating under performance-based risk to support these ACOs in coordinating care across settings to meet the needs of their patient populations.

To provide ACOs time to consider the new participation options and prepare for program changes, make investments and other business decisions about participation, obtain buy-in from their governing bodies and executives, and complete and submit a Shared Savings Program application for a performance year beginning in 2019, we intend to forgo the application cycle in 2018 for an agreement start date of January 1, 2019, and instead propose to offer a July 1, 2019 start date. This midyear start in 2019 would also allow both new applicants and ACOs currently participating in the program an opportunity to make any changes to the structure and composition of their ACO as may be necessary to comply with the new program requirements for the ACO's preferred participation option, if changes to the participation options are finalized as proposed. Additionally, ACOs with a participation agreement ending on December 31, 2018, would have an opportunity to extend their current agreement period for an additional 6-month performance year and to apply for a new agreement period under the BASIC track or ENHANCED track beginning on July 1, 2019. ACOs entering a new agreement period on July 1, 2019, would have the opportunity to participate in the program under an agreement period spanning 5 years and 6 months, where the first performance year is the 6-month period between July 1, 2019, and December 31, 2019. This proposed rule includes the proposed methodology for determining ACO financial performance for these two, 6-month performance years during CY 2019.

Further, this proposed rule would make other timely updates to the program's regulations, for consistency with other changes in program policies or Medicare policies more generally, such as: (1) Modifying the definition of primary care services used in beneficiary assignment to add new codes and revising how we determine whether evaluation and management services were furnished in a SNF; (2) extending policies previously adopted for performance year 2017 to performance year 2018 and subsequent years to address quality performance scoring and the determination of shared losses (under two-sided models) in the event of extreme or uncontrollable circumstances; and (3) promoting interoperability in Medicare by establishing a new Shared Savings Program eligibility requirement related to adoption of CEHRT by an ACO's eligible clinicians, while discontinuing use of the existing quality measure on use of CEHRT.

B. Overall Impact

We examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Executive Order 13771 directs agencies to categorize all impacts which generate or alleviate costs associated with regulatory burden and to determine the action's net incremental effect.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA, which to the best of our ability presents the costs and benefits of the rulemaking.

In keeping with our standard practice, the main analysis presented in this RIA compares the expected outcomes if the full set of proposals in this rule were finalized to the expected outcomes under current regulations. We provide our analysis of the expected costs of the proposed payment model under section 1899(i)(3) of the Act to the costs that would be incurred under the statutory payment model under section 1899(d) of the Act in section IV.E. of this proposed rule.

C. Anticipated Effects

1. Effects on the Medicare Program

a. Background

The Shared Savings Program is a voluntary program operating since 2012 that provides financial incentives for demonstrating quality of care and efficiency gains within FFS Medicare. In developing the proposed policies, we evaluated the impact of the quality and financial results of the first 4 performance years of the program. We also considered our earlier projections of the program's impacts as described in the November 2011 final rule (see Table 8, 76 FR 67963), the June 2015 final rule (80 FR 32819), and June 2016 final rule (81 FR 38002).

(1) ACO Performance 2012 Through 2016

We have four performance years of financial performance results available for the Shared Savings Program.[27] Table 14 describes performance year 2016

[27] The first performance year for the program concluded December 31, 2013, which included a 21-period for April 2012 starters, an 18-month period for July 2012 starters, and a 12-month period for January 2013 starters. Thereafter, results have been determined for the calendar year performance year for 2014 through 2016 for all ACOs that participated in the program for the relevant year. Performance year 2017 results are not available at the time of publication of this proposed rule.

results for ACOs segmented by track. These results show that in performance year 2016, the 410 Track 1 ACOs spent more on average relative to their financial benchmarks, resulting in a net loss of $49 million, or $7 per beneficiary. Because these ACOs were in a one-sided shared savings only model, CMS did not recoup any portion of these losses. Further, in performance year 2016, the 6 Track 2 and 16 Track 3 ACOs spent less on average relative to their financial benchmarks. Track 2 ACOs produced net savings of $18 million or $308 per beneficiary, and Track 3 ACOs produced net savings of $14 million or $39 per beneficiary. These results (albeit from a relatively small sample of ACOs that in a number of cases moved to a performance-based risk track only after showing strong performance in a first agreement period under Track 1) indicate that ACOs under performance-based risk were more successful at lowering expenditures in performance year 2016 than ACOs under Track 1.

The same performance year 2016 data also show that ACOs produce a higher level of net savings and more optimal financial performance results the longer they have been in the Shared Savings Program and with additional participation experience. In performance year 2016, 42 percent of ACOs that started participating in the Shared Savings Program in 2012 and remained in the program shared in savings and 36 percent of both 2013 and 2014 starters shared in savings. In contrast, 26 percent of 2015 starters shared in savings and 18 percent of 2016 starters shared in savings in performance year 2016.

TABLE 14—PY 2016 RESULTS BY SHARED SAVINGS PROGRAM TRACK

Track	Two-sided risk?	Number of ACOs reconciled	Parts A and B spending above benchmark [A]	Parts A and B spending below benchmark [B]	Shared savings payments from CMS to ACOs [C]	Shared loss payments from ACOs to CMS [D]	Net effect in aggregate [A − B + C − D]	Net effect per beneficiary per year
Track 1	No	410	$1.021 billion	$1.562 billion	$590 million	$0	$49 million	$7
Track 2	Yes	6	0	42 million	24 million	0	−18 million	−308
Track 3	Yes	16	25 million	95 million	64 million	9 million	−14 million	−39

Table 15 indicates that when analyzing the performance of ACOs in Track 1, which is the track in which the majority of Shared Savings Program ACOs participated as of performance year 2016, it becomes clear that low revenue ACOs are saving CMS money while high revenue ACOs are resulting in additional spending by CMS before accounting for market-wide and potential spillover effects. Low revenue Track 1 ACOs produced net savings of $182 million relative to their benchmarks or $73 per enrollee, and high revenue Track 1 ACOs produced a net loss of $231 million or $46 per enrollee. For the purpose of this analysis, an ACO whose ACO participants' Medicare FFS revenue for assigned beneficiaries was less than 10 percent of the ACO's assigned beneficiary population's Parts A and B expenditures, was identified as a ''low revenue ACO,'' while an ACO whose ACO participants' Medicare FFS revenue for assigned beneficiaries was at least 10 percent of the ACO's assigned beneficiary population's Parts A and B expenditures, was identified as a ''high revenue ACO''. Nationally, evaluation and management spending accounts for about 10 percent of total Parts A and B per capita spending. Because ACO assignment focuses on evaluation and management spending, applying a 10 percent limit to identify low revenue ACOs would capture all ACOs that participated in the Shared Savings Program in performance year 2016 that were solely comprised of providers and suppliers billing physician fee schedule services and generally exclude ACOs with providers and suppliers that bill inpatient services for their assigned beneficiaries. The use of a threshold of 10 percent of the Parts A and B expenditures for the ACO's assigned beneficiary population to classify ACOs as either ''low revenue'' or ''high revenue'' also showed the most significant difference in performance between the two types of ACOs. We note that this approach differs from the proposed definitions for low revenue ACO and high revenue ACO discussed in section II.A.5.b. of this proposed rule. However, our analysis has confirmed that the simpler and more practical proposed policy for identifying low revenue ACOs using a 25-percent threshold in terms of the ratio of ACO participants' total Medicare Parts A and B FFS revenue relative to total Medicare Parts A and B expenditures for the ACO's assigned beneficiary population produces a comparable subgroup of ACOs with similarly-elevated average financial performance and physician-based ACO participant composition.

TABLE 15—PY 2016 RESULTS FOR LOW REVENUE AND HIGH REVENUE TRACK 1 ACOS

Track 1 ACO composition	Number of ACOs (total 410)	Parts A and B spending above benchmark	Parts A and B spending below benchmark [A]	Shared savings payments from CMS to ACOs [B]	Shared loss payments from ACOs to CMS [C]	Net effect in aggregate [A − B + C − D] [D]	Net effect per beneficiary per year
Low revenue	188	$339 million	−$863 million	$343 million	$0	−$182 million	−$73
High revenue	222	682 million	−698 million	247 million	0	231 million	46

With respect to ACO quality, the Shared Savings Program's quality measure set includes both process and outcome measures that evaluate preventive care, clinical care for at-risk populations, patient experience of care, and care coordination. ACOs have consistently achieved higher average performance rates compared to group practices reporting similar quality measures. In addition, ACOs that have participated in the program over a

longer time period have shown greater improvement in quality performance. For example, across all Shared Savings Program ACOs that reported quality in both performance year 2013 and performance year 2016, average quality performance improved by 15 percent across 25 measures used consistently across the performance years. Further, for performance year 2016, 93 percent of Shared Savings Program ACOs received bonus points for improving quality performance in at least one of the four quality measure domains with an average quality score increase for the applicable domain of 3 percentage points.

(2) ACO Market-Wide Effects and Potential Spillover

Analysis of wider program claims data indicates Medicare ACOs have considerable market-wide impact, including significant spillover effects not directly measurable by ACO benchmarks. Whereas spending relative to benchmark (Tables 14 and 15) indicates Shared Savings Program ACOs as a group are not producing net savings for the Medicare FFS program, a study of wider claims data indicates significant net savings are likely being produced. Table 16 includes data through performance year 2016 on the cumulative per capita Medicare FFS expenditure trend (on a price-standardized and risk-adjusted basis) in markets that include Medicare ACOs, including ACOs participating in the Shared Savings Program as well as in the Pioneer and Next Generation ACO Models. Table 16 illustrates that, compared to the results in relation to ACOs' historical benchmarks discussed previously (see Table 14), more savings are likely being generated when both the spillover effects on related populations and the feedback effect of growing ACO participation on the national average FFS program spending growth, which in turn has been used to update ACO benchmarks, are factored in. Table 16 expresses combined market average per capita spending growth since 2011 relative to a baseline FFS per capita trend observed for hospital referral regions continuing to have less than 10 percent of total assignable FFS beneficiaries assigned to Medicare ACOs through 2016. Markets that have been ''ACO active'' longer (defined by the year a market first reached at least 10 percent assignment of assignable FFS beneficiaries to Medicare ACOs) show the greatest relative reduction in average adjusted growth in per capita Medicare FFS spending. Markets that have included Medicare ACOs since 2012, particularly the relatively small subset of 10 hospital referral regions reaching significant ACO participation in risk (defined as at least 30 percent assignment by 2016 to ACOs participating in a Shared Savings Program track or Medicare ACO model with performance-based risk), show the most significant reductions in Medicare FFS spending through 2016.

TABLE 16—AVERAGE ADJUSTED CUMULATIVE PER CAPITA MEDICARE FFS TREND 2011 – 2016 (BY YEAR MARKETS BECOME ACO ACTIVE RELATIVE TO CUMULATIVE TREND FOR MARKETS WITHOUT SIGNIFICANT ACO ACTIVITY)

Markets Grouped	Adjusted Per Capita Change in Spending from Non-ACO Markets					
By ACO Activity	2011	2012	2013	2014	2015	2016
First Active 2016	0.0%	-0.5%	0.0%	-0.5%	-0.3%	-0.5%
First Active 2015	0.0%	-0.2%	0.2%	-0.1%	0.2%	0.1%
National Average	**0.0%**	**-0.3%**	**-0.3%**	**-0.7%**	**-0.7%**	**-1.2%**
First Active 2014	0.0%	-0.5%	-0.3%	-0.5%	-0.7%	-1.5%
First Active 2013	0.0%	0.0%	-0.1%	-1.0%	-1.1%	-1.8%
First Active 2012	0.0%	-0.3%	-0.8%	-1.3%	-1.5%	-2.0%
2012 Subset with Risk	0.0%	-0.9%	-1.9%	-2.5%	-2.9%	-3.4%

Based on an analysis of Medicare Shared Savings Program and Pioneer ACO Model performance data, we observe that the sharpest declines in spending are for post-acute facility services (particularly skilled nursing facility services), with smaller rates of savings (but more dollars saved overall) from prevented hospital admissions and reduced spending for outpatient hospital episodes. These findings become apparent when assessing hospital referral regions both with (>10 percent of assignable Medicare FFS beneficiaries assigned to ACOs in 2012) and without (<10 percent through 2016) a significant portion of assignable Medicare FFS beneficiaries assigned to ACOs. Comparing price-standardized per capita changes in spending from 2011 to 2016, regions with significant ACO penetration yielded larger declines in expenditures in the following areas relative to those without significant ACO penetration: Post-acute care facilities (relative decrease of 9.0 percent), inpatient (1.6 percent relative decrease), and outpatient (3.5 percent relative decrease). These relative decreases were accompanied by declines in evaluation and management services (2.5 percent relative decrease), emergency department (ED) utilization (1.6 percent relative decrease), hospital admissions (1.9 percent decrease), and hospital readmissions (3.5 percent decrease). There also appears to be substitution of higher cost services with lower cost services. For example, during the same period, home health expenditures increased by 5.0 percent and ambulatory surgery center expenditures increased by 1.4 percent, indicating that some beneficiaries could be forgoing care in institutional and inpatient settings in favor of lower cost sites of care.

These findings are supported by outside literature and research. For example, a study conducted by J. Michael McWilliams and colleagues (JAMA, 2017) found that Shared Savings Program ACOs that began participating in 2012 reduced post-acute care

spending by 9 percent by 2014.[28] Another study by Ulrika Winblad and colleagues (Health Affairs, 2017) determined that ACO-affiliated hospitals reduced readmissions from skilled nursing facilities at a faster rate than non-ACO-affiliated hospitals through 2013.[29] In addition, a study by John Hsu and colleagues (Health Affairs, 2017) concluded that using care management programs, large Pioneer ACOs generated 6 percent fewer ED visits, 8 percent fewer hospitalizations, and overall 6 percent less Medicare spending relative to a comparison group through 2014.[30]

Assuming Medicare ACOs were responsible for all relative deviations in trend from non-ACO markets produces an optimistic estimate that total combined Medicare ACO efforts potentially reduced total FFS Medicare Parts A and B spending in 2016 by about 1.2 percent, or $4.2 billion (after accounting for shared savings payments but before accounting for the potential impact on MA plan payment). However, it is likely that ACOs are not the only factor responsible for lower spending growth found in early-ACO-active markets. Health care providers in such markets are likely to be more receptive to other models and/or interventions, potentially including the following, for example: (1) Health Care Innovation Award payment and service delivery models funded by the Innovation Center; (2) advanced primary care functionality promoted by other payers, independent organizations like the National Committee for Quality Assurance, and/or through Innovation Center initiatives including the Multi-Payer Advanced Primary Care Practice Demonstration and Comprehensive Primary Care Initiative; and (3) care coordination funded through other Medicare initiatives, including, for example, the Community-based Care Transitions Program. Furthermore, the markets making up the non-ACO comparison group only cover about 10 percent of the national assignable FFS population in 2016 and may offer an imperfect counterfactual from which to estimate ACO effects on other markets.

An alternative (and likely more precise) estimate for the overall Medicare ACO effect on spending through 2016 involves assuming a spillover multiplier mainly for savings on non-assigned beneficiaries whose spending is not explicitly included in benchmark calculations and combining primary and spillover effects to estimate the degree that ACO benchmarks were reduced by the feedback such efficiency gains would have on national average spending growth. Analysis of claims data indicates an average ACO's providers and suppliers provide services to roughly 40 to 50 percent more beneficiaries than are technically assigned to the ACO in a given year. In addition, savings would potentially extend to spending greater than the large claims truncation amount, IME payments, DSH payments, and other pass-through payments that are excluded from ACO financial calculations. Assuming proportional savings accrue for non-assigned beneficiaries and the excluded spending categories, as previously described, supports a spillover savings assumption of 1.6 (that is, 60 cents of savings on non-benchmark spending for every dollar of savings on benchmark spending). Total implied savings, including the assumed spillover savings, would imply Medicare ACOs were responsible for about 50 percent of the lower spending growth in ACO markets (after becoming ACO active), or roughly 0.5 percent lower total FFS Parts A and B spending in 2016 after accounting for shared savings payments.

There are several other key takeaways from the available evidence and literature regarding the performance of Medicare ACOs, including the following:

Independent Research Finds ACOs Reduce Medicare Trust Fund Outlays. The implications from studying market-level trends described in the previous section are compatible with findings reported by independent researchers. J. Michael McWilliams (JAMA, 2016) found that in 2014, Shared Savings Program ACOs generated estimated program savings of $628 million, or about 2.5 times higher than the savings in relation to participating ACOs' historical benchmarks and nearly twice the total shared savings payments of $341 million.[31] Another study by McWilliams and colleagues (JAMA, 2013) on a commercial ACO initiative, the Alternative Quality Contract, estimated a net 3.4 percent reduction in spending on Medicare beneficiaries due to spillover from a commercial non-Medicare ACO initiative.[32] This research supports the hypothesis that changes in delivery implemented by Medicare ACO clinicians would in turn cause efficiency gains in the wider Medicare FFS population. In another study supporting this hypothesis, Madeleine Phipps-Taylor and Stephen Shortell (NEJM, 2016) conducted a set of case studies which concluded that ACOs were making system and process changes that would improve the value of services provided to all patients, regardless of payer.[33]

Low revenue ACOs (including small and physician-only ACOs) have produced stronger average benchmark savings to date than high revenue ACOs (likely including institutional providers). We also find lower spending growth in the handful of markets that happen to be virtually exclusively populated by low revenue ACOs; however, the sample size of such markets is too small for us to confidently estimate relative performance but does offer some corroboration of the stronger results observed for low revenue ACOs on average relative to their historical benchmarks. Further, evidence suggests that overall payment reform has been associated with little acceleration in consolidation of health care providers that surpasses trends already underway (Post et al., 2017),[34] although there is some evidence of potential defensive consolidation in response to new payment models (Neprash et al., 2017).[35] Anecdotally, ACOs provide physician practices with a way to stay independent and offer a viable alternative to merging with a hospital (Mostashari, 2016).[36]

[28] McWilliams JM, et al. Changes in Postacute Care in the Medicare Shared Savings Program. *JAMA Intern Med.* 2017; 177(4):518–526. doi:10.1001/jamainternmed.2016.9115.

[29] Winblad U, et al. ACO-Affiliated Hospitals Reduced Rehospitalizations from Skilled Nursing Facilities Faster than Other Hospitals. *Health Affairs.* 2017 January; 36(1): 67–73. doi:10.1377/hlthaff.2016.0759.

[30] Hsu J, et al. Bending The Spending Curve By Altering Care Delivery Patterns: The Role Of Care Management Within A Pioneer ACO. *Health Affairs.* 2017 May 1; 36(5):876–884. doi:10.1377/hlthaff.2016.0922.

[31] McWilliams JM. Changes in Medicare Shared Savings Program Savings From 2013 to 2014. *JAMA.* 2016; 316(16):1711–1713. doi:10.1001/jama.2016.12049.

[32] McWilliams JM, et al. Changes in Health Care Spending and Quality for Medicare Beneficiaries Associated With a Commercial ACO Contract. *JAMA.* 2013; 310(8):829–836. doi:10.1001/jama.2013.276302.

[33] Madeleine Phipps-Taylor & Stephen M. Shortell. ACO Spillover Effects: An Opportunity Not to Be Missed, *NEJM Catalyst* (September 21, 2016); available at *https://catalyst.nejm.org/aco-spillover-effects-opportunity-not-missed/.*

[34] See for example, Brady Post, Tom Buchmueller, and Andrew M. Ryan. Vertical Integration of Hospitals and Physicians: Economic Theory and Empirical Evidence on Spending and Quality. *Medical Care Research and Review.* August 2017. *https://doi.org/10.1177/1077558717727834.* See also, Liaw WR, et al. Solo and Small Practices: A Vital, Diverse Part of Primary Care. *Ann Fam Med.* 2016;14(1):8–15. doi:10.1370/afm.1839.

[35] Neprash HT, Chernew ME & McWilliams JM. Little Evidence Exists to Support the Expectation That Providers Would Consolidate to Enter New Payment Models. *Health Affairs.* 2017; 36(2): 346–354. doi:10.1377/hlthaff.2016.0840.

[36] See for example, Mostashari, F. The Paradox of Size: How Small, Independent Practices Can Thrive

Continued

Generating savings is difficult for ACOs. It may take time as well as trial and error for ACOs to build more efficient care delivery infrastructure. Small absolute savings compound over time in an incremental fashion. This gradual change is evidenced by ACOs' financial performance results to date, which indicate that ACOs produce more net savings the longer they participate in programs such as the Shared Savings Program.

Shared savings are not profits. Program experience since 2012 indicates that ACOs make upfront investments in care delivery infrastructure, including data analytics and staffing, with the intent of saving money through improvements in care management and coordination. ACOs that do not achieve savings must still fund these operational costs.

Sustainably rewarding attained efficiency and continued improvement is the central challenge. Therefore, optimizing program design elements for ACO initiatives such as the Shared Savings Program is key to ensuring that both of these goals are attained. Such elements include the methodology used to set and reset the ACO's historical benchmark, the approach used to calculate the ACO's shared savings and/or shared losses, the level of performance-based risk for ACOs, and the methodology for assigning beneficiaries to the ACOs. Striking this balance correctly would foster increased participation in ACO initiatives, which is required to produce higher levels of net savings.

b. Assumptions and Uncertainties

The changes to the Shared Savings Program proposed in this rule could result in a range of possible outcomes. We considered a number of uncertainties related to determining future participation and performance by ACOs in the Shared Savings Program.

Changes to the existing benchmark calculations described previously would benefit program cost savings by producing benchmarks with improved accuracy (most notably by limiting the effect of the regional benchmark adjustment to positive or negative 5 percent of the national per capita spending amount). However, such savings would be partly offset by increased shared savings payments to ACOs benefiting from our proposal to apply the methodology incorporating factors based on regional FFS expenditures beginning with the ACO's first agreement period, revising risk adjustment to include up to a 3 percent increase in average HCC risk score over the course of an agreement period, and blending national trend with regional trend when calculating ACO benchmarks. Such trade-offs reflect the intention of our proposal to strengthen the balance between rewarding ACOs for attainment of efficiency in an absolute sense in tandem with incentivizing continual improvement relative to an ACO's recent baseline.

More predictable relationships, that is, an ACO's knowledge of its costs relative to the FFS expenditures in its region used to adjust its benchmark, can allow risk-averse ACOs to successfully manage significant exposure to performance-based risk. However, the proposed policy would limit regional adjustments so that they still incentivize low cost ACOs to take on risk while mitigating excessive windfall payments to ACOs that, for a variety of reasons, may be very low cost at baseline. The proposed policy also increases the possibility that higher cost ACOs would find a reasonable business case to remain in the program and thereby continue to lower their cost over time.

We also considered the possibility that providers and suppliers would have differing responses to changing financial incentives offered by the program, including for example the varying levels of savings sharing rates and/or loss sharing limits proposed for the BASIC and ENHANCED tracks. Participation decisions are expected to continue to be based largely on an ACO's expectation of the effect of rebasing and the regional adjustment on its ability to show spending below an expected future benchmark. We also considered the incentive for ACOs to participate under the highest level of risk and reward in the BASIC track or in the ENHANCED track in order to be considered an Advanced APM Entity for purposes of the Quality Payment Program. Eligible clinicians in an ACO that is an Advanced APM Entity may become Qualifying APM Participants for a year if they receive a sufficient percentage of their payments for Part B covered professional services or a sufficient percentage of Medicare patients through the ACO.

We also gave consideration to the effect on program entry and renewal as a result of discontinuing Track 1 and Track 2, and offering instead the BASIC track (including the glide path for eligible ACOs) and ENHANCED track, including the option for ACOs currently under 3-year agreements for participation in Track 1, Track 2, and Track 3 to terminate their agreement to quickly enter a new agreement period under the BASIC track or the ENHANCED track. For example, if 2014 starters complete a second 3-year agreement period under Track 1 and are eligible to enter the BASIC track's glide path under a one-sided model in 2020, these ACOs could have 7 performance years under a one-sided model. Modeling indicates that while such allowance could slow the transition to risk for some ACOs that might otherwise have enough of a business case to make an immediate transition to performance-based risk, the longer glide path would likely result in greater overall program participation by the end of the projection period and marginally increase overall program savings. We also considered the effect on participation from the proposals to permit ACOs to change their beneficiary assignment method selection prior to the start of each performance year, to allow ACOs in the BASIC track's glide path the option annually to elect to transition to a higher level of risk and reward within the glide path, and to offer a July 1, 2019 start date (including the proposed extension of an existing agreement period through June 30, 2019).

We also considered the potential effects of policies proposed to promote participation by low revenue ACOs as follows. By allowing low revenue ACOs to enter the BASIC track (potentially immediately entering the maximum level of risk and potential reward under such track) and continue their participation in the BASIC track for a subsequent agreement period (under the highest level of risk and potential reward), the proposal would offer low revenue ACOs a longer period under a more acceptable degree of risk given their revenue constraints, before transitioning to more significant risk exposure under the ENHANCED track.

Low revenue ACOs can still choose to enter the ENHANCED track, and take on additional downside risk in exchange for the opportunity to share in a higher percentage of any savings. Such migration is likeliest for low revenue ACOs expecting a favorable regional adjustment to their rebased historical benchmark. The proposal to include the regional adjustment in the methodology for determining an ACO's benchmark for its first agreement period should help provide such ACOs the degree of certainty necessary for earlier election of performance-based risk, while capping the regional adjustment at positive or negative 5 percent of national per capita expenditures for Parts A and B services for assignable beneficiaries helps CMS avoid unnecessarily large windfall payments for ACOs that would have

in Value-Based Care. *Ann Fam Med.* 2016; 14(1):5–7. doi:10.1370/afm.1899.

already been properly incentivized to aggressively participate with a regional adjustment set at the level of the cap.

In addition, we considered related impacts of the proposed changes to the program's benchmarking methodology, as used to establish, adjust, update and reset the ACO's benchmark. For renewing ACOs—especially ACOs that are concerned about competition from operating in a highly-competitive ACO market or ACOs that make up a large portion of their market—several proposed changes are likely to help mitigate concerns about the long term business case of the model. Most notably, the use of a regional/national blend to determine the growth rates for the trend and update factors should reduce the degree to which ACO savings (and/or neighboring ACO savings) affect an ACO's own benchmark updates. Furthermore, the proposal to use full HCC risk ratios (capped at positive or negative 3 percent) regardless of the assignment status of a beneficiary should help to assuage concerns that risk adjustment could adversely affect an ACO that increasingly serves a higher morbidity population inside of its market.

To best reflect these uncertainties, we continue to utilize a stochastic model that incorporates assumed probability distributions for each of the key variables that would impact participation, changes in care delivery, and the overall financial impact of the Shared Savings Program. The model continues to employ historical baseline variation in trends for groups of beneficiaries assigned using the program's claim-based assignment methodology to simulate the effect of benchmark calculations as described in the June 2016 final rule (81 FR 38005 through 38007). We used several unique assumptions and assumption ranges in the updated model.

To estimate the number of ACOs that would participate in the program, we assumed that up to approximately 250 existing 2018 ACOs would be affected by the proposed policies starting with a potential third agreement period beginning on July 1, 2019, or in 2020 or 2021. We also assumed that up to approximately 300 existing 2018 ACOs would be affected by the proposed policies starting with a potential second agreement period beginning on July 1, 2019, in 2020, or 2021. In addition, between 20 and 50 new ACOs were assumed to form annually from 2019 through 2028.

We assumed ACO decision making regarding participation would reflect each ACO's updated circumstances including prior year performance as well as expected difference in spending in relation to future anticipated adjusted benchmark spending. Specific related assumptions are as follows:

For one, the potential that existing ACOs would renew under the policies in the proposed rule would be related to expectations regarding the effect of the proposed changes to the regional adjustment on the ACO's rebased benchmark. ACOs expecting adjusted historical benchmarks from 2 to 10 percent higher than actual per capita cost are assumed to select the highest-risk option (Track 3 in the baseline or the ENHANCED track under the proposed rule); such range is reduced for second or later rebasing under the policies in the proposed rule to 1 to 5 percent higher than actual per capita cost. Otherwise, ACOs expecting adjusted rebased benchmarks from 0 to 3 percent higher than actual per capita cost are assumed to select the Track 1+ Model (baseline) or BASIC track, Level E (proposed). ACOs expecting adjusted rebased historical benchmarks from zero to 5 percent lower than actual per capita cost are expected not to renew unless another agreement in Track 1 is allowed (baseline), or are assumed to have between zero and 50 percent chance of electing the BASIC track (proposed).

Second, all other renewal decisions would follow the same assumptions as the preceding description except for the following cases. For the baseline scenario, a Track 1 ACO eligible for a second Track 1 agreement period during the projection period that does not otherwise select renewal in Track 3 or the Track 1+ Model would only renew in Track 1 if the ACO had earned shared savings in either of the first 2 years of the existing agreement period or if the ACO anticipates an adjusted historical benchmark no lower than 3 percent below actual cost. For the proposed scenario, an ACO not otherwise choosing the ENHANCED track would only renew in the BASIC track if the following conditions were met: (1) The ACO expects an adjusted historical benchmark no lower than 0 to 3 percent below actual cost; (2) the ACO did not experience a loss in the existing agreement period; and (3) the ACO is low revenue (as high revenue ACOs would be precluded from renewing in the BASIC track).

Third, we used the following approach to make assumptions about participation decisions for ACOs encountering a shared loss. An adjusted shared loss (L) was calculated by netting out the total expected incentive payments that would be made under the Quality Payment Program to ACO providers/suppliers who are Qualifying APM Participants during the payment year that is 2 years after the performance year for which the ACO is accountable for shared losses. In each trial a random variable (X) was chosen from a skewed distribution ranging from zero to 3 percent of benchmark (mode 1 percent of benchmark) for determining participation decisions affecting years prior to 2023 (alternatively X was sampled from the range zero to 2 percent of benchmark with mode of 0.5 percent of benchmark for participation decisions for 2023 and subsequent years when the incentive to participate in an Advanced APM as a Qualifying APM Participant is reduced). If $L>X$ then the ACO is assumed to drop out. Otherwise, if $L>X/2$ then the ACO is assumed to have a 50 to 100 percent chance of leaving the program. Otherwise, the ACO has a relatively smaller loss ($L<X/2$) and the ACO is assumed to have roughly double the chance of persisting relative to the prior scenario.

Fourth, we used the following approach to make assumptions about the potential that ACOs in the BASIC track would elect early transition to the BASIC track, Level E. An adjusted shared savings (S) was calculated by adding the total potential incentive payments expected under the Quality Payment Program (2 years after the potential transition to Level E) to ACO providers/suppliers who would expect to become Qualifying APM Participants (due to the transition to Level E) to the ACO's most recent shared savings—with such sum expressed as a percentage of benchmark. In each trial a random variable (Y) was chosen from a skewed distribution ranging from 1 to 4 percent of benchmark (mode 2 percent of benchmark). If $S>Y$, then the ACO is assumed to elect immediate transition to the BASIC track, Level E for the following performance year.

Assumptions for ACO effects on claims costs reflect a combination of factors. First, ACO revenue is assumed to be inversely proportional to historical savings achieved prior to implementation of the new rule. This is because, as noted earlier, low revenue ACOs (that tend to have low ACO participant Medicare FFS revenue relative to the ACO's benchmark spending) have generally shown stronger financial performance over the first 5 years of the program than high revenue ACOs. For existing low revenue ACOs, baseline savings immediately prior to renewal under the proposed rule are estimated to range from 1 to 4 percent of spending accounted for by the program benchmark, with an additional spillover effect on extra-benchmark spending accounting for an

additional 25 to 75 percent savings relative to the directly assumed savings on benchmark spending. Conversely, existing high revenue ACOs are assumed to have baseline savings of only 25 percent of the assumed baseline savings for low revenue ACOs, as previously enumerated.

Residual baseline savings are then potentially assumed to gradually diminish if participation ends. Specifically, zero to 100 percent of baseline savings are assumed to erode by the fifth year after an existing ACO drops out of participation as a Medicare ACO.

Alternatively, future savings for each type of ACO are assumed to scale according to the incentive presented by each potential track of participation. Future savings in Track 3 or the ENHANCED track during the projection period for low revenue ACOs are assumed to range from zero to 4 percent of benchmark spending for existing ACOs and 1 to 5 percent of benchmark spending for new ACOs. High revenue ACOs are assumed to have zero to 100 percent of the savings assumed for low revenue ACOs. Ultimate savings are assumed to phase in over 5 to 10 years for all types of ACOs. Savings for the Track 1+ Model or the BASIC track, Level E, are assumed to be 50 to 100 percent of the savings assumed for Track 3/ENHANCED track (as previously described). Savings for the BASIC track, Levels C and D, or Track 1 are assumed to be 30 to 70 percent of the savings assumed for Track 3/ENHANCED track. Lastly, savings for the BASIC track, Levels A and B, are assumed to be 20 to 60 percent of the savings assumed for Track 3/ENHANCED track.

We also assumed that selection effects would implicitly include the renewal decisions of ACOs simulated in the model. Further assumptions included the following: (1) The proposed adoption of full HCC adjustment (capped at positive or negative 3 percent) allows each ACO to increase its benchmark according to a skewed distribution from zero to 3 percent (mode 0.5 percent); and (2) for both the baseline and proposed scenarios, each ACO is assumed to be able to influence its comparable spending to region by zero to 5 percent (skewed with mode 1 percent) for example via changes in ACO participant TIN composition or other methods to direct assignment in a favorable manner given the financial incentive from the regional adjustment to the benchmark.

c. Detailed Stochastic Modeling Results

A simulation model involving the assumptions and assumption ranges described in the previous section was constructed and a total of 1,000 randomized trials were produced. Table 17 summarizes the annual projected mean impact (projected differences under the proposed changes to the program relative to the current baseline program) on ACO participation, federal spending on Parts A and B claims, ACO earnings from shared savings net of shared losses, and the net federal impact (effect on claims net of the change in shared savings/shared losses payments). The overall average projection of the impact of the proposed program changes is approximately $2.24 billion in lower overall federal spending over 10 years from 2019 through 2028. The 10th and 90th percentile from the range of projected 10 year impacts range from −$4.43 billion in lower spending to $0.09 billion in higher spending, respectively. The mean impact is comprised of about $0.51 billion in lower claims spending, $2.17 billion in reduced shared savings payments, net of shared loss receipts, and approximately $0.44 billion in additional incentive payments made under the Quality Payment Program to additional ACO providers/suppliers expected to become Qualifying APM Participants (mainly for performance years prior to 2023 where the Quality Payment Program incentive made during the corresponding payment year is 5 percent of Physician Fee Schedule revenue).

TABLE 17—10-YEAR ESTIMATED IMPACT OF PROPOSED RULE ON ACO PARTICIPATION, SPENDING ON PARTS A AND B CLAIMS, ACO SHARED SAVINGS NET OF LOSSES AND NET FEDERAL IMPACT

(Impact on claims, ACO shared savings, Advanced APM incentive payments, and net federal spending are expressed in $ millions)

Performance Year	ACO Participation	Claims	ACO Net Earnings	Federal Impact Before APM Incentives	Advanced APM Incentives to QPs	Net Federal Impact
2019	-20	60	60	120	0	120
2020	-33	80	40	120	0	120
2021	-49	50	20	70	0	70
2022	-29	20	-150	-130	70	-60
2023	-17	-40	-200	-240	130	-110
2024	-21	-110	-160	-280	220	-60
2025	-90	-160	-290	-450	0	-450
2026	-109	-190	-400	-590	30	-560
2027	-107	-150	-500	-650	0	-650
2028	-109	-80	-570	-650	-10	-660
10-Year Total		**-510**	**-2,170**	**-2,680**	**440**	**-2,240**
Low (10th Percentile)		-2,140	-4,310	-4,840	110	-4,430
High (90th Percentile)		1,040	270	-440	740	90

The overall drop in expected participation is mainly due to the expectation that the program will be less likely to attract new ACO formation in future years as the number of risk-free years available to new ACOs would be reduced from 6 years (two, 3-year agreement periods in current Track 1) to 2 years in the BASIC track, which also has reduced attractiveness with a lower 25 percent maximum sharing rate during the 2 risk-free years. However, the changes are expected to increase continued participation from existing ACOs, especially those currently facing mandated transition to risk in a third agreement period starting in 2019, 2020, or 2021 under the existing regulations, as well as certain other higher cost ACOs for which the capped regional adjustment would not reduce their benchmark as significantly as prescribed by current regulation.

Relatively small increases in spending in years 2019 through 2021 are largely driven by expectations for more favorable risk adjustment to ACOs' updated benchmarks and a temporary delay in migration of certain existing ACOs to performance-based risk. Savings grow significantly in the out years as a greater share of existing ACOs eventually transition to higher levels of risk and the savings from capping the regional adjustment to the benchmark grow because ACOs would increasingly have become eligible for higher uncapped adjustments under the baseline in the later years of the projection period.

The mean projection of $2.24 billion reduced overall federal spending is a reasonable point estimate of the impact of the proposed changes to the Shared Savings Program during the period between 2019 through 2028. However, we emphasize the possibility of outcomes differing substantially from the median estimate, as illustrated by the estimate distribution. Accordingly, this RIA presents the costs and benefits of this proposed rule to the best of our ability. To help further develop and potentially improve this analysis, we request comment on the aspects of the rule that may incentivize behavior that could affect participation in the program and potential shared savings payments. As further data emerges and is analyzed, we may improve the precision of future financial impact estimates.

To the extent that proposed changes to the Shared Savings Program will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums would also be correspondingly lower or higher. In addition, because MA payment rates depend on the level of spending within traditional FFS Medicare, savings or costs arising from the proposed changes to the Shared Savings Program would result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

2. Effects on Beneficiaries

Earlier in this analysis we describe evidence for the Shared Savings Program's positive effects on the efficiency of care delivered by ACO providers/suppliers over the first five years of the program. Reduced unnecessary utilization can lead to financial benefits for beneficiaries by way of lower Part B premiums or reduced out of pocket cost sharing or both. Certain beneficiaries may also benefit from the provision of in-kind items and services by ACOs that are reasonably connected to the beneficiary's medical care and are preventive care items or services or advance a clinical goal for the beneficiary. The value of care delivered to beneficiaries also depends on the quality of that care. Evidence indicates there have been incremental improvements in quality of care reported for ACO providers/suppliers. As previously noted in the Background

section of this RIA, for all ACOs that participated during performance year 2016 that had four or more years of experience in the program, average quality performance improved by 15 percent across the 25 measures used consistently across performance years 2013 to 2016.

As explained in more detail previously, we believe the proposed changes would provide additional incentives for ACOs to improve care management efforts and maintain program participation. In addition, ACOs with low baseline expenditures relative to their region are more likely to transition to and sustain participation in a risk track (either the BASIC track (Level E) or the ENHANCED track) in future agreement periods. Consequently, the changes in this rule would also benefit beneficiaries through greater beneficiary engagement and active participation in their care (via beneficiary incentives) and broader improvements in accountability and care coordination (such as through expanded use of telehealth services and extending eligibility for the waiver of the SNF 3-day rule to all ACOs accepting performance-based risk) than would occur under current regulations. Lastly, we estimate that the net impacts on federal spending, as previously detailed, would correspond to savings to beneficiaries in the form of reductions in Part B premium payments of approximately $310 million over the 10 year projection period through 2028.

We intend to continue to analyze emerging program data to monitor for any potential unintended effect that the use of a regional adjustment (as modified by the proposed rule) to determine the historical benchmarks for additional cohorts of ACOs could potentially have on the incentive for ACOs to serve vulnerable populations (and for ACOs to maintain existing partnerships with providers and suppliers serving such populations).

3. Effects on Providers and Suppliers

As noted previously, changes in this proposed rule aim to improve the ability for ACOs to transition to performance-based risk and provide higher value care. We believe the contemporaneous growth of ACO agreements with other payers is sufficiently mature (and invariably heterogeneous in structure) that it would not be materially affected by the proposed changes to specific features of the Shared Savings Program; however, we seek comment if stakeholders disagree with such assumption, as we would want to consider impacts on other payers and patient populations, if evidenced, as part of the development of the policies to be included in the final rule. Although the proposed elimination of Track 1 is expected to ultimately reduce the overall number of ACOs participating in the program, this proposed change might also create opportunities for more effective ACOs to step in and serve the beneficiaries who were previously assigned to other ACOs that leave the program. In addition, other proposed policies (including changes to HCC risk adjustment, longer five year agreement periods, gradual expansion of exposure to risk in the BASIC track, and allowing eligible low revenue ACOs to renew for a second agreement period in the BASIC track under Level E) are expected to increase the number of existing and new ACOs that ultimately make a sustained transition to performance-based risk. Such transition is expected to help ACOs more effectively engage with their ACO participants and ACO providers/suppliers in transforming care delivery.

Proposed changes to the methodology for making regional adjustments to the historical benchmark are expected to affect ACOs differently depending on their circumstances. Similar to observations described in the June 2016 final rule, certain ACOs that joined the program from a high expenditure baseline relative to their region and that showed savings under the first and/or second agreement period benchmark methodology would likely expect lower benchmarks and greater likelihood of shared losses under a methodology that includes a 35 percent weight on the regional expenditure adjustment. Additionally, certain ACOs that joined the program with relatively low expenditures relative to their region might expect significant shared savings payments even if they failed to generate shared savings in their first agreement period prior to the application of the regional adjustment to the benchmark. Limiting the weight of the regional adjustment to the benchmark to 50 percent and capping the adjustment at positive or negative 5 percent of national average per capita FFS spending for assignable beneficiaries would serve to preserve the incentive for low cost ACOs to maintain participation and accept performance-based risk while also improving the business case for high cost ACOs to continue to participate and drive their costs down toward parity with or even below their regional average. Therefore, the proposed changes to the regional adjustment are expected to increase participation by ACOs in risk tracks by broadening the mix of ACOs with plausible business cases for participation without creating excessive residual windfall payments to ACOs with very low baseline cost or unreasonably punitive decreases to benchmarks for ACOs serving very high cost populations at baseline. The increase in sustained participation in performance-based risk is evidenced by the projection of $440 million in increased incentive payments under the Quality Payment Program to ACO providers/suppliers achieving status as Qualifying APM Participants due to increased ACO participation in risk-based tracks of the Shared Savings Program. Conversely, the projected $2.17 billion in lower overall 10-year shared savings payments to ACOs reflects the prudent limitations that would be placed on the regional adjustment to the benchmark for ACOs that are very low cost relative to their region prior to rebasing.

Several other changes are expected to provide certain ACOs with stronger business cases for participating in the program. Transition to full HCC risk adjustment (capped at positive or negative 3 percent) regardless of beneficiary assignment status is expected to increase the resulting adjusted updated benchmark for the average ACO and better reflect actual shifts in assigned patient morbidity. Blending national with regional trend for ACO benchmark calculations is also expected to mitigate some ACOs' concerns regarding the problem of hyper competition against other ACOs in highly-saturated markets, as well as the potential that large ACOs would drive the regional trend they are ultimately measured against. These factors contribute to the expanded participation expected in performance-based risk and the resulting increase in savings on claims through more efficient care delivery.

We have made program data available that can help stakeholders evaluate the impact the proposed changes, as previously described, may have on individual ACOs in various markets. The Center for Medicare (CM) has created standard analytical files incorporating factors based on regional FFS expenditures (currently available for CYs 2014, 2015, and 2016) that specifically tabulate—(1) aggregate expenditure and risk score data for assignable beneficiaries by county; and (2) the number of beneficiaries assigned to ACOs, by county. These public use files can be obtained at the following website *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/*

SSPACO/SSP_Benchmark_Rebasing.html.

CM has also created standard analytical files that contain ACO-specific metrics as well as summarized beneficiary and provider information for each performance year of the Shared Savings Program. These files include ACO-specific annual data on financial and quality performance, person years and demographic characteristics of assigned beneficiaries, aggregate expenditure and utilization, and participant composition of the ACO. The public use files for 2013 through 2016 can be obtained at the following website *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html.*

4. Effect on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most physician practices, hospitals, and other providers are small entities either by virtue of their nonprofit status or by qualifying as a small business under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in any 1 year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's website at *http://www.sba.gov/content/small-business-size-standards.* For purposes of the RFA, approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the Physician Fee Schedule.

Although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a FFS basis, we acknowledge that the program can affect many small entities and have developed our rules and regulations accordingly in order to minimize costs and administrative burden on such entities as well as to maximize their opportunity to participate. (For example: Networks of individual practices of ACO professionals are eligible to form an ACO; the use of an MSR under Level A and Level B of the BASIC track, and, if elected by the ACO, under the ENHANCED track and BASIC track, Levels C through E, that varies by the size of the ACO's population and is calculated based on confidence intervals so that smaller ACOs have relatively lower MSRs; and low revenue ACOs may remain under reduced downside risk in a second agreement period under the BASIC track, Level E.)

Small entities are both allowed and encouraged to participate in the Shared Savings Program, provided the ACO has a minimum of 5,000 assigned beneficiaries, thereby potentially realizing the economic benefits of receiving shared savings resulting from the utilization of enhanced and efficient systems of care and care coordination. Therefore, a solo, small physician practice or other small entity may realize economic benefits as a function of participating in this program and the utilization of enhanced clinical systems integration, which otherwise may not have been possible. We believe the policies included in this proposed rule, such as the proposal to allow low revenue ACOs up to 2 agreement periods in in the BASIC track (with the second agreement period at the highest level of risk and potential reward) where downside risk exposure is limited to a percentage of ACO provider/supplier revenue (capped at a percentage of the ACO's benchmark), may further encourage participation by small entities in existing ACOs that may otherwise not find it possible to quickly assume the much higher exposure to downside risk required under the ENHANCED track.

As detailed in this RIA, total expected incentive payments made under the Quality Payment Program to Qualifying APM Participants are expected to increase by $440 million over the 2019 to 2028 period as a result of changes that will increase participation in the Shared Savings Program by certain ACOs and therefore increase the average small entity's earnings from such incentives. We also note that the proposal to extend each agreement period to at least 5 years offers greater certainty to ACOs, including small entities, regarding their benchmark as they approach the higher levels of risk required in the later years of the BASIC track and under the ENHANCED track.

5. Effect on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Although the Shared Savings Program is a voluntary program, this proposed rule would have a significant impact on the operations of a substantial number of small rural hospitals. We have proposed changes to our regulations such that benchmark adjustments for regional spending are limited to at most a 50 percent weight and are capped at positive or negative 5 percent of national average per capita FFS spending for assignable beneficiaries. Additionally we have proposed to blend national and regional trend in benchmark calculations, and have proposed allowing full HCC risk adjustment with a positive or negative 3 percent cap regardless of beneficiary assignment status. Such changes could help provide a stronger business case for ACOs built around rural hospitals that may have otherwise been concerned about serving a higher-risk population in their region or driving the local trends against which they would be compared. We seek comment from small rural hospitals on the proposed changes with special focus on the impact of the proposed changes to the adjustment to the benchmark to reflect regional FFS expenditures. (See the Effects on Providers and Suppliers section for a description of data currently available on the CMS website that may be useful for commenters to estimate the effects of such proposed changes for their particular ACO and/or market.)

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that is approximately $150 million. This proposed rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $150 million in any 1 year. Further, participation in this program is voluntary and is not mandated.

7. Regulatory Review Cost Estimation

We assume all 561 ACOs currently participating in the Medicare Shared Savings Program will review on average half of this proposed rule. For example, it is possible that certain ACOs may limit review to issues related only to the BASIC track and not the ENHANCED track or rely on a partnership with a management company, health plan, trade association or other entity that reviews the proposed rule and advises

multiple ACO partners. However, we acknowledge that this assumption may understate or overstate the costs of reviewing this rule. We welcome any comments on the approach in estimating the number of entities reviewing the proposed rule and the scope of the average review.

Using the wage information from the Bureau of Labor Statistics for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.39 per hour, where the assumed hourly wage of $53.69 has been increased by a factor of 2 to account for fringe benefits.[37] Assuming an average reading speed of 200 words per minute, we estimate it would take approximately 6 hours for the staff to review half of this proposed rule. For each ACO the estimated cost is $644.34 (6 hours × $107.39 per hour). Therefore, we estimate the total cost of reviewing this proposed regulation is approximately $361,500 ($644.34 × 561 ACOs).

8. Other Impacts on Regulatory Burden

We estimate that extending the agreement period to 5 years may reduce certain administrative costs incurred by ACOs. In its review of the Physician Group Practice demonstration, GAO estimated the average entity spent $107,595 on initial startup for administrative processes. We assume roughly one-tenth of such total startup amount would represent the administrative expenses of renewal for an ACO entering a renewed agreement period ($10,760 per ACO). Therefore, we estimate extending the agreement period to 5 years would reduce ACO administrative burden by approximately $6 million over 10 years ($10,760 × 561 ACOs).

We do not believe that the proposals included in this proposed rule would otherwise materially impact the burden on ACOs for compliance with the requirements of the Shared Savings Program. The annual certification and application process would remain comparable to the existing program (setting aside the change to five year agreement periods as noted in the previous paragraph). However, we seek comment if stakeholders have reason to believe the proposed changes would materially change the burden of participation in the program beyond what we have estimated, as described previously.

[37] Occupational Employment Statistics available online at *https://www.bls.gov/oes/current/oes_nat.htm.*

D. Alternatives Considered

A particularly significant element of the proposed changes to the benchmarking methodology included in this proposed rule is the proposal to limit the effect of regional adjustments on rebased ACO historical benchmarks via a cap of positive or negative 5 percent of national average per capita FFS expenditures for assignable beneficiaries. If the proposal were amended to remove this cap then shared savings payments to low cost ACOs and selective participation decisions would increase the cost of the proposed rule by roughly $5 billion such that the estimated $2.24 billion savings relative to current regulation baseline (as estimated for the proposed rule in the previous sections) would instead be projected as a $2.75 billion cost.

Another alternative considered would be to push back the first agreement periods under the proposed new participation options and all other applicable proposed changes to a January 1, 2020 start date. This would avoid the complexity of a July 1, 2019 midyear start date. ACOs otherwise eligible to renew their participation in the program in 2019 would be offered a one year extension under their current agreement periods. This alternative would have differing impacts on federal spending.

Forgoing the proposed July 1, 2019 start date and providing for the next available start date of January 1, 2020, would likely marginally increase spending on claims through a combination of factors. This approach would delay, by 6 months, the transition into performance-based risk for certain ACOs whose current agreement periods will end on December 31, 2018. We also would anticipate a temporary increase in overall shared savings payments to such ACOs during the one year extension in 2019 because of the additional year lag between the historical baseline expenditures and the 2019 performance year expenditures under the extended agreement period. However, this alternative would also have a slightly greater effect in reducing Federal spending in later years through a combination of factors. Under this approach, the third historical benchmark year of the subsequent agreement period for such ACOs would be CY 2019 rather than CY 2018, as would be the case under the proposed July 1, 2019 start date. The use of historical expenditures from 2017 through 2019, rather than 2016 through 2018, to determine the benchmark for these ACOs would marginally reduce the cumulative variation affecting benchmark accuracy in 2024, the final year of these ACOs' first agreement period under the policies in this proposed rule. We would also anticipate a reduction in incentive payments made under the Quality Payment Program in 2021 (which are based on participation by eligible clinicians in Advanced APMs during 2019) by delaying the transition to performance-based risk for certain ACOs to 2020 instead of July 1, 2019.

Overall, it is estimated that the shift to a January 1, 2020 start date for new agreement periods under the proposed changes, combined with a 1-year extension of the existing agreement period for most ACOs otherwise expected to enter a new agreement period in 2019, would reduce overall Federal spending by approximately an additional $100 million relative to the estimated $2.24 billion reduction in spending estimated for the proposal to offer a July 1, 2019 start date for new agreement periods under the proposed changes.

We also considered the potential impact of the alternative of allowing ACOs to elect a beneficiary opt-in based assignment methodology supplemented by a modified claims-based assignment methodology for beneficiaries who have received the plurality of their primary care and at least seven primary care services, from one or more ACO professionals in the ACO during the applicable assignment window and voluntary alignment. However, significant uncertainties potentially impacting the program in offsetting ways make projecting the impact of such proposal difficult. Although it is possible that ACOs electing such methodology could more effectively target care management to more engaged and/or needier subpopulations of patients, it is also possible that such targeting could deter ACOs from deploying more comprehensive care delivery reform across a wider mix of patients served by ACO providers/suppliers. It is also unclear if many ACOs would see value in a more restrictive assignment approach as they may be hesitant to voluntarily reduce their overall number of assigned beneficiaries and consequently lower their total benchmark spending and the magnitude of potential shared savings. Furthermore, it is not currently empirically possible to determine if the potential method for adjusting benchmark expenditures that is described in the proposed rule would provide sufficient accuracy in setting spending targets or if it could be vulnerable to higher claims variation and/or bias because of the selective

nature of beneficiaries who opt in, voluntarily align, or meet the modified claims-based assignment criteria in order to be assigned to the ACO. Such uncertainties and challenges may be likely to dissuade ACOs from electing such alternative assignment methodology over the existing options rooted in a broader claims-based assignment methodology supplemented by voluntary alignment, which current experience shows generally duplicates assignment for a subset of beneficiaries that would have been assigned regardless via the existing claims-based assignment methodology. If few ACOs were to elect this potential alternative assignment methodology then the impact on program spending would also be minimal.

E. Compliance With Requirements of Section 1899(i)(3)(B) of the Act

Certain policies, including both existing policies and the proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare FFS beneficiaries. Section 1899(i)(3)(B) of the Act requires that such other payment model must not result in additional program expenditures. Policies falling under the authority of section 1899(i)(3) of the Act include— (1) performance-based risk; (2) refining the calculation of national expenditures used to update the historical benchmark to reflect the assignable subpopulation of total FFS enrollment; (3) updating benchmarks with a blend of regional and national trends as opposed to the national average absolute growth in per capita spending; (4) reconciling the two 6-month performance years during 2019 based on expenditures for all of CY 2019, and pro-rating any resulting shared savings or shared losses; and (5) adjusting performance year expenditures to remove IME, DSH, and uncompensated care payments.

A comparison was constructed between the projected impact of the payment methodology that incorporates all changes and a hypothetical baseline payment methodology that excludes the elements described previously that require section 1899(i)(3) of the Act authority—most importantly performance-based risk in the ENHANCED track and Levels C, D, and E of the BASIC track and updating benchmarks using a blend of regional and national trends. The hypothetical baseline was assumed to include adjustments allowed under section 1899(d)(1)(B)(ii) of the Act including the up to 50 percent weight used in calculating the regional adjustment to the ACO's rebased historical benchmark, as proposed in this rule (depending on the number of rebasings and the direction of the adjustment), capped at positive or negative 5 percent of national average per capita FFS expenditures for assignable beneficiaries. The stochastic model and associated assumptions described previously in this section were adapted to reflect a higher range of potential participation given the perpetually sharing-only incentive structure of the hypothetical baseline model. Such analysis estimated approximately $3 billion greater average net program savings under the alternative payment model that includes all policies that require the authority of section 1899(i)(3) of Act than would be expected under the hypothetical baseline in total over the 2019 to 2028 projection period. The alternative payment model, as proposed in this rule, is projected to result in greater savings on benefit costs and reduced net payments to ACOs. In the final projection year, the alternative payment model is estimated to have 14 percent greater savings on benefit costs, 9 percent lower spending on net shared savings payments to ACOs, with 46 percent reduced overall ACO participation compared to the hypothetical baseline model.

Participation in performance-based risk in the ENHANCED track and the later years of the BASIC track is assumed to improve the incentive for ACOs to increase the efficiency of care for beneficiaries (similar to the assumptions used in the modeling of the impacts, described previously). Such added savings are partly offset by lower participation associated with the requirement to transition to performance-based risk. Despite the higher maximum sharing rate of 75 percent in the ENHANCED track under the alternative payment model under section 1899(i)(3) of the Act relative to the 50 percent maximum sharing rate assumed for the single one-sided risk track under the hypothetical baseline, shared savings payments are expected to be reduced relative to the hypothetical baseline because of lower expected participation resulting from the elimination of Track 1, more accurate benchmarks due to the incorporation of regional factors into the calculation of benchmark updates for all ACOs, and the cap on the regional benchmark adjustment of positive or negative 5 percent of the national average per capita FFS spending amount for assignable beneficiaries.

We will reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

F. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866, in Table 18, we have prepared an accounting statement showing the change in—(1) net federal monetary transfers; (2) shared savings payments to ACOs net of shared loss payments from ACOs; and (3) incentive payments made under the Quality Payment Program to additional ACO providers/suppliers expected to become Qualifying APM Participants from 2019 to 2028 who would not have been expected to achieve such status absent the proposed changes.

TABLE 18—ACCOUNTING STATEMENT ESTIMATED IMPACTS

[CYs 2019–2028]

Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation (RIA, preamble, etc.)
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%.	−168.9 million	103.3 million	−427.6 million	Table 17.

TABLE 18—ACCOUNTING STATEMENT ESTIMATED IMPACTS—Continued

[CYs 2019–2028]

Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation (RIA, preamble, etc.)
Annualized monetized: Discount rate: 3%.	−199.8 million	78.9 million	−466.0 million	

Notes: Negative values reflect reduction in federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

G. Regulatory Reform Analysis Under Executive Order 13771

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. The proposed modifications in this proposed rule are expected to primarily have effects on transfers via lower claims spending and shared savings outlays as described previously in this regulatory impact analysis. However these modifications are also anticipated to marginally reduce the administrative burden on participating ACOs by roughly $5.67 million over 10 years (as detailed previously in this RIA); therefore this proposed rule, if finalized, would be considered a deregulatory action under Executive Order 13771.

H. Conclusion

The analysis in this section, together with the remainder of this preamble, provides a regulatory impact analysis. As a result of this proposed rule, the median estimate of the financial impact of the Shared Savings Program for CYs 2019 through 2028 would be net federal savings of $2.24 billion greater than the expected savings if no changes were made. Although this is the best estimate of the financial impact of the Shared Savings Program during CYs 2019 through 2028, a relatively wide range of possible outcomes exists. While roughly 89 percent of the stochastic trials resulted in an overall increase in net program savings over 10 years, the 10th and 90th percentiles of the estimated distribution show a net increase in costs by $0.09 billion and a net decrease in costs by $4.43 billion, respectively.

Overall, our analysis projects that faster transition from one-sided model agreements—tempered by the option for eligible ACOs of a gentler exposure to downside risk calculated as a percentage of ACO participants' total Medicare Parts A and B FFS revenue and capped at a percentage of the ACO's benchmark—can affect broader participation in performance-based risk in the Shared Savings Program and reduce overall claims costs. A second key driver of estimated net savings is the reduction in shared savings payments from the proposed limitation on the amount of the regional adjustment to the ACO's historical benchmark. Such reduction in overall shared savings payments is projected to result despite the benefit of higher net adjustments expected for a larger number of ACOs from the use of a simpler HCC risk adjustment methodology, the blending of national and regional trends for benchmark calculations, and longer 5-year agreement periods that allow ACOs a longer horizon from which to benefit from efficiency gains before benchmark rebasing.

Therefore, the proposed changes are expected to improve the incentive for ACOs to invest in effective care management efforts, increase the number of ACOs participating under performance-based risk by discontinuing Track 1 and Track 2, and offering instead a BASIC track (which includes a glide path from a one-sided model to performance-based risk for eligible ACOs) or the ENHANCED track (based on the current design of Track 3), reduce the number of ACOs with poor financial and quality performance (by eliminating Track 1, requiring faster transition to performance-based risk, limiting high revenue ACOs to one agreement period in the BASIC track and low revenue ACOs to 2 agreement periods in the BASIC track (second agreement period at Level E), and increasing the monitoring of ACO financial performance), and result in greater overall gains in savings on FFS benefit claims costs while decreasing expected shared savings payments to ACOs.

We intend to monitor emerging results for ACO effects on claims costs, changing participation (including risk for cost due to selective changes in participation), and unforeseen bias in benchmark adjustments due to diagnosis coding intensity shifts.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR parts 414 and 425 as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 2. Section 414.1415(a)(1)(ii) is revised to read as follows:

§ 414.1415 Advanced APM criteria.

(a) * * *

(1) * * *

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of

CEHRT of the eligible clinicians in the APM Entity.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 1. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302, 1306, 1395hh, and 1395jjj).

■ 2. Section 425.20 is amended—

■ a. By revising the definition of ''Agreement period'';

■ b. By adding in alphabetical order definitions for ''Certified Electronic Health Record Technology (CEHRT)'', ''Eligible clinician'', ''Experienced with performance-based risk Medicare ACO initiatives'', ''High revenue ACO'', ''Inexperienced with performance-based risk Medicare ACO initiatives'', and ''Low revenue ACO'';

■ c. By revising the definition of ''Performance year''; and

■ d. By adding in alphabetical order definitions for ''Performance-based risk Medicare ACO initiative'', ''Re-entering ACO'', and ''Renewing ACO''.

The revisions and additions read as follows:

§ 425.20 Definitions.

* * * * *

Agreement period means the term of the participation agreement.

* * * * *

Certified Electronic Health Record Technology (CEHRT) has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

Eligible clinician has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

Experienced with performance-based risk Medicare ACO initiatives means an ACO that CMS determines meets the criteria in either paragraph (1) or (2) of this definition.

(1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative as defined under this section, or that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, as defined under this section, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years prior to the agreement start date.

* * * * *

High revenue ACO means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is at least 25 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

* * * * *

Inexperienced with performance-based risk Medicare ACO initiatives means an ACO that CMS determines meets all of the following:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under this section, and has not deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, as defined under this section, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years prior to the agreement start date.

Low revenue ACO means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 25 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

* * * * *

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement.

Performance-based risk Medicare ACO initiative means, for purposes of this part, an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period, including the following options and initiatives:

(1) Participation options within the Shared Savings Program as follows:

(i) BASIC track (Levels A through E).

(ii) ENHANCED track.

(iii) Track 2.

(2) The Innovation Center ACO models under which an ACO accepts risk for shared losses as follows:

(i) Pioneer ACO Model.

(ii) Next Generation ACO Model.

(iii) Comprehensive ESRD Care Model two-sided risk tracks.

(iv) Track 1+ Model.

(3) Other initiatives involving two-sided risk as may be specified by CMS.

* * * * *

Re-entering ACO means an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions:

(1) Is the same legal entity as an ACO, as defined in this section, that previously participated in the program and is applying to participate in the program after a break in participation, because it is either—

(i) An ACO whose participation agreement expired without having been renewed; or

(ii) An ACO whose participation agreement was terminated under § 425.218 or § 425.220.

(2) Is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

Renewing ACO means an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either —

(1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or

(2) An ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program.

* * * * *

§ 425.100 [Amended]

■ 3. Section 425.100 is amended—

■ a. In paragraph (b) by removing the phrase ''under § 425.604, § 425.606 or § 425.610'' and adding in its place the phrase ''under § 425.604, § 425.605, § 425.606, § 425.609 or § 425.610''; and

■ b. In paragraph (c) by removing the phrase ''under § 425.606 or § 425.610'' and adding in its place the phrase ''under § 425.605, § 425.606, § 425.609 or § 425.610''.

■ 4. Section 425.110 is amended by revising paragraph (b) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

* * * * *

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218.

(1) While under a CAP, the ACO remains eligible for shared savings and losses.

(2) If the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year.

(3) In determining financial performance for an ACO with fewer than 5,000 assigned beneficiaries, the MSR/MLR is calculated as follows:

(i) For ACOs with a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) are set at a level consistent with the number of assigned beneficiaries.

(ii) For performance years starting before January 1, 2019, for ACOs with a fixed MSR/MLR, the MSR/MLR remains fixed at the level consistent with the choice of MSR and MLR that the ACO made at the start of the agreement period.

(iii) For performance years starting in 2019 and in subsequent years, for ACOs that selected a fixed MSR/MLR at the start of the agreement period or prior to entering a two-sided model during their agreement period, the MSR/MLR is calculated as follows:

(A) The MSR/MLR is set at a level based on the number of beneficiaries assigned to the ACO.

(*1*) The MSR is the same as the MSR that would apply in a one-sided model under § 425.604(b) (for Track 2 ACOs) or § 425.605(b)(1) (for BASIC track and ENHANCED track ACOs) and is based on the number of assigned beneficiaries.

(*2*) The MLR is equal to the negative MSR.

(B) The MSR and MLR revert to the fixed level previously selected by the ACO for any subsequent performance year in the agreement period in which the ACO's assigned beneficiary population is 5,000 or more.

§ 425.118 [Amended]

■ 5. Section 425.118 is amended in paragraph (b)(1)(iii) by removing the phrase ''screening performed under § 425.304(b)'' and adding in its place the phrase ''screening performed under § 425.305(a)''.

■ 6. Section 425.200 is amended—

■ a. By revising paragraph (a);

■ b. By revising the heading of paragraph (b);

■ c. By removing paragraph (b)(2) introductory text, adding a heading for paragraph (b)(2), and revising paragraph (b)(2)(ii);

■ d. By removing paragraph (b)(3) introductory text, adding a heading for paragraph (b)(3), and revising paragraph (b)(3)(ii);

■ e. By adding paragraphs (b)(4) and (5);

■ f. By revising paragraphs (c) and (d);

■ g. By redesignating paragraphs (e)(1)(i) through (v) as paragraphs (e)(1)(ii) through (vi); and

■ h. By adding a new paragraph (e)(1)(i).

The revisions and additions read as follows:

§ 425.200 Participation agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than the number of years specified in this section.

(b) *Agreement period.* * * *

(2) *For 2013 and through 2016.* * * *

(ii) The term of the participation agreement is 3 years unless all of the following conditions are met to extend the participation agreement by 6 months:

(A) The ACO entered an agreement period starting on January 1, 2016.

(B) The ACO elects to extend its agreement period until June 30, 2019.

(*1*) The ACO's election to extend its agreement period is made in the form and manner and according to the timeframe established by CMS; and

(*2*) An ACO executive who has the authority to legally bind the ACO must certify the election described in paragraph (b)(2)(ii)(B) of this section.

(3) *For 2017 and 2018.* * * *

(ii) The term of the participation agreement is 3 years, except for an ACO whose first agreement period in Track 1 began in 2014 or 2015, in which case the term of the ACO's initial agreement period under Track 1 (as described under § 425.604) may be extended, at the ACO's option, for an additional year for a total of 4 performance years if the conditions specified in paragraph (e) of this section are met.

(4) *For 2019.* (i) The start date is January 1, 2019, and the term of the participation agreement is 3 years for ACOs whose first agreement period began in 2015 and who deferred renewal of their participation agreement under paragraph (e) of this section; or

(ii) The start date is July 1, 2019, and the term of the participation agreement is 5 years and 6 months.

(5) *For 2020 and subsequent years.* (i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 5 years.

(c) *Performance year.* The ACO's performance year under the participation agreement is the 12 month period beginning on January 1 of each year during the term of the participation agreement unless otherwise noted in its participation agreement, and except as follows:

(1) For an ACO with a start date of April 1, 2012, or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(2) For an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period under paragraph (b)(2)(ii)(B) of this section, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

(3) For an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019.

(d) *Submission of measures.* For each performance year of the agreement period, ACOs must submit measures in the form and manner required by CMS according to § 425.500(c), and as applicable according to §§ 425.608 and 425.609.

(e) * * *

(1) * * *

(i) The ACO's first agreement period in the Shared Savings Program under Track 1 began in 2014 or 2015.

* * * * *

■ 7. Section 425.202 is amended by adding paragraph (b) introductory text to read as follows:

§ 425.202 Application procedures.

* * * * *

(b) * * * For determining eligibility for agreement periods beginning before July 1, 2019:

* * * * *

■ 8. Section 425.204 is amended—

■ a. By adding paragraph (c)(7);

■ b. By revising paragraph (f); and

■ c. In paragraph (g) introductory text by removing the phrase ''under § 425.602,'' and adding in its place the phrase ''under § 425.601, § 425.602, § 425.603 or § 425.609,''.

The addition and revision read as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(7) The ACO must certify, in a form and manner specified by CMS, that the

percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay all shared losses for which it may be liable under a two-sided model.

(2) An ACO that will participate in a two-sided model must establish one or more of the following repayment mechanisms in an amount and by a deadline specified by CMS in accordance with this section:

(i) An escrow account with an insured institution.

(ii) A surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies.

(iii) A line of credit at an insured institution (as evidenced by a letter of credit that the Medicare program can draw upon).

(3) An ACO that will participate under a two-sided model of the Shared Savings Program must submit for CMS approval documentation that it is capable of repaying shared losses that it may incur during its agreement period, including details supporting the adequacy of the repayment mechanism.

(i) An ACO participating in Track 2 or the ENHANCED track must demonstrate the adequacy of its repayment mechanism prior to the start of each agreement period in which it takes risk and at such other times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period and at such other times as requested by CMS.

(iii) An ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to a two-sided model, Level C, Level D, or Level E, of the BASIC track, and at such other times as requested by CMS.

(iv) An ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the ACO, provided that the ACO submits documentation establishing that the amount and duration of the existing repayment mechanism have been revised to comply with paragraphs (f)(4)(iv) and (f)(6)(ii) of this section.

(4) CMS calculates the amount of the repayment mechanism as follows:

(i) For a Track 2 or ENHANCED track ACO, the repayment mechanism amount must be equal to at least 1 percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.

(ii) For a BASIC track ACO, the repayment mechanism amount must be equal to the lesser of the following:

(A) One percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.

(B) Two percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

(iii) For agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period in accordance with this section based on the certified ACO participant list for the relevant performance year.

(A) If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 10 percent or $100,000, whichever is the lesser value, CMS notifies the ACO that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount.

(B) Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS approval documentation that the amount of its repayment mechanism has been increased to the amount specified by CMS.

(iv) In the case of an ACO that has submitted a request to renew its participation agreement and wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to the greater of the following:

(A) The amount calculated by CMS in accordance with either paragraph (f)(4)(i) or (ii) of this section, as applicable.

(B) The repayment mechanism amount that the ACO was required to maintain during the last performance year of the participation agreement it seeks to renew.

(5) After the repayment mechanism has been used to repay any portion of shared losses owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days.

(6) The repayment mechanism must be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period, except as follows:

(i) CMS may require the ACO to extend the duration of the repayment mechanism if necessary to ensure that the ACO fully repays CMS any shared losses for each of the performance years of the agreement period.

(ii) In the case of a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the duration of the existing repayment mechanism must be extended by an amount of time specified by CMS and must be periodically extended thereafter upon notice from CMS.

(iii) The repayment mechanism may be terminated at the earliest of the following conditions:

(A) The ACO has fully repaid CMS any shared losses owed for each of the performance years of the agreement period under a two-sided model.

(B) CMS has exhausted the amount reserved by the ACO's repayment mechanism and the arrangement does not need to be maintained to support the ACO's participation under the Shared Savings Program.

(C) CMS determines that the ACO does not owe any shared losses under the Shared Savings Program for any of the performance years of the agreement period.

* * * * *

§ 425.220 [Amended]

■ 9. Section 425.220 is amended in paragraph (a) by removing the phrase ''60 days'' and adding in its place the phrase ''30 days''.

■ 10. Section 425.221 is amended by revising paragraph (b) to read as follows:

§ 425.221 Close-out procedures and payment consequences of early termination.

* * * * *

(b) *Payment consequences of early termination*—(1) *Receipt of shared savings.* (i) Except as set forth in paragraph (b)(3)(i) of this section, an ACO that terminates its participation agreement under § 425.220 is eligible to receive shared savings for the performance year during which the termination becomes effective only if all of the following conditions are met:

(A) CMS designates or approves an effective date of termination of one of the following:

(*1*) December 31st for a 12-month performance year.

(*2*) December 31st for a 6-month performance year starting on July 1, 2019.

(*3*) June 30th for a 6-month performance year starting on January 1, 2019.

(B) The ACO has completed all close-out procedures by the deadline specified by CMS.

(C) The ACO has satisfied the criteria for sharing in savings for the performance year.

(ii) If the participation agreement is terminated at any time by CMS under § 425.218, the ACO is not eligible to receive shared savings for the performance year during which the termination becomes effective.

(2) *Payment of shared losses.* Except as set forth in paragraphs (b)(3)(i) and (ii) of this section, for performance years beginning in 2019 and subsequent performance years, an ACO under a two-sided model is liable for a pro-rated share of any shared losses as follows if its participation agreement is terminated effective before the last day of a performance year:

(i) An ACO under a two-sided model that terminates its participation agreement under § 425.220 with an effective date of termination after June 30th of a 12-month performance year is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective.

(ii) An ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective.

(iii) The pro-rated share of losses described in paragraphs (b)(2)(i) and (ii) of this section is calculated as follows:

(A) In the case of a 12-month performance year: The shared losses incurred during the 12 months of the performance year are multiplied by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12.

(B) In the case of a 6-month performance year during 2019: The shared losses incurred during CY 2019 are multiplied by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12.

(3) *Exceptions.* (i) An ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and that enters a new agreement period beginning on July 1, 2019, is eligible for pro-rated shared savings or shared losses for the 6-month period from January 1, 2019, through June 30, 2019, as determined in accordance with § 425.609.

(ii) An ACO under a two-sided model that terminates its participation agreement under § 425.220 during a 6-month performance year with an effective date of termination prior to the last calendar day of the performance year is not liable for shared losses incurred during the performance year.

■ 11. Section 425.222 is amended by revising the section heading and paragraphs (a), (b), and (c) introductory text to read as follows:

§ 425.222 Eligibility to re-enter the program for agreement periods beginning before July 1, 2019.

(a) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, the ACO may participate in the Shared Savings Program again only after the date on which the term of its original participation agreement would have expired if the ACO had not been terminated.

(b) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, an ACO whose participation agreement was previously terminated must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it remains in compliance with the terms of the new participation agreement.

(c) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, an ACO whose participation agreement was previously terminated or expired without having been renewed may re-enter the program for a subsequent agreement period.

* * * * *

■ 12. Section 425.224 is amended—

■ a. By revising the section heading and paragraph (a);

■ b. By revising paragraph (b) heading and paragraphs (b)(1) introductory text and (b)(1)(ii);

■ c. By removing paragraphs (b)(1)(iv) and (v);

■ d. By redesignating paragraphs (b)(1)(iii) and (vi) as paragraphs (b)(1)(iv) and (v);

■ e. By adding a new paragraph (b)(1)(iii);

■ f. By revising newly redesignated paragraphs (b)(1)(iv) and (v);

■ g. In paragraph (b)(2) introductory text by removing the phrase ''Renewal requests'' and adding in its place the phrase ''Applications'';

■ h. In paragraph (b)(2)(i) by removing the phrase ''renewal request'' and adding in its place the phrase ''application''; and

■ i. In paragraphs (c)(1) and (2) introductory text by removing the phrase ''renewal request'' and adding in its place the phrase ''application''.

The revisions and addition read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

(a) *General rules.* A renewing ACO or a re-entering ACO may apply to enter a new participation agreement with CMS for participation in the Shared Savings Program.

(1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, the ACO must submit a complete application in the form and manner and by the deadline specified by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to enter a new participation agreement under the Shared Savings Program and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of its application with the Antitrust Agencies.

(4) The ACO must select a participation option in accordance with the requirements specified in § 425.600. Regardless of the date of termination or expiration of the participation agreement, a renewing ACO or re-entering ACO that was previously under a two-sided model, or a one-sided

model of the BASIC track's glide path (Level A or Level B), may only reapply for participation in a two-sided model.

(b) *Review of application.* (1) CMS determines whether to approve a renewing ACO's or re-entering ACO's application based on an evaluation of all of the following factors:

* * * * *

(ii) The ACO's history of noncompliance with the requirements of the Shared Savings Program, including, but not limited to, the following factors:

(A)(*1*) For an ACO that entered into a participation agreement for a 3-year period, we consider whether the ACO failed to meet the quality performance standard during 1 of the first 2 performance years of the previous agreement period.

(*2*) For an ACO that entered into a participation agreement for a period longer than 3 years, we consider whether the ACO failed to meet the quality performance standard in either of the following:

(*i*) In 2 consecutive performance years and was terminated as specified in § 425.316(c)(2).

(*ii*) For 2 or more performance years of the previous agreement period, regardless of whether the years are in consecutive order.

(B) For 2 performance years of the ACO's previous agreement period, regardless of whether the years are in consecutive order, whether the average per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiary population exceeded its updated benchmark by an amount equal to or exceeding either of the following:

(*1*) The ACO's negative MSR, under a one-sided model.

(*2*) The ACO's MLR, under a two-sided model.

(C) Whether the ACO failed to repay shared losses in full within 90 days as required under subpart G of this part for any performance year of the ACO's previous agreement period in a two-sided model.

(D) For an ACO that has participated in a two-sided model authorized under section 1115A of the Act, whether the ACO failed to repay shared losses for any performance year as required under the terms of the ACO's participation agreement for such model.

(iii) Whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused any noncompliance identified in paragraph (b)(1)(ii) of this section to occur, and any other factors that may have caused the ACO to be terminated from the Shared Savings Program, and has processes in place to ensure that it remains in compliance with the terms of the new participation agreement.

(iv) Whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program to enter a new participation agreement, including the ability to repay losses by establishing an adequate repayment mechanism under § 425.204(f), if applicable.

(v) The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.305(a)).

* * * * *

■ 13. Section 425.226 is added to subpart C to read as follows:

§ 425.226 Annual participation elections.

(a) *General.* This section applies to ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. Before the start of a performance year, an ACO may make elections related to its participation in the Shared Savings Program, as specified in this section, effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election in accordance with this section.

(1) *Selection of beneficiary assignment methodology.* An ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under subpart E of this part. An ACO may select either of the following:

(i) Preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2).

(ii) Prospective assignment, as described in § 425.400(a)(3).

(2) *Selection of BASIC track level.* An ACO participating under the BASIC track in the glide path may select a higher level of risk and potential reward, as provided in this section.

(i) An ACO participating under the BASIC track's glide path may elect to transition to a higher level of risk and potential reward within the glide path than the level of risk and potential reward that the ACO would be automatically transitioned to in the applicable year as specified in § 425.605(d)(1). The automatic transition to higher levels of risk and potential reward within the BASIC track's glide path continues to apply to all subsequent years of the agreement period in the BASIC track.

(ii) An ACO transitioning to a higher level of risk and potential reward under paragraph (a)(2)(i) of this section must meet all requirements to participate under the selected level of performance-based risk, including both of the following:

(A) Establishing an adequate repayment mechanism as specified under § 425.204(f).

(B) Selecting a MSR/MLR from the options specified under § 425.605(b).

(b) *Election procedures.* (1) All annual elections must be made in a form and manner and according to the timeframe established by CMS.

(2) ACO executive who has the authority to legally bind the ACO must certify the elections described in this section.

■ 14. Section 425.302 is amended—

■ a. In paragraph (a)(3)(i) by removing the phrase ''requirements; and'' and adding in its place the phrase ''requirements;'';

■ b. In paragraph (a)(3)(ii) by removing the phrase ''owed to CMS.'' and adding in its place the phrase ''owed to CMS; and''; and

■ c. Adding paragraph (a)(3)(iii).

The addition reads as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iii) That the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

■ 15. Section 425.304 is revised to read as follows:

§ 425.304 Beneficiary incentives.

(a) *General.* (1) Except as set forth in this section, or as otherwise permitted by law, ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Nothing in this section shall be construed as prohibiting an ACO from using shared savings received under this part to cover the cost of an in-kind item or service or incentive payment provided to a beneficiary under paragraph (b) or (c) of this section.

(b) *In-kind incentives.* ACOs, ACO participants, ACO providers/suppliers,

and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to Medicare fee-for-service beneficiaries if all of the following conditions are satisfied:

(1) There is a reasonable connection between the items and services and the medical care of the beneficiary.

(2) The items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.

(3) The in-kind item or service is not a Medicare-covered item or service for the beneficiary on the date the in-kind item or service is furnished to the beneficiary.

(c) *Monetary incentives*—(1) *General.* For performance years beginning on July 1, 2019 and for subsequent performance years, an ACO that is participating under Track 2, Levels C, D, or E of the BASIC track, or the ENHANCED track may, in accordance with this section, establish a beneficiary incentive program to provide monetary incentive payments to Medicare fee-for-service beneficiaries who receive a qualifying service.

(2) *Application procedures.* (i) To establish or reestablish a beneficiary incentive program, an ACO must submit a complete application in the form and manner and by a deadline specified by CMS.

(ii) CMS evaluates an ACO's application to determine whether the ACO satisfies the requirements of this section, and approves or denies the application.

(3) *Beneficiary incentive program requirements.* An ACO must begin to operate its approved beneficiary incentive program beginning on July 1, 2019 or January 1 of the relevant performance year.

(i) *Duration.* (A) Subject to the termination provision at paragraph (c)(7) of this section, an ACO must operate a beneficiary incentive program for an initial period of 18 months in the case of an ACO approved to operate a beneficiary incentive program beginning on July 1, 2019, or 12 months in the case of an ACO approved to operate a beneficiary incentive program beginning on January 1 of a performance year.

(B) For each consecutive year that an ACO wishes to operate its beneficiary incentive program after the CMS-approved initial period, it must certify both of the following by a deadline specified by CMS:

(*1*) Its intent to continue to operate the beneficiary incentive program for the entirety of the relevant performance year.

(*2*) That the beneficiary incentive program meets all applicable requirements.

(ii) *Beneficiary eligibility.* A fee-for-service beneficiary is eligible to receive an incentive payment under a beneficiary incentive program if the beneficiary is assigned to the ACO through either of the following:

(A) Preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2).

(B) Prospective assignment, as described in § 425.400(a)(3).

(iii) *Qualifying service.* For purposes of this section, a qualifying service is a primary care service (as defined in § 425.20) with respect to which coinsurance applies under Part B, if the service is furnished through an ACO by one of the following:

(A) An ACO professional who has a primary care specialty designation included in the definition of primary care physician under § 425.20.

(B) An ACO professional who is a physician assistant, nurse practitioner, or certified nurse specialist.

(C) A FQHC or RHC.

(iv) *Incentive payments.* (A) An ACO that establishes a beneficiary incentive program must furnish an incentive payment for each qualifying service furnished to a beneficiary described in paragraph (c)(3)(ii) of this section in accordance with this section.

(B) Each incentive payment made by an ACO under a beneficiary incentive program must satisfy all of the following conditions:

(*1*) The incentive payment is in the form of a check, debit card, or a traceable cash equivalent.

(*2*) The value of the incentive payment does not exceed $20, as adjusted annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, rounded to the nearest whole dollar amount.

(*3*) The incentive payment is provided by the ACO to the beneficiary no later than 30 days after a qualifying service is furnished.

(*4*) The incentive payment is not offered as part of an advertisement or solicitation to a beneficiary or any potential patient whose care is paid for in whole or in part by a Federal health care program (as defined at 42 U.S.C. 1320a–7b(f)).

(C) An ACO must furnish incentive payments in the same amount to each eligible Medicare fee-for-service beneficiary without regard to enrollment of such beneficiary in a Medicare supplemental policy (described in section 1882(g)(1) of the Act), in a State Medicaid plan under title XIX or a waiver of such a plan, or in any other health insurance policy or health benefit plan.

(4) *Program integrity requirements*—(i) *Record retention.* An ACO that establishes a beneficiary incentive program must maintain records related to the beneficiary incentive program that include the following:

(A) Identification of each beneficiary that received an incentive payment, including beneficiary name and HICN or Medicare beneficiary identifier.

(B) The type and amount of each incentive payment made to each beneficiary.

(C) The date each beneficiary received a qualifying service, the corresponding HCPCS code for the qualifying service, and identification of the ACO provider/supplier that furnished the qualifying service.

(D) The date the ACO provided each incentive payment to each beneficiary.

(ii) *Source of funding.* (A) An ACO must not use funds from any entity or organization outside of the ACO to establish or operate a beneficiary incentive program.

(B) An ACO must not directly, through insurance, or otherwise, bill or otherwise shift the cost of establishing or operating a beneficiary incentive program to a Federal health care program.

(5) *Effect on program calculations.* CMS disregards incentive payments made by an ACO under paragraph (c) of this section in calculating an ACO's benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses.

(6) *Income exemptions.* Incentive payments made under a beneficiary incentive program are not considered income or resources or otherwise taken into account for purposes of either of the following:

(i) Determining eligibility for benefits or assistance (or the amount or extent of benefits or assistance) under any Federal program or under any State or local program financed in whole or in part with Federal funds.

(ii) Any Federal or State laws relating to taxation.

(7) *Termination.* CMS may require an ACO to terminate its beneficiary incentive program at any time for either of the following:

(i) Failure to comply with the requirements of this section.

(ii) Any of the grounds for ACO termination set forth in § 425.218(b).

■ 16. Section 425.305 is added to read as follows:

§ 425.305 Other program safeguards.

(a) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers are reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(b) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from doing the following:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

■ 17. Section 425.308 is amended by revising paragraph (b)(6) and adding paragraph (b)(7) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(6) Use of payment rule waivers under § 425.612, if applicable or telehealth services under § 425.613, if applicable or both.

(7) Information about a beneficiary incentive program established under § 425.304(c), if applicable, including the following, for each performance year:

(i) Total number of beneficiaries who received an incentive payment.

(ii) Total number of incentive payments furnished.

(iii) HCPCS codes associated with any qualifying service for which an incentive payment was furnished.

(iv) Total value of all incentive payments furnished.

(v) Total of each type of incentive payment (for example, check or debit card) furnished.

* * * * *

■ 18. Section 425.310 is amended by revising paragraph (c)(3) to read as follows:

§ 425.310 Marketing requirements.

* * * * *

(c) * * *

(3) Comply with § 425.304 regarding beneficiary incentives.

* * * * *

■ 19. Section 425.312 is amended by revising the section heading and paragraph (a) and adding paragraph (b) to read as follows:

§ 425.312 Beneficiary notifications.

(a) An ACO participant must notify Medicare fee-for-service beneficiaries at the point of care about all of the following:

(1) Its ACO providers/suppliers are participating in the Shared Savings Program.

(2) The beneficiary's opportunity to decline claims data sharing under § 425.708.

(3) Beginning July 1, 2019, the beneficiary's ability to, and the process by which, he or she may identify or change identification of a primary care provider for purposes of voluntary alignment (as described in § 425.402(e)).

(b) Notification of the information specified in paragraph (a) of this section must be carried out by an ACO participant through all of the following methods:

(1) Posting signs in its facilities and, in settings in which beneficiaries receive primary care services, making standardized written notices available upon request.

(2) Beginning July 1, 2019, providing each beneficiary with a standardized written notice at the first primary care visit of each performance year in the form and manner specified by CMS.

* * * * *

■ 20. Section 425.314 is amended by adding paragraph (a)(4) and revising paragraph (b)(1) to read as follows:

§ 425.314 Audits and record retention.

(a) * * *

(4) The ACO's operation of a beneficiary incentive program.

(b) * * *

(1) To maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, information related to operation of a beneficiary incentive program, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

* * * * *

§ 425.315 [Amended]

■ 21. Section 425.315 is amended in paragraph (a)(1)(ii) by removing the phrase ''§ 425.604(f), § 425.606(h) or § 425.610(h)'' and adding in its place the phrase ''§ 425.604(f), § 425.605(e), § 425.606(h), § 425.609(e) or § 425.610(h)''.

■ 22. Section 425.316 is amended by adding paragraph (d) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(d) *Monitoring ACO financial performance.* (1) For performance years beginning in 2019 and subsequent performance years, CMS determines whether the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model, or the ACO's MLR under a two-sided model.

(2) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section, CMS may take any of the pre-termination actions set forth in § 425.216.

(3) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section for another performance year of the agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement under § 425.218.

■ 23. Section 425.400 is amended—

■ a. In paragraph (a)(1)(ii) by adding before the period, ''and, with respect to ACOs participating in a 6-month performance year during CY 2019, during the entirety of CY 2019 as specified in § 425.609'';

■ b. By revising the headings for paragraphs (a)(2) and (3);

■ c. In paragraph (a)(3)(i) by removing the phrase ''under Track 3'';

■ d. By adding paragraph (a)(4);

■ e. By revising paragraphs (c)(1)(iv) introductory text, (c)(1)(iv)(A), (c)(1)(iv)(B) introductory text, and (c)(1)(iv)(B)(*5*); and

■ f. By adding paragraphs (c)(1)(iv)(B)(*6*) through (*10*).

The revisions and additions read as follows:

§ 425.400 General.

(a) * * *

(2) *Preliminary prospective assignment with retrospective reconciliation.** * *

(3) *Prospective assignment.* * * *

(4) *Assignment methodology applied to ACO.* (i) For agreement periods beginning before 2019, the applicable assignment methodology is determined based on track as specified in § 425.600(a).

(A) Preliminary prospective assignment with retrospective reconciliation as described in paragraph (a)(2) of this section applies to Track 1 and Track 2 ACOs.

(B) Prospective assignment as described in paragraph (a)(3) of this section applies to Track 3 ACOs.

(ii) For agreement periods beginning on July 1, 2019 and in subsequent years, an ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under this subpart.

(A) An ACO may select either of the following:

(*1*) Preliminary prospective assignment with retrospective reconciliation, as described in paragraph (a)(2) of this section.

(*2*) Prospective assignment, as described in paragraph (a)(3) of this section.

(B) This selection is made prior to the start of each agreement period, and may be modified prior to the start of each performance year as specified in § 425.226.

* * * * *

(c) * * *

(1) * * *

(iv) For performance years starting on January 1, 2019, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*2*) 99304 through 99318 (codes for professional services furnished in a nursing facility; services identified by these codes furnished in a SNF are excluded).

(*3*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*4*) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).

(*5*) 99487, 99489 and 99490 (codes for chronic care management).

(*6*) 99495 and 99496 (codes for transitional care management services).

(*7*) 99497 and 99498 (codes for advance care planning).

(*8*) 96160 and 96161 (codes for administration of health risk assessment).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(B) HCPCS codes:

* * * * *

(*5*) G0444 (codes for annual depression screening service).

(*6*) G0442 (code for alcohol misuse screening service).

(*7*) G0443 (code for alcohol misuse counseling service).

(*8*) GPC1X (add-on code, for visit complexity inherent to evaluation and management associated with primary medical care services).

(*9*) GCG0X (add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care).

(*10*) GPRO1 (add-on code, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

■ 24. Section 425.401 is amended by revising paragraph (b) introductory text to read as follows:

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

* * * * *

(b) A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii) and (c)(1)(ii), if the beneficiary meets any of the following criteria during the performance or benchmark year:

* * * * *

■ 25. Section 425.402 is amended by revising paragraphs (e)(2) and (e)(3)(i) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) * * *

(2) Beneficiaries are added to the ACO's list of assigned beneficiaries if all of the following conditions are satisfied:

(i) For performance year 2018:

(A) The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(B) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to ACOs under all tracks based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section.

(C) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for coordinating their overall care.

(D) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as

defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary is not added to the ACO's list of assigned beneficiaries under the assignment methodology in paragraph (b) of this section.

(ii) For performance years starting on January 1, 2019, and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year or the ACO's list of assigned beneficiaries for a 6-month performance year, which is based on the entire CY 2019 as provided in § 425.609.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

(3) * * *

(i) Offering anything of value to the Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section. Any items or services provided in violation of paragraph (e)(3) of this section are not considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(b)(1).

* * * * *

§ 425.404 [Amended]

■ 26. Section 425.404 is amended in paragraph (b) by removing the phrase ''For performance year 2019 and subsequent performance years'' and adding in its place the phrase ''For performance years starting on January 1, 2019, and subsequent performance years''.

■ 27. Section 425.502 is amended—

■ a. In paragraph (e)(4)(v) by removing the phrase ''in the third year of the previous agreement period'' and adding in its place the phrase ''in the last year of the previous agreement period'';

■ b. In paragraph (e)(4)(vi) by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ c. By adding a new paragraph (e)(4)(vii);

■ d. By revising paragraph (f) introductory text;

■ e. By redesignating paragraphs (f)(1) and (2) as paragraphs (f)(2)(i) and (ii);

■ f. By adding a new paragraph (f)(1);

■ g. By adding a new paragraph (f)(2) introductory text;

■ h. In newly redesignated paragraph (f)(2)(i) by removing the phrase ''for performance year 2017'' and adding in its place the phrase ''for the relevant performance year'';

■ i. By removing paragraph (f)(4); and

■ j. By redesignating paragraph (f)(5) as paragraph (f)(4).

The revisions and additions read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(e) * * *

(4) * * *

(vii) For performance year 2017 and subsequent performance years, if an ACO receives the mean Shared Savings Program ACO quality score under paragraph (f) of this section, in the next performance year for which the ACO receives a quality performance score based on its own quality reporting, quality improvement is measured based on a comparison between the performance in that year and the most recently available prior performance year in which the ACO reported quality.

(f) *Extreme and uncontrollable circumstances.* For performance year 2017 and subsequent performance years, including the applicable quality data reporting period for the performance year if the quality reporting period is not extended, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraphs (a) through (e) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination for performance year 2017, CMS uses the final list of beneficiaries assigned to the ACO for the performance year. For performance year 2018 and subsequent performance years, CMS uses the list of assigned beneficiaries used to generate the Web Interface quality reporting sample.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (f)(1) of this section, CMS calculates the ACO's quality score as follows:

* * * * *

■ 28. Section 425.506 is amended—

■ a. In paragraph (b) by removing the phrase ''As part of the quality performance score'' and adding in its place the phrase ''For performance years 2012 through 2018, as part of the quality performance score'';

■ b. In paragraph (c) by removing the phrase ''Performance on this measure'' and adding in its place the phrase ''For performance years 2012 through 2018, performance on this measure'';

■ c. In paragraph (e) introductory text by removing the phrase ''For 2017 and subsequent years'' and adding in its place the phrase ''For 2017 and 2018''; and

■ d. By adding paragraph (f).

The addition reads as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(f) For performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track or a payment model within a track that—

(1) Does not meet the financial risk standard to be an Advanced APM must certify annually and at the time of application that the percentage of eligible clinicians participating in the

ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds 50 percent; or

(2) Meets the financial risk standard to be an Advanced APM must certify annually and at the time of application that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold established under § 414.1415(a)(1)(i) of this chapter.

■ 29. Section 425.600 is amended—

■ a. In paragraph (a) introductory text by removing the phrase ''For its initial agreement period, an ACO'' and adding in its place ''An ACO'';

■ b. By revising paragraphs (a)(1), (2) and (3);

■ c. By adding paragraph (a)(4);

■ d. By revising paragraphs (b) introductory text and (c); and

■ e. By adding paragraphs (d), (e) and (f).

The revisions and additions read as follows:

§ 425.600 Selection of risk model.

(a) * * *

(1) *Track 1.* For agreement periods beginning before July 1, 2019, an ACO in Track 1 operates under the one-sided model (as described under § 425.604) for the agreement period.

(2) *Track 2.* For agreement periods beginning before July 1, 2019, an ACO in Track 2 operates under a two-sided model (as described under § 425.606), sharing both savings and losses with the Medicare program for the agreement period.

(3) *ENHANCED track.* An ACO in the ENHANCED track operates under a two-sided model (as described under § 425.610), sharing both savings and losses with the Medicare program for the agreement period. For purposes of this part, all references to the ENHANCED track are deemed to include Track 3.

(4) *BASIC track.* For agreement periods beginning on July 1, 2019, and in subsequent years, an ACO in the BASIC track operates under either a one-sided model or a two-sided model (as described under § 425.605), either sharing savings only or sharing both savings and losses with the Medicare program, as specified in this paragraph (a)(4).

(i)(A) Under the BASIC track's glide path, the level of risk and potential reward phases in over the course of the agreement period in the following order:

(*1*) *Level A.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(i).

(*2*) *Level B.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(ii).

(*3*) *Level C.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iii).

(*4*) *Level D.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iv).

(*5*) *Level E.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(v).

(B)(*1*)(*i*) Except for an ACO that previously participated in Track 1 under paragraph (a)(1) of this section or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO, an ACO eligible to enter the BASIC track's glide path as determined under paragraphs (d)(1)(i) and (d)(2)(i) of this section may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section.

(*ii*) An ACO that previously participated in Track 1 under paragraph (a)(1) of this section or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*2*) through (*5*) of this section.

(*2*) Unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i), the ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track, except as provided in paragraph (a)(4)(i)(B)(*2*)(*i*) of this section.

(*i*) The automatic advancement does not apply at the start of the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019.

(*ii*) For performance year 2020, the ACO remains in the same level of the BASIC track's glide path that it entered for the July 1, 2019 through December 31, 2019 performance year, unless the ACO chooses to advance more quickly in accordance with § 425.226(a)(2)(i).

(*iii*) The ACO is automatically advanced to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period.

(*iv*) Prior to entering performance-based risk, an ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b).

(*3*) If the ACO fails to meet the requirements to participate under performance-based risk under paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section, the agreement is terminated.

(*4*) If, in accordance with § 425.226(a)(2)(i), the ACO elects to transition to a higher level of risk and reward available under paragraphs (a)(4)(i)(A)(*3*) through (*5*) of this section, then the automatic transition to levels of higher risk and reward specified in paragraph (a)(4)(i)(B)(*2*) of this section applies to all subsequent performance years of the agreement period.

(ii) If an ACO enters the BASIC track and is ineligible to participate under the glide path described in paragraph (a)(4)(i) of this section, as determined under paragraph (d) of this section, Level E as described in paragraph (a)(4)(i)(A)(*5*) of this section applies to all performance years of the agreement period.

(b) For agreement periods beginning before July 1, 2019, ACOs may operate under the one-sided model for a maximum of 2 agreement periods. An ACO may not operate under the one-sided model for a second agreement period unless the—

* * * * *

(c) For agreement periods beginning before July 1, 2019, an ACO experiencing a net loss during a previous agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period.

(d) For agreement periods beginning on July 1, 2019, and in subsequent years, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

(1) If an ACO is identified as a high revenue ACO, the ACO is eligible for the participation options indicated in paragraph (a) of this section as follows:

(i) If the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and

potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, except as provided in paragraph (a)(4)(i)(B) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(ii) If the ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter the ENHANCED track under paragraph (a)(3) of this section.

(2) If an ACO is identified as a low revenue ACO, the ACO is eligible for the participation options indicated in paragraph (a) of this section as follows:

(i) If the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, except as provided in paragraph (a)(4)(i)(B) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(ii) If the ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section, except as provided in paragraph (d)(3) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(3) Low revenue ACOs may participate under the BASIC track for a maximum of two agreement periods. A low revenue ACO may only participate in the BASIC track for a second agreement period if it satisfies either of the following:

(i) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track only one time.

(ii) For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track only one time.

(e) CMS monitors low revenue ACOs identified as experienced with performance-based risk Medicare ACO initiatives, during an agreement period in the BASIC track, for changes in the revenue of ACO participants that would cause the ACO to be considered a high revenue ACO and ineligible for participation in the BASIC track. If the ACO meets the definition of a high revenue ACO (as specified in § 425.20)—

(1) The ACO is permitted to complete the remainder of its current performance year under the BASIC track, but is ineligible to continue participation in the BASIC track after the end of that performance year if it continues to meet the definition of a high revenue ACO; and

(2) CMS takes compliance action as specified in §§ 425.216 and 425.218, up to and including termination of the participation agreement, to ensure the ACO does not continue in the BASIC track for subsequent performance years of the agreement period if it continues to meet the definition of a high revenue ACO.

(f) For agreement periods beginning on July 1, 2019, and in subsequent years, CMS determines the agreement period an ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods, as follows:

(1) An ACO entering an initial agreement period is considered to be entering a first agreement period in the Shared Savings Program.

(2) A re-entering ACO is considered to be entering a new agreement period in the Shared Savings Program as follows—

(i) An ACO whose participation agreement expired without having been renewed re-enters the program under the next consecutive agreement period in the Shared Savings Program;

(ii) An ACO whose participation agreement was terminated under § 425.218 or § 425.220 re-enters the program at the start of the same agreement period in which it was participating at the time of termination from the Shared Savings Program, beginning with the first performance year of that agreement period; or

(iii) A new ACO identified as a re-entering ACO enters the program in an agreement period that is determined based on the prior participation of the ACO in which the majority of the new ACO's participants were participating.

(A) If the participation agreement of the ACO used in this determination expired without having been renewed or was terminated, the agreement period of the re-entering ACO is determined in accordance with paragraph (f)(2)(i) or (ii) of this section, as applicable.

(B) If the ACO used in this determination is currently participating in the program, the new ACO is considered to be entering into the same agreement period as this currently participating ACO, beginning with the first performance year of that agreement period.

(3) A renewing ACO is considered to be entering the next consecutive agreement period in the Shared Savings Program.

(4) For purposes of this paragraph (f), program requirements that phase in over multiple agreement periods are as follows:

(i) The quality performance standard as described in § 425.502(a).

(ii) The weight used in calculating the regional adjustment to the ACO's historical benchmark as described in § 425.601(f).

(iii) The use of equal weights to weight each benchmark year as specified in § 425.601(e).

■ 30. Section 425.601 is added to read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures for an ACO's first agreement period.* For agreement periods beginning on July 1, 2019 and in subsequent years, in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.226(a)(1). CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) This calculation includes individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures

at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using a blend of national and regional growth rates.

(i) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year.

(iii) Regional growth rates are computed using expenditures for the ACO's regional service area for each of the years making up the historical benchmark as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the relevant benchmark year.

(B) Determine the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section.

(iv) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3, as calculated in paragraph (a)(5)(v) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(v) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area.

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures using BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark for an ACO's initial agreement period using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) Adjusts the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. CMS does all of the following:

(i) Calculates an average per capita amount of expenditures for the ACO's regional service area as follows:

(A) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(B) Determines the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section for BY3.

(C) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area identified for the 12-month calendar year that corresponds to BY3.

(ii) Calculates the adjustment as follows:

(A) Determines the difference between the average per capita amount of expenditures for the ACO's regional service area as specified under paragraph (a)(8)(i) of this section and the average per capita amount of the ACO's historical benchmark determined under paragraphs (a)(1) through (7) of this section, for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible for Medicare and Medicaid.

(*4*) Aged/non-dual eligible for Medicare and Medicaid.

(B) Applies a percentage, as determined in paragraph (f) of this section.

(C) Caps the per capita dollar amount for each Medicare enrollment type (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (a)(8)(ii)(B) of this section at a dollar amount equal to 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

(*1*) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(*2*) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted in accordance with § 425.118(b) for the addition and removal of ACO participants or ACO providers/suppliers, for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or both. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO under the ACO's most recent beneficiary assignment methodology selection in any of the 3 most recent years prior to the start of the agreement period using the most recent certified ACO participant list for the relevant performance year.

(ii) Redetermines the regional adjustment amount under paragraph (a)(8) of this section, according to the ACO's assigned beneficiaries for BY3 resulting from the ACO's most recent certified ACO participant list, the ACO's beneficiary assignment methodology selection under § 425.226(a)(1) for the relevant performance year, or both.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix of the ACO's assigned beneficiary population as described under §§ 425.605(a), 425.609(c), and 425.610(a).

(b) *Updating the benchmark.* For all agreement periods beginning on July 1, 2019 and in subsequent years, CMS updates the historical benchmark annually for each year of the agreement

period using a blend of national and regional growth rates.

(1) To update the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to each year.

(3) Regional growth rates are computed using expenditures for the ACO's regional service area for BY3 and the performance year, computed as follows:

(i) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year.

(ii) Determine the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section.

(4) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(i) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year as specified in paragraph (a)(5)(v) of this section; and

(ii) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(c) *Calculating county expenditures.* For all agreement periods beginning on July 1, 2019 and in subsequent years, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area, where assignable beneficiaries are identified for the 12-month calendar year corresponding to the relevant benchmark or performance year.

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments; and

(ii) Considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective CMS–HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(d) *Calculating regional expenditures.* For all agreement periods beginning on July 1, 2019 and in subsequent years, CMS calculates an ACO's risk adjusted regional expenditures by—

(1) Weighting the risk-adjusted county-level fee-for-service expenditures determined under paragraph (c) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries;

(2) Aggregating the values determined under paragraph (d)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area; and

(3) Weighting the aggregate expenditure values determined for each population of beneficiaries (according to Medicare enrollment type) under paragraph (d)(2) of this section by a weight reflecting the proportion of the ACO's overall beneficiary population in the applicable Medicare enrollment type for the relevant benchmark or performance year.

(e) *Resetting the benchmark.* (1) An ACO's benchmark is reset at the start of each subsequent agreement period.

(2) For second or subsequent agreements periods beginning on July 1, 2019 and in subsequent years, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with paragraphs (a) through (d) of this section with the following modifications:

(i) Rather than weighting each year of the benchmark using the percentages provided in paragraph (a)(7) of this section, each benchmark year is weighted equally.

(ii) For a renewing ACO or re-entering ACO whose prior agreement period benchmark was calculated according to § 425.603(c), to determine the weight used in the regional adjustment calculation described in paragraph (f) of this section, CMS considers the agreement period the ACO is entering into according to § 425.600(f) in combination with either of the following—

(A) The weight previously applied to calculate the regional adjustment to the ACO's benchmark under § 425.603(c)(9) in its most recent prior agreement period; or

(B) For a new ACO identified as a re-entering ACO, CMS considers the weight previously applied to calculate the regional adjustment to the benchmark under § 425.603(c)(9) in its most recent prior agreement period of the ACO in which the majority of the new ACO's participants were participating previously.

(f) *Phase-in of weights used in regional adjustment calculation.* (1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is

determined to have lower spending than the ACO's regional service area.

(ii) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(4) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under either paragraph (a)(8)(ii)(A) or (e) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY 3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (f)(4)(i) of this section across the populations of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If CMS adjusts the ACO's benchmark for the addition or removal of ACO participants or ACO providers/suppliers during the term of the agreement period or a change to the ACO's beneficiary assignment methodology selection as specified in paragraph (a)(9) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) and (2) of this section used in calculating the adjustment under either paragraph (a)(8) or (e) of this section.

(g) *July 1, 2019 through December 31, 2019 performance year.* In determining performance for the July 1, 2019 through December 31, 2019 performance year described in § 425.609(c) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(10) of this section and § 425.609(c), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (b) of this section and § 425.609(c), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 31. Section 425.602 is amended—

■ a. By revising the section heading and paragraph (a) introductory text;

■ b. In paragraph (a)(1)(ii)(B) by removing the phrase ''For agreement periods beginning in 2018 and subsequent years'' and adding in its place the phrase ''For agreement periods beginning in 2018 and on January 1, 2019'';

■ c. In paragraphs (a)(4)(ii) and (a)(5)(ii) by removing the phrase ''For agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For agreement periods beginning in 2017, 2018 and on January 1, 2019''; and

■ d. By adding paragraph (c).

The revisions and addition read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period beginning on or before January 1, 2019.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures.* For agreement periods beginning on or before January 1, 2019, in computing an ACO's fixed historical benchmark that is adjusted for historical growth and beneficiary characteristics, including health status, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the ACO participants' TINs identified at the start of the agreement period. CMS does all of the following:

* * * * *

(c) *January 1, 2019 through June 30, 2019 performance year.* In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(9) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (b) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 32. Section 425.603 is amended—

■ a. By revising the section heading;

■ b. In paragraph (c) introductory text by removing the phrase ''For second or subsequent agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For second or subsequent agreement periods beginning in 2017, 2018 and on January 1, 2019'';

■ c. In paragraph (c)(1)(ii)(B) by removing the phrase ''For agreement periods beginning in 2018 and subsequent years'' and adding in its place the phrase ''For agreement periods beginning in 2018 and on January 1, 2019'';

■ d. In paragraphs (d) introductory text and (e) introductory text by removing the phrase ''For second or subsequent agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For second or subsequent agreement periods beginning in 2017, 2018 and on January 1, 2019'';

■ e. In paragraph (e)(2)(ii)(B) by removing the phrase ''For agreement periods beginning in 2018 and subsequent years'' and adding in its

place the phrase ''For agreement periods beginning in 2018 and on January 1, 2019'';

■ f. In paragraph (f) introductory text by removing the phrase ''For second or subsequent agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For second or subsequent agreement periods beginning in 2017, 2018, and on January 1, 2019''; and

■ g. By adding paragraph (g).

The revision and addition reads as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period beginning on or before January 1, 2019.

* * * * *

(g) In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (c)(10) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (d) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 33. Section 425.604 is amended—

■ a. In paragraph (a) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.602 or § 425.603'';

■ b. In paragraph (a)(3) introductory text by removing the phrase ''described in § 425.602(a)'' and adding in its place the phrase ''described in § 425.602(a) or § 425.603(c)'';

■ c. In paragraph (b) by revising the table; and

■ d. By adding paragraph (g).

The revision and addition read as follows:

§ 425.604 Calculation of savings under the one-sided model.

* * * * *

(b) * * *

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
1–499	≥12.2	
500–999	12.2	8.7
1,000–2,999	8.7	5.0
3,000–4,999	5.0	3.9
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0
60,000 +	2.0	2.0

* * * * *

(g) *January 1, 2019 through June 30, 2019 performance year.* Shared savings for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 34. Section 425.605 is added to read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

(a) *General rules.* For each performance year, CMS determines whether the estimated average per capita Medicare Parts A and B fee-for-service expenditures for Medicare fee-for-service beneficiaries assigned to the ACO are above or below the updated benchmark determined under § 425.601. In order to qualify for a shared savings payment under the BASIC track, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section.

(1) CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in the assigned beneficiary population between BY3 and the performance year.

(i) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(ii) Negative adjustments in prospective HCC risk scores are subject to a cap of negative 3 percent.

(iii) These caps are the maximum change in risk scores for each agreement period, such that the adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent in either direction.

(2) In risk adjusting the benchmark as described in § 425.601(a)(10), CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Medicare Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare Parts A and B fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

(4) CMS uses a 3-month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(5) Calculations of the ACO's expenditures include the payment amounts included in Medicare Parts A and B fee-for-service claims.

(i) These calculations exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations take into consideration individually beneficiary

identifiable final payments made under a demonstration, pilot or time limited program.

(6) In order to qualify for a shared savings payment, the ACO's average per capita Medicare Parts A and B fee-for-service expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings or loss rate.* (1) For ACOs under a one-sided model of the BASIC track's glide path, as specified under paragraphs (d)(1)(i) and (ii) of this section, CMS uses a sliding scale, based on the number of beneficiaries assigned to the ACO under subpart E of this part, to establish the MSR for the ACO as follows:

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
1–499	≥12.2	
500–999	12.2	8.7
1,000–2,999	8.7	5.0
3,000–4,999	5.0	3.9
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0
60,000+	2.0	2.0

(2) Prior to entering a two-sided model of the BASIC track, the ACO must select the MSR/MLR. For an ACO making this selection as part of an application for, or renewal of, participation in a two-sided model of the BASIC track, the selection applies for the duration of the agreement period under the BASIC track. For an ACO making this selection during an agreement period, as part of the application cycle prior to entering a two-sided model of the BASIC track, the selection applies for the remaining duration of the applicable agreement period under the BASIC track.

(i) The ACO must choose from the following options for establishing the MSR/MLR:

(A) Zero percent MSR/MLR.

(B) Symmetrical MSR/MLR in a 0.5 percent increment between 0.5 and 2.0 percent.

(C) Symmetrical MSR/MLR that varies, based on the number of beneficiaries assigned to the ACO under subpart E of this part. The MSR is the same as the MSR that would apply under paragraph (b)(1) of this section for an ACO under a one-sided model of the BASIC track's glide path, and is based on the number of assigned beneficiaries. The MLR under the BASIC track is equal to the negative MSR.

(ii) The ACO selects its MSR/MLR as part of one the following:

(A) Application for, or renewal of, program participation in a two-sided model of the BASIC track.

(B) Election to participate in a two-sided model of the BASIC track during an agreement period under § 425.226.

(C) Automatic transition from Level B to Level C of the BASIC track's glide path under § 425.600(a)(4)(i).

(3) To qualify for shared savings under the BASIC track, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below its updated benchmark costs for the year by at least the MSR established for the ACO.

(4) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be above its updated benchmark costs for the year by at least the MLR established for the ACO.

(c) *Qualification for shared savings payment.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Levels of risk and potential reward.* (1) An ACO eligible to enter the BASIC track's glide path as specified under § 425.600(d) may elect to enter its agreement period at any of the levels of risk and potential reward under paragraphs (d)(1)(i) through (v) of this section, with the exception that an ACO that previously participated in Track 1 under § 425.600(a)(1), or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO, may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (d)(1)(ii) through (v) of this section.

(i) *Level A (one-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of up to 25 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(i)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level A, may not exceed 10 percent of its updated benchmark.

(ii) *Level B (one-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of up to 25 percent of all the savings under the updated benchmark,

as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(ii)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level B, may not exceed 10 percent of its updated benchmark.

(iii) *Level C (two-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of up to 30 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(iii)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level C may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(iii)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed 2 percent of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(iii)(D)(*1*) of this section, the loss recoupment limit for the ACO is 1 percent of the ACO's updated benchmark as determined under § 425.601, if the amount determined under paragraph (d)(1)(iii)(D)(*1*) of this section exceeds the amount that is 1 percent of the ACO's updated benchmark as determined under § 425.601.

(iv) *Level D (two-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(iv)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level D, may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(iv)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed 4 percent of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(iv)(D)(*1*) of this section, the loss recoupment limit for the ACO is 2 percent of the ACO's updated benchmark as determined under § 425.601, if the amount determined under paragraph (d)(1)(iv)(D)(*1*) of this section exceeds the amount that is 2 percent of the ACO's updated benchmark as determined under § 425.601.

(v) *Level E (two-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(v)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level E, may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(v)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed the percentage, as specified in § 414.1415(c)(3)(i)(A) of this chapter, of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(v)(D)(*1*) of this section, the loss recoupment limit for the ACO is 1 percentage point higher than the percentage, as specified in § 414.1415(c)(3)(i)(B) of this chapter, based on the ACO's updated benchmark as determined under § 425.601, if the amount determined under paragraph (d)(1)(v)(D)(*1*) of this section exceeds this percentage of the ACO's updated benchmark as determined under § 425.601.

(2) Level E risk and reward as specified in paragraph (d)(1)(v) of this section applies to an ACO eligible to enter the BASIC track that is determined to be experienced with performance-based risk Medicare ACO initiatives as specified under § 425.600(d).

(e) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(f) *Extreme and uncontrollable circumstances.* The following adjustment is made in calculating the amount of shared losses, after the application of the shared loss rate and the loss recoupment limit.

(1) CMS determines the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance.

(2) CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

(i) For an ACO that is liable for a pro-rated share of losses under § 425.221(b)(2), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (f)(2).

(ii) [Reserved]

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

(g) *July 1, 2019 through December 31, 2019 performance year.* Shared savings or shared losses for the July 1, 2019 through December 31, 2019 performance year are calculated as described in § 425.609.

■ 35. Section 425.606 is amended—

■ a. In paragraph (a) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.602 or § 425.603'';

■ b. In paragraph (a)(3) introductory text by removing the phrase ''described in § 425.602(a)'' and adding in its place the phrase ''described in § 425.602(a) or § 425.603(c)'';

■ c. In paragraph (g) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.602 or § 425.603'';

■ d. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ e. In paragraph (i)(1) remove the phrase ''2017''; and

■ f. By adding paragraph (i)(2)(i), reserved paragraph (i)(2)(ii), and paragraph (j).

The additions read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(i) * * *

(2) * * *

(i) For an ACO that is liable for a pro-rated share of losses under § 425.221(b)(2) or (b)(3)(i), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (i)(2).

(ii) [Reserved]

* * * * *

(j) *January 1, 2019 through June 30, 2019.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 36. Section 425.609 is added to read as follows:

§ 425.609 Determining performance for 6-month performance years during CY 2019.

(a) *General.* An ACO's financial and quality performance for a 6-month performance year during 2019 are determined as described in this section.

(b) *January 2019 through June 2019.* For ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019 under § 425.200(b)(2)(ii)(B) and for ACOs eligible for pro-rated shared savings or shared losses in accordance with § 425.221(b)(3)(i) for the performance period from January 1, 2019, through June 30, 2019, CMS reconciles the ACO after the conclusion of CY 2019 for the period from January 1, 2019, through June 30, 2019, based on the 12-month calendar year and pro-rates shared savings or shared losses to reflect the ACO's participation from January 1, 2019, through June 30, 2019. CMS does all of the following to determine financial and quality performance:

(1) Uses the ACO participant list in effect for the performance year beginning January 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400.

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) Medicare fee-for-service beneficiaries are prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available; and

(B) Beneficiaries remain prospectively assigned to the ACO at the end of CY 2019 if they do not meet any of the exclusion criteria under § 425.401(b) during the calendar year.

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502.

(i) The ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019, is used to determine the quality reporting samples for the 2019 reporting year for the following ACOs:

(A) An ACO that extends its participation agreement for a 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), and enters a new agreement period beginning on July 1, 2019.

(B) An ACO that participates in the program for the first 6 months of a 12-month performance year during 2019, and is eligible for pro-rated shared savings or shared losses in accordance with § 425.221(b)(3)(i).

(ii) The ACO's latest certified ACO participant list is used to determine the quality reporting samples for the 2019 reporting year for an ACO that extends its participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), and does not enter a new agreement period beginning on July 1, 2019.

(3) Uses the methodology for calculating shared savings or shared losses applicable to the ACO under the terms of the participation agreement that was in effect on January 1, 2019.

(i) The ACO's historical benchmark is determined according to either § 425.602 (first agreement period) or § 425.603 (second agreement period) except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY 3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.602(b), § 425.603(b), or § 425.603(d), based on whether the ACO is in its first or second agreement period, and for an ACO in a second agreement period, the date on which that agreement period began.

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), unless otherwise specified. In determining ACO financial performance, CMS does all of the following:

(A) Average per capita Medicare Parts A and B fee-for-service expenditures for CY 2019 are calculated for the ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section.

(B) Expenditures calculated in paragraph (b)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (b)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section is used to determine the MSR for Track 1 ACOs and the variable MSR/

MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population identified in paragraph (b)(1) of this section is below 5,000 beneficiaries, the MSR/MLR is determined based on the number of assigned beneficiaries as specified in § 425.110(b)(3)(iii).

(*2*) To qualify for shared savings an ACO must do all of the following:

(*i*) Have average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 below its updated benchmark costs for the year by at least the MSR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (b)(2) of this section.

(*iii*) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(*3*) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 must be above its updated benchmark costs for the year by at least the MLR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive shared savings payment under paragraph (b)(3)(ii)(C)(*2*) of this section—

(*1*) The final sharing rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the performance payment limit for the ACO based on its track; and

(*2*) After applying the applicable performance payment limit, CMS pro-rates any shared savings amount determined under paragraph (b)(3)(ii)(D)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(E) For an ACO responsible for shared losses under paragraph (b)(3)(ii)(C)(*3*) of this section—

(*1*) The shared loss rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the loss recoupment limit for the ACO based on its track; and

(*2*) After applying the applicable loss recoupment limit, CMS pro-rates any shared losses amount determined under paragraph (b)(3)(ii)(E)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(c) *July 2019 through December 2019.* For ACOs entering an agreement period beginning on July 1, 2019, the ACO's first performance year is from July 1, 2019, through December 31, 2019, as specified in § 425.200(c)(3). CMS reconciles the ACO after the conclusion of CY 2019 for the period from July 1, 2019, through December 31, 2019, based on the 12-month calendar year and pro-rates shared savings or shared losses to reflect the ACO's participation from July 1, 2019, through December 31, 2019. CMS does all of the following to determine financial and quality performance:

(1) Uses the ACO participant list in effect for the performance year beginning on July 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, consistent with the methodology the ACO selected at the start of its agreement period under § 425.400(a)(4)(ii).

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) Medicare fee-for-service beneficiaries are prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available; and

(B) Beneficiaries remain prospectively assigned to the ACO at the end of CY 2019 if they do not meet any of the exclusion criteria under § 425.401(b) during the calendar year.

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502. The ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019, is used to determine the quality reporting samples for the 2019 reporting year for all ACOs.

(3) Uses the methodology for calculating shared savings or shared loses applicable to the ACO for its first performance year under its agreement period beginning on July 1, 2019.

(i) The ACO's historical benchmark is determined according to § 425.601 except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY 3 and CY 2019 based on growth in prospective HCC risk scores, subject to a symmetrical cap of positive or negative 3 percent as described under § 425.605(a)(1) or § 425.610(a)(2).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.601(b).

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 (BASIC track) or § 425.610 (ENHANCED track)), unless otherwise specified. In determining ACO financial performance, CMS does all of the following:

(A) Average per capita Medicare Parts A and B fee-for-service expenditures for CY 2019 are calculated for the ACO's performance year assigned beneficiary population identified in paragraph (c)(1) of this section.

(B) Expenditures calculated in paragraph (c)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (c)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (c)(1) of this section is used to determine the MSR for ACOs in BASIC track Level A or Level B, and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population identified in paragraph (c)(1) of this section is below 5,000 beneficiaries, the MSR/MLR is determined based on the number of assigned beneficiaries as specified in § 425.110(b)(3)(iii).

(*2*) To qualify for shared savings an ACO must do all of the following:

(*i*) Have average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 below its updated benchmark costs for the year by

at least the MSR established for the ACO based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610) and paragraph (c)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (c)(2) of this section.

(*iii*) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(*3*) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 must be above its updated benchmark costs for the year by at least the MLR established for the ACO based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610) and paragraph (c)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive shared savings payment under paragraph (c)(3)(ii)(C)(*2*) of this section—

(*1*) The final sharing rate, determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (c)(3)(i) of this section, not to exceed the performance payment limit for the ACO based on its track; and

(*2*) After applying the applicable performance payment limit, CMS pro-rates any shared savings amount determined under paragraph (c)(3)(ii)(D)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the July 1, 2019 through December 31, 2019 performance year.

(E) For an ACO responsible for shared losses under paragraph (c)(3)(ii)(C)(*3*) of this section—

(*1*) The shared loss rate, determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (c)(3)(i) of this section, not to exceed the loss recoupment limit for the ACO based on its track; and

(*2*) After applying the applicable loss recoupment limit, CMS pro-rates any shared losses amount determined under paragraph (c)(3)(ii)(E)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the July 1, 2019 through December 31, 2019 performance year.

(d) *Extreme and uncontrollable circumstances.* For ACOs affected by extreme and uncontrollable circumstances during CY 2019—

(1) In calculating the amount of shared losses owed, CMS makes adjustments to the amount determined in paragraph (b)(3)(ii)(E)(*1*) or (c)(3)(ii)(E)(*1*) of this section, as specified in § 425.605(f), § 425.606(i), or § 425.610(i), as applicable; and

(2) In determining the ACO's quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in § 425.502(f).

(e) *Notification of savings and losses.* CMS notifies the ACO of shared savings or shared losses separately for the January 1, 2019 through June 30, 2019 performance year (or performance period) and the July 1, 2019 through December 31, 2019 performance year, consistent with the notification requirements specified in §§ 425.604(f), 425.605(e), 425.606(h), and 425.610(h), as applicable:

(1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(4) If an ACO is reconciled for both the January 1, 2019 through June 30, 2019 performance year (or performance period) and the July 1, 2019 through December 31, 2019 performance year, CMS issues a separate notice of shared savings or shared losses for each performance year (or performance period), and if the ACO has shared savings for one performance year (or performance period) and shared losses for the other performance year (or performance period), CMS reduces the amount of shared savings by the amount of shared losses.

(i) If any amount of shared savings remains after completely repaying the amount of shared losses owed, the ACO is eligible to receive payment for the remainder of the shared savings.

(ii) If the amount of shared losses owed exceeds the amount of shared savings earned, the ACO is accountable for payment of the remaining balance of shared losses in full.

■ 37. Section 425.610 is amended—

■ a. By revising the section heading;

■ b. In paragraph (a) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.601, § 425.602 or § 425.603'' and by removing the phrase ''Track 3'' and adding in its place the phrase ''the ENHANCED track'';

■ c. By revising paragraph (a)(1) through (3);

■ d. In paragraph (b)(1)(iii) by removing all instances of the phrase ''Track 3'' and, in each instance, adding in its place the phrase ''the ENHANCED track'' and by removing the phrase ''§ 425.604(b)'' and adding in its place the phrase ''either § 425.604(b) (for ACOs entering an agreement period on or before January 1, 2019) or § 425.605(b)(1) (for ACOs entering an agreement period on July 1, 2019, and in subsequent years)'';

■ e. In paragraphs (b)(2), (d), (e)(2) by removing the phrase ''Track 3'' and adding in its place the phrase ''the ENHANCED track'';

■ f. In paragraph (g) by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.601, § 425.602 or § 425.603'';

■ g. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ h. In paragraph (i)(1) by removing the phrase ''2017''; and

■ i. By adding paragraph (i)(2)(i), reserved paragraph (i)(2)(ii), and paragraphs (j) and (k).

The revisions and additions read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

(a) * * *

(1) Risk adjustment for ACOs in agreement periods beginning on or before January 1, 2019. CMS does the following to adjust the benchmark each performance year:

(i) *Newly assigned beneficiaries.* CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in this population.

(ii) *Continuously assigned beneficiaries.* (A) CMS uses demographic factors to adjust the benchmark for changes in the continuously assigned beneficiary population.

(B) If the prospective HCC risk score is lower in the performance year for this population, CMS adjusts the benchmark for changes in severity and case mix for this population using this lower prospective HCC risk score.

(2) Risk adjustment for ACOs in agreement periods beginning on July 1,

2019, and in subsequent years. CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in the assigned beneficiary population between BY3 and the performance year.

(i) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(ii) Negative adjustments in prospective HCC risk scores are subject to a cap of negative 3 percent.

(iii) These caps are the maximum change in risk scores for each agreement period, such that the adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent in either direction.

(3) In risk adjusting the benchmark as described in §§ 425.601(a)(10), 425.602(a)(9) and 425.603(c)(10), CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

* * * * *

(i) * * *

(2) * * *

(i) For an ACO that is liable for a pro-rated share of losses under § 425.221(b)(2) or (b)(3)(i), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (i)(2).

(ii) [Reserved]

* * * * *

(j) *January 1, 2019 through June 30, 2019 performance year.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

(k) *July 1, 2019 through December 31, 2019 performance year.* Shared savings or shared losses for the July 1, 2019 through December 31, 2019 performance year are calculated as described in § 425.609.

■ 38. Section 425.612 is amended—

■ a. By revising paragraphs (a)(1) introductory text and (a)(1)(ii)(A);

■ b. By redesignating paragraphs (a)(1)(ii)(B) through (G) as paragraphs (a)(1)(ii)(C) through (H);

■ c. By adding new paragraph (a)(1)(ii)(B);

■ d. By revising paragraphs (a)(1)(iii)(A), (a)(1)(iv), and (a)(1)(v) introductory text;

■ e. Redesignating paragraphs (a)(1)(v)(A) through (C) as paragraphs (a)(1)(v)(C) through (E);

■ f. Adding new paragraphs (a)(1)(v)(A) and (B);

■ g. Revising newly redesignated paragraph (a)(1)(v)(D); and

■ h. By adding paragraphs (a)(1)(vi) and (f).

The revisions and additions read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) *SNF 3-day rule.* For performance year 2017 and subsequent performance years, CMS waives the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare-covered post-hospital extended care service for eligible beneficiaries assigned to ACOs participating in a two-sided model and as provided in paragraph (a)(1)(iv) of this section during a grace period for beneficiaries excluded from prospective assignment to an ACO in a two-sided model, who receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. Eligible SNFs include providers furnishing SNF services under swing bed agreements. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply. ACOs identified under paragraph (a)(1)(vi) of this section may request to use the SNF 3-day rule waiver for performance years beginning on July 1, 2019, and in subsequent years.

* * * * *

(ii) * * *

(A) In the case of a beneficiary who is assigned to an ACO that has selected preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2), the beneficiary must appear on the list of preliminarily prospectively assigned beneficiaries at the beginning of the performance year or on the first, second, or third quarterly preliminary prospective assignment list for the performance year in which they are admitted to the eligible SNF, and the SNF services must be provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year.

(B) In the case of a beneficiary who is assigned to an ACO that has selected prospective assignment under § 425.400(a)(3), the beneficiary must be prospectively assigned to the ACO for the performance year in which they are admitted to the eligible SNF.

* * * * *

(iii) * * *

(A) Providers eligible to be included in the CMS 5-star Quality Rating System must have and maintain an overall rating of 3 or higher.

* * * * *

(iv) For a beneficiary who was included on the ACO's prospective assignment list or preliminary prospective assignment list at the beginning of the performance year or on the first, second, or third quarterly preliminary prospective assignment list for the performance year, for an ACO for which a waiver of the SNF 3-day rule has been approved under paragraph (a)(1) of this section, but who was subsequently removed from the assignment list for the performance year, CMS makes payment for SNF services furnished to the beneficiary by a SNF affiliate if the following conditions are met:

(A)(*1*) The beneficiary was prospectively assigned to an ACO that selected prospective assignment under § 425.400(a)(3) at the beginning of the applicable performance year, but was excluded in the most recent quarterly update to the assignment list under § 425.401(b), and the beneficiary was admitted to a SNF affiliate within 90 days following the date that CMS delivered the quarterly exclusion list to the ACO; or

(*2*) The beneficiary was identified as preliminarily prospectively assigned to an ACO that has selected preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2) in the report provided under § 425.702(c)(1)(ii)(A) at the beginning of the performance year or for the first, second, or third quarter of the performance year, the SNF services were provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year, and the beneficiary meets the criteria to be assigned to an ACO under § 425.401(a)(1) and (2).

(B) But for the beneficiary's removal from the ACO's assignment list, CMS would have made payment to the SNF affiliate for such services under the waiver under paragraph (a)(1) of this section.

(v) The following beneficiary protections apply when a beneficiary receives SNF services without a prior 3-day inpatient hospital stay from a SNF affiliate that intended to provide services under a SNF 3-day rule waiver under paragraph (a)(1) of this section, the SNF affiliate services were non-covered only because the SNF affiliate stay was not preceded by a qualifying hospital stay under section 1861(i) of the Act, and in the case of a beneficiary where the ACO selected one of the following:

(A) Prospective assignment under § 425.400(a)(3), the beneficiary was not prospectively assigned to the ACO for the performance year in which they received the SNF services, or was prospectively assigned but was later excluded and the 90-day grace period, described in paragraph (a)(1)(iv)(A) of this section, has lapsed.

(B) Preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2), the beneficiary was not identified as preliminarily prospectively assigned to the ACO for the performance year in the report provided under § 425.702(c)(1)(ii)(A) at the beginning of the performance year or for the first, second, or third quarter of the performance year before the SNF services were provided to the beneficiary.

* * * * *

(D) CMS makes no payments for SNF services to a SNF affiliate of an ACO for which a waiver of the SNF 3-day rule has been approved when the SNF affiliate admits a FFS beneficiary who was not prospectively or preliminarily prospectively assigned to the ACO prior to the SNF admission or was prospectively assigned but was later excluded and the 90-day grace period under paragraph (a)(1)(iv)(A) of this section has lapsed.

* * * * *

(vi) The following ACOs may request to use the SNF 3-day rule waiver:

(A) An ACO participating in performance-based risk within the BASIC track under § 425.605.

(B) An ACO participating in the ENHANCED track under § 425.610.

* * * * *

(f) *Waiver for payment for telehealth services.* For performance year 2020 and subsequent performance years, CMS waives the originating site requirements in section 1834(m)(4)(C)(i) and (ii) of the Act and makes payment for telehealth services furnished to a beneficiary, if the following conditions are met:

(1) The beneficiary was prospectively assigned to an ACO that is an applicable ACO for purposes of § 425.613 at the beginning of the applicable performance year, but the beneficiary was excluded in the most recent quarterly update to the prospective assignment list under § 425.401(b).

(2) The telehealth services are provided by a physician or practitioner billing under the TIN of an ACO participant in the ACO within 90 days following the date CMS delivers the quarterly exclusion list to the ACO.

(3) But for the beneficiary's exclusion from the ACO's prospective assignment list, CMS would have made payment to the ACO participant for such services under § 425.613.

■ 39. Section 425.613 is added to subpart G to read as follows:

§ 425.613 Telehealth services.

(a) *General.* Payment is available for otherwise covered telehealth services furnished on or after January 1, 2020, by a physician or other practitioner billing through the TIN of an ACO participant in an applicable ACO, without regard to the geographic requirements under section 1834(m)(4)(C)(i) of the Act, in accordance with the requirements of this section.

(1) For purposes of this section:

(i) An applicable ACO is an ACO that is participating under a two-sided model under § 425.600 and has elected prospective assignment under § 425.400(a)(3) for the performance year.

(ii) The home of the beneficiary is treated as an originating site under section 1834(m)(4)(C)(ii) of the Act.

(2) For payment to be made under this section, the following requirements must be met:

(i) The beneficiary is prospectively assigned to the ACO for the performance year in which the beneficiary received the telehealth service.

(ii) The physician or practitioner who furnishes the telehealth service must bill under the TIN of an ACO participant that is included on the certified ACO participant list under § 425.118 for the performance year in which the service is rendered.

(iii) The originating site must comply with applicable State licensing requirements.

(iv) When the originating site is the beneficiary's home, the telehealth services must not be inappropriate to furnish in the home setting. Services that are typically furnished in an inpatient setting may not be furnished as a telehealth service when the originating site is the beneficiary's home.

(v) CMS does not pay a facility fee when the originating site is the beneficiary's home.

(b) *Beneficiary protections.* (1) When a beneficiary who is not prospectively assigned to an applicable ACO or in a 90-day grace period under § 425.612(f) receives a telehealth service from a physician or practitioner billing through the TIN of an ACO participant participating in an applicable ACO, CMS makes no payment for the telehealth service to the ACO participant.

(2) In the event that CMS makes no payment for a telehealth service furnished by a physician or practitioner billing through the TIN of an ACO participant, and the only reason the claim was non-covered is because the beneficiary is not prospectively assigned to the ACO or in the 90-day grace period under § 425.612(f), all of the following beneficiary protections apply:

(i) The ACO participant must not charge the beneficiary for the expenses incurred for such service.

(ii) The ACO participant must return to the beneficiary any monies collected for such service.

(iii) The ACO may be required to submit a corrective action plan under § 425.216(b) for CMS approval. If the ACO is required to submit a corrective action plan and, after being given an opportunity to act upon the corrective action plan, the ACO fails to implement the corrective action plan or demonstrate improved performance upon completion of the corrective action plan, CMS may terminate the participation agreement as specified under § 425.216(b)(2).

(c) *Termination date for purposes of payment for telehealth services.* (1) Payment for telehealth services under paragraph (a) of this section does not extend beyond the end of the applicable ACO's participation agreement.

(2) If CMS terminates the participation agreement under § 425.218, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the date specified by CMS in the termination notice.

(3) If the ACO terminates the participation agreement, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the effective date of termination as specified in the written notification required under § 425.220.

(d) *Monitoring of telehealth services.* (1) CMS monitors and audits the use of telehealth services by the ACO and its ACO participants and ACO providers/suppliers, in accordance with § 425.316.

(2) CMS reserves the right to take compliance action, up to and including termination of the participation agreement, as specified in §§ 425.216 and 425.218, with respect to an applicable ACO for non-compliance with program requirements, including inappropriate use of telehealth services.

■ 40. Section 425.702 is amended—

■ a. By revising paragraphs (c)(1)(ii)(A) introductory text, (c)(1)(ii)(B) introductory text and (c)(1)(ii)(C); and

■ b. By adding paragraph (d).

The revisions and addition read as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(A) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), the following information is made available regarding preliminarily prospectively assigned beneficiaries and beneficiaries that received a primary care service during the previous 12 months from one of the ACO participants that submits claims for primary care services used to determine the ACO's assigned population under subpart E of this part:

* * * * *

(B) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available regarding preliminarily prospectively assigned beneficiaries:

* * * * *

(C) The information under paragraphs (c)(1)(ii)(A) and (B) of this section is made available to ACOs participating under prospective assignment as specified under § 425.400(a)(3), but is limited to the ACO's prospectively assigned beneficiaries.

* * * * *

(d) For an ACO eligible to be reconciled under § 425.609(b), CMS shares with the ACO quarterly aggregate reports as provided in paragraphs (b) and (c)(1)(ii) of this section for CY 2019.

■ 41. Section 425.704 is amended by revising paragraph (d)(1) to read as follows:

§ 425.704 Beneficiary-identifiable claims data.

* * * * *

(d) * * *

(1) For an ACO participating under—

(i) Preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), the beneficiary's name appears on the preliminary prospective assignment list provided to the ACO at the beginning of the performance year, during each quarter (and in conjunction with the annual reconciliation) or the beneficiary has received a primary care service from an ACO participant upon whom assignment is based (under subpart E of this part) during the most recent 12-month period; or

(ii) Prospective assignment as specified under § 425.400(a)(3), the beneficiary's name appears on the prospective assignment list provided to the ACO at the beginning of the performance year.

* * * * *

■ 42. Section 425.800 is amended—

■ a. In paragraph (a)(4) by removing the phrase ''under §§ 425.602, 425.604, 425.606, and 425.610'' and adding in its place the phrase ''in accordance with section 1899(d) of the Act, as implemented under §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, and 425.610'';

■ b. In paragraph (a)(5) by removing the phrase ''established under §§ 425.604, 425.606, and 425.610'' and adding in its place the phrase ''established under §§ 425.604, 425.605, 425.606, and 425.610''; and

■ c. By adding paragraph (a)(7).

The addition reads as follows:

§ 425.800 Preclusion of administrative and judicial review.

(a) * * *

(7) The termination of a beneficiary incentive program established under § 425.304(c).

* * * * *

Dated: June 11, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–17101 Filed 8–9–18; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 83 Friday,
No. 160 August 17, 2018

Part IV

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1 and 301
Centralized Partnership Audit Regime; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–136118–15, REG–119337–17; REG–118067–17; REG–120232–17 and REG–120233–17]

RIN 1545–BO03; 1545–BO04

Centralized Partnership Audit Regime

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; notice of public hearing; withdrawal and partial withdrawal of notices of proposed rulemaking.

SUMMARY: This document contains proposed regulations implementing the centralized partnership audit regime. This document withdraws and reproposes certain portions of proposed regulations implementing the centralized partnership audit regime that have not been finalized to reflect the changes made by the Technical Corrections Act of 2018, contained in Title II of the Consolidated Appropriations Act of 2018 (TTCA). The proposed regulations affect partnerships with respect to partnership taxable years beginning after December 31, 2017, as well as partnerships that make the election under the Bipartisan Budget Act of 2015 (BBA), to apply the centralized partnership audit regime to partnership taxable years beginning on or after November 2, 2015 and before January 1, 2018.

DATES: Written or electronic comments must be received by October 1, 2018. Outlines of topics to be discussed at the public hearing scheduled for October 9, 2018, at 10 a.m. must be received by October 1, 2018.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–136118–15), Room 5207, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–136118–15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–136118–15).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations under sections 6221, 6226, 6235, and 6241, Jennifer M. Black of the Office of Associate Chief Counsel (Procedure and Administration), (202) 317–6834; concerning the proposed regulations under sections 6225, 6231, and 6234, Joy E. Gerdy-Zogby of the Office of Associate Chief Counsel (Procedure and Administration), (202) 317–6834; concerning the proposed regulations under sections 6222, 6227, 6232, and 6233, Steven L. Karon of the Office of Associate Chief Counsel (Procedure and Administration), (202) 217–6834; concerning the proposed regulations under section 6225 relating to creditable foreign tax expenditures, Larry R. Pounders, Jr. of the Office of Associate Chief Counsel (International), (202) 317–5465; concerning the proposed regulations relating to chapters 3 and 4 of subtitle A of the Internal Revenue Code (other than section 1446), Subin Seth of the Office of Associate Chief Counsel (International), (202) 317–5003; concerning the proposed regulations relating to section 1446, Ronald M. Gootzeit of the Office of Associate Chief Counsel (International), (202) 317–4953; concerning the proposed regulations under sections 704 through 706 and §§ 301.6225–4 and 301.6226–4, Allison R. Carmody or Meghan M. Howard of the Office of Associate Chief Counsel (Passthroughs and Special Industries), (202) 317–5279; concerning the submission of comments, the hearing, or to be placed on the building access list to attend the hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed regulations under sections 704 through 706 to amend the Income Tax Regulations (26 CFR part 1) under Subpart—Partners and Partnerships and proposed regulations under sections 6221 through 6241 to amend the Procedure and Administration Regulations (26 CFR part 301) under Subpart—Tax Treatment of Partnership Items to implement the centralized partnership audit regime enacted by section 1101 of the BBA, Public Law 114–74 (BBA), as amended by the Protecting Americans from Tax Hikes Act of 2015, Public Law 114–113 (PATH Act) and sections 201 through 207 of the TTCA, Public Law 115–141. This document also withdraws portions of proposed regulations under sections 704 through 706 and 6221 through 6241 that were published in the **Federal Register** on June 14, 2017 (REG–136118–15, 82 FR 27334), November 30, 2017(REG–119337–17, 82 FR 56765), December 19, 2017(REG–120232–17 and REG–120233–17, 82 FR 27071), and February 2, 2018 (REG–118067–17, 83 FR 4868).

Section 1101(a) of the BBA removed subchapter C of chapter 63 of the Internal Revenue Code (Code) effective for partnership taxable years beginning after December 31, 2017. Subchapter C of chapter 63 of the Code (subchapter C of chapter 63) contained the unified partnership audit and litigation rules that were commonly referred to as the TEFRA partnership procedures or simply TEFRA. Section 1101(b) of the BBA also removed subchapter D of chapter 63 of the Code and part IV of subchapter K of chapter 1 of the Code, rules applicable to electing large partnerships, effective for partnership taxable years beginning after December 31, 2017. Section 1101(c) of the BBA replaced the TEFRA partnership procedures and the rules applicable to electing large partnerships with a centralized partnership audit regime that, in general, determines, assesses, and collects tax at the partnership level.

On December 18, 2015, section 1101 of the BBA was amended by the PATH Act. The amendments under the PATH Act are effective as if included in section 1101 of the BBA, and therefore, subject to the effective dates in section 1101(g) of the BBA.

On June 14, 2017, the Treasury Department and the IRS published in the **Federal Register** (82 FR 27334) a notice of proposed rulemaking (REG–136118–15) (June 2017 NPRM) proposing rules under section 6221 regarding the scope and election out of the centralized partnership audit regime, section 6222 regarding consistent treatment by partners, section 6223 regarding the partnership representative, section 6225 regarding partnership adjustments made by the IRS and determination of the amount of the partnership's liability (referred to as the imputed underpayment), section 6226 regarding the election for partners to take partnership adjustments into account, section 6227 regarding administrative adjustment requests (AARs), and section 6241 regarding definitions and special rules. The Treasury Department and the IRS received written public comments in response to the regulations proposed in the June 2017 NPRM, and a public hearing regarding the proposed regulations was held on September 18, 2017.

On November 30, 2017, the Treasury Department and the IRS published in the **Federal Register** (82 FR 56765) a notice of proposed rulemaking (REG–119337–17) (November 2017 NPRM) proposing rules regarding international provisions under the centralized partnership audit regime, including rules relating to the withholding of tax

on foreign persons, the withholding of tax to enforce reporting on certain foreign accounts, and the treatment of creditable foreign tax expenditures of a partnership. No written comments were submitted in response to this NPRM, and no hearing was requested or held.

On December 19, 2017, the Treasury Department and the IRS published in the **Federal Register** (82 FR 27071) a notice of proposed rulemaking (REG–120232–17 and REG–120233–17) (December 2017 NPRM) proposing administrative and procedural rules under the centralized partnership audit regime, including rules addressing assessment and collection, penalties and interest, periods of limitations on making partnership adjustments, and judicial review of partnership adjustments. The regulations proposed in the December 2017 NPRM also provided rules addressing how pass-through partners take into account adjustments under the alternative to payment of the imputed underpayment described in section 6226 and under rules similar to section 6226 when a partnership files an AAR under section 6227. Written comments were received in response to the December 2017 NPRM. However, no hearing was requested or held.

On January 2, 2018, the Treasury Department and the IRS published in the **Federal Register** (82 FR 28398) final regulations under section 6221(b) providing rules for electing out of the centralized partnership audit regime.

On February 2, 2018, the Treasury Department and the IRS published in the **Federal Register** (83 FR 4868) a notice of proposed rulemaking (REG–118067–17) (February 2018 NPRM) proposing rules for adjusting tax attributes under the centralized partnership audit regime. Written comments were received in response to the February 2018 NPRM. However, no hearing was requested or held.

On March 23, 2018, Congress enacted the TTCA, which made a number of technical corrections to the rules under the centralized partnership audit regime. The amendments under the TTCA are effective as if included in section 1101 of the BBA, and therefore, subject to the effective dates in section 1101(g) of the BBA.

On August 9, 2018, the Treasury Department and the IRS published in the **Federal Register** (83 FR 39331) final regulations under section 6223 providing rules relating to partnership representatives and final regulations under § 301.9100–22 providing rules for electing into the centralized partnership audit regime for taxable years beginning on or after November 2, 2015 and before January 1, 2018. Corresponding temporary regulations under § 301.9100–22T were also withdrawn.

In light of the technical corrections made by the TTCA, to the extent regulations have not already been finalized, this document withdraws the regulations proposed in the June 2017 NPRM, the November 2017 NPRM, the December 2017 NPRM, and the February 2018 NPRM (collectively, the prior NPRMs) and proposes regulations reflecting the technical corrections made by the TTCA. The regulations proposed in this document also include clarifications, unrelated to the TTCA as discussed in the Explanation of Provisions section of this preamble. In addition, certain regulations have been reordered and renumbered, typographical errors have been corrected, nonsubstantive editorial changes have been made, and the applicability date provisions in the regulations have been revised to replace references to § 301.9100–22T with references to § 301.9100–22. Finally, the assumed highest rate of tax for corporations in the examples for all applicable periods is now 20 percent to more closely reflect the corporate tax rate in effect under section 11 (as amended by section 13001 of ''[a]n Act to provide for the reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018,'' Public Law 115–97 (the ''Act'')).

Although this document withdraws the prior NPRMs, the Explanation of Provisions sections contained in the preambles of the withdrawn NPRMs remain relevant. Therefore, to the extent not inconsistent with the Explanation of Provisions section of this preamble or the preamble to the portions of the proposed regulations that have already been finalized, those Explanation of Provision sections are incorporated by reference in this document. **Federal Register** citations are provided to assist with locating the relevant section of the preamble in the prior NPRMs. The prior NPRMs are also included in the rulemaking docket for this notice of proposed rulemaking on *www.regulations.gov.*

This document does not address written comments that were submitted in response to the regulations proposed in the prior NPRMs or respond to any statements made during the public hearing held on September 18, 2017. Except to the extent that the written comments relate to the final regulations under section 6221(b) and section 6223, such comments and any comments received in response to this notice of proposed rulemaking will be addressed when the regulations proposed in this document are finalized.

Explanation of Provisions

1. Scope of the Centralized Partnership Audit Regime and Partnership-Related Item

Section 6221(a) provides for the determination of certain adjustments at the partnership level under the centralized partnership audit regime. Prior to amendment by the TTCA, section 6221(a) provided that any adjustment to items of income, gain, loss, deduction, or credit of a partnership for a partnership taxable year (and any partner's distributive share thereof) shall be determined, any tax attributable thereto shall be assessed and collected, and the applicability of any penalty, addition to tax, or additional amount which relates to an adjustment to any such item or share shall be determined at the partnership level. Prior to amendment by the TTCA, section 6241(a)(2) provided that the term ''partnership adjustment'' meant any adjustment in the amount of any item of income, gain, loss, deduction, or credit of a partnership, or any partner's distributive share thereof.

Section 201(c)(2) of the TTCA amended section 6221(a) by replacing the phrase ''items of income, gain, loss, deduction, or credit of a partnership for a partnership taxable year (and any partner's distributive share thereof)'' with the phrase ''a partnership-related item.'' Section 6221(a) now provides that any adjustment to a partnership-related item and the applicability of any penalty, addition to tax, or additional amount which relates to an adjustment to any partnership-related item shall be determined at the partnership level. Additionally, section 6221(a) provides that any tax attributable to an adjustment to a partnership-related item shall be assessed and collected at the partnership level.

Section 201(a) of the TTCA amended section 6241(2) to provide that the term ''partnership adjustment'' means any adjustment to a partnership-related item, and the term ''partnership-related item'' means any item or amount with respect to the partnership (without regard to whether or not such item or amount appears on the partnership's return and including an imputed underpayment and any item or amount relating to any transaction with, basis in, or liability of, the partnership) which is relevant (determined without regard to subchapter C of chapter 63) in determining the tax liability of any person under chapter 1 of the Code

(chapter 1) and any partner's distributive share thereof.

By eliminating the reference to items of income, gain, loss, deduction, or credit of a partnership, and instead referring to partnership-related items, which is broadly defined, the amendments by the TTCA clarify that the scope of the centralized partnership audit regime is not narrower than the scope of the partnership audit procedures under TEFRA. Joint Comm. on Taxation, JCX–6–18, *Technical Explanation of the Revenue Provisions of the House Amendment to the Senate Amendment to H.R. 1625 (Rules Committee Print 115–66),* 37 (2018) (JCX–6–18). Rather, the centralized partnership audit regime is intended to have a scope sufficient to address those items that would have been considered partnership items, affected items, and computational adjustments under TEFRA, including the regulations. *Id.*

A. Proposed § 301.6221(a)–1

Proposed rules under § 301.6221(a)–1 were previously published in the **Federal Register** (82 FR 27372–73) in the June 2017 NPRM and the November NPRM (82 FR 56776) (former proposed § 301.6221(a)–1). Former proposed § 301.6221(a)–1(a) provided that the centralized partnership audit regime covers any adjustment to items of income, gain, loss, deduction, or credit of a partnership and any partner's distributive share of those adjusted items. Former proposed § 301.6221(a)–1(b)(1)(i) defined the phrase ''items of income, gain, loss, deduction or credit'' to mean all items and information required to be shown, or reflected, on a return of the partnership under section 6031, the regulations thereunder, and the forms and instructions prescribed by the IRS for the partnership's taxable year, and any information in the partnership's books and records for the taxable year. In addition, former proposed § 301.6221(a)–1(b)(1)(ii) provided that any factors that needed to be taken into account to determine or allocate the tax treatment of items adjusted under the centralized partnership audit regime were also to be determined at the partnership level. Former proposed § 301.6221(a)–1(b)(2) also addressed items included within the phrase ''partner's distributive share.'' Because the TTCA's amendment of the scope of the centralized partnership audit regime is accomplished by adding a new defined term—''partnership-related item''—the majority of the rules under former proposed § 301.6221(a)–1(b) that addressed the scope of what is adjusted at the partnership level are now incorporated into proposed § 301.6241–6 which defines the term ''partnership-related item.''

Proposed § 301.6221(a)–1(a) now provides the general rule that, except as otherwise provided under the centralized partnership audit regime, any adjustments to partnership-related items and the applicability of any penalty, addition to tax, or additional amount that relates to an adjustment to any such items are determined at the partnership level. In addition, proposed § 301.6221(a)–1(a) provides that any chapter 1 tax attributable to an adjustment to a partnership-related item is assessed and collected at the partnership level. See section 13 of the preamble for a discussion of special enforcement matters pertaining to partnership-related items that may be adjusted outside of the centralized partnership audit regime.

Proposed § 301.6221(a)–1(a) further provides that any consideration necessary to make a determination at the partnership level under the centralized partnership audit regime is made at the partnership level. This would include the period of limitations on making adjustments under section 6235 as well as any facts necessary to calculate any imputed underpayment under section 6225, except as otherwise provided under the centralized partnership audit regime. These determinations previously constituted factors described under former proposed § 301.6221(a)–1(b)(1)(ii)(F) and (I).

B. Proposed § 301.6241–6

Proposed § 301.6241–6 defines the term ''partnership-related item.'' Proposed § 301.6241–6(a) provides the general rule that a partnership-related item is any item or amount with respect to the partnership which is relevant in determining the tax liability of any person under chapter 1 and any partner's distributive share of any such item or amount.

Proposed § 301.6241–6(b) provides that an item or amount is with respect to a partnership without regard to whether or not such item or amount appears on the partnership return. An item or amount is with respect to a partnership if: The item or amount is shown or reflected, or required to be shown, or reflected, on a return of the partnership; the item or amount is in the partnership's books and records; the item or amount is an imputed underpayment; the item or amount relates to any transaction with, basis in, or liability of the partnership; or the item or amount relates to a transaction under section 707(a)(2), 707(b), or 707(c).

Under proposed § 301.6241–6(b)(4) and (7), an item or amount that relates to any transaction with, or liability of, the partnership, is with respect to a partnership only if the item or amount relates to a transaction or liability between the partnership and a partner acting in its capacity as a partner or an indirect partner (as defined in proposed § 301.6241–1(a)(4)) acting in its capacity as an indirect partner. Accordingly, an item or amount that relates to any transaction with or liability of the partnership is not with respect to the partnership if the item or amount is reported (or reportable) solely by a person other than the partnership, a partner not acting in its capacity as a partner, or an indirect partner not acting in its capacity as an indirect partner (except for transactions under section 707). Proposed § 301.6241–6(b)(8) provides that any determination necessary to make an adjustment to an item or amount described in proposed § 301.6241–6(b)(1) through (b)(7) is also an item or amount with respect to the partnership.

Proposed § 301.6241–6(c) provides that the determination of whether an item or amount is relevant in determining the tax liability of any person under chapter 1 is made without regard to the provisions of the centralized partnership audit regime. Proposed § 301.6241–6(c) also clarifies that an item or amount of a partnership is relevant in determining the liability of any person under chapter 1 without regard to whether such item or amount, or adjustment to such item or amount, has an effect on the tax liability of any particular person under chapter 1. Section 6241(2)(B)(i) does not limit whether an item is relevant in determining tax liability under chapter 1 to whether the item is relevant to determining the tax liability of a partner of the partnership under chapter 1. Rather, the statutory language refers to liability under chapter 1 of ''any person.'' An item or amount is a partnership-related item if the item or amount is relevant in determining any person's liability under chapter 1 if the item might have any effect on any person's liability under chapter 1 regardless of whether it actually does have such an effect. Consequently, the IRS is not required to determine if an adjustment would have an actual effect on any person's chapter 1 liability under the Code.

Proposed § 301.6241–6(d) provides a list of examples of partnership-related items. These examples are largely the same as the items described in former proposed § 301.6221(a)–1(b)(1) with a few minor revisions. First, the

references to ''foreign,'' ''tax,'' and ''§ 1.704–1(b)(4)(viii)(b)'' in the example regarding creditable expenditures were removed to clarify that partnership-related item includes any creditable expenditures, not just a creditable foreign tax expenditure. Also, the ''including . . .'' phrase from each example was removed to be consistent with the broad scope of the centralized partnership audit regime and does not reflect a substantive change. No inference should be drawn from the removal of that language.

Proposed § 301.6241–6(e) provides examples that illustrate the rules under proposed § 301.6241–6.

2. Partner's Return Must Be Consistent With Partnership Return

Prior to enactment of the TTCA, section 6222 provided that a partner shall treat on the partner's return ''each item of income, gain, loss, deduction, or credit attributable to a partnership'' subject to subchapter C of chapter 63 in a manner that is consistent with the treatment of such item on the partnership return. Section 201(c) of the TTCA amended section 6222 to provide that a partner shall treat on the partner's return ''any partnership-related item'' in a manner which is consistent with the treatment of such item on the partnership return.

A. Proposed § 301.6222–1

Proposed rules under § 301.6222–1 were previously published in the **Federal Register** (82 FR 27375–78) in the June 2017 NPRM (former proposed § 301.6222–1). For an explanation of the rules under former proposed 301.6222–1, see 82 FR 27345–46.

Former proposed § 301.6222–1(a) provided that a partner's treatment of each item of income, gain, loss, deduction, or credit attributable to a partnership must be consistent with the treatment of those items on the partnership return, including treatment with respect to the amount, timing, and characterization of those items. The reference in former proposed § 301.6222–1(a) to ''each item of income, gain, loss, deduction, or credit attributable to a partnership'' has been replaced with a reference to ''any partnership-related item'' to reflect the statutory change to section 6222(a). In addition, references throughout former proposed § 301.6222–1 to the term ''item'' have been replaced with references to the term ''partnership-related item,'' as appropriate.

3. Imputed Underpayment, Modification of Imputed Underpayment, and Adjustments That Do Not Result in an Imputed Underpayment

Section 6225 provides rules governing the determination of the imputed underpayment, modification of the imputed underpayment, and the treatment of adjustments that do not result in an imputed underpayment. Section 202(c) of the TTCA amended section 6225(a) to reflect the new term ''partnership-related item'' and to provide that in the case of adjustments to partnership-related items that result in an imputed underpayment the partnership shall pay an amount equal to the imputed underpayment in the adjustment year as provided in section 6232. In the case of adjustments that do not result in an imputed underpayment, such adjustments shall be taken into account by the partnership in the adjustment year.

Section 202(a) of the TTCA amended section 6225(b)(1) to provide that the Secretary shall determine any imputed underpayment with respect to any reviewed year by appropriately netting all partnership adjustments to such reviewed year and applying the highest rate of tax in effect for that year under section 1 or 11. Section 202(a) of the TTCA also amended section 6225(b)(2) to provide that in the case of any adjustment that reallocates the distributive share of any item from one partner to another, such adjustment shall be taken into account by disregarding so much of such adjustment as results in a decrease in the amount of the imputed underpayment.

Section 202(a) of the TTCA also added paragraphs (b)(3) and (b)(4) to section 6225. Section 6225(b)(3) provides that partnership adjustments for any reviewed year shall first be separately determined (and netted as appropriate) within each category of items that are required to be taken into account separately under section 702(a) or other provision of the Code. Section 6225(b)(4) provides if any adjustment would (but for section 6225(b)(4)) result in a decrease in the amount of the imputed underpayment, and could be subject to any additional limitation under the provisions of the Code (or not allowed, in whole or in part, against ordinary income) if such adjustment were taken into account by any person, such adjustment shall not be taken into account when appropriately netting partnership adjustments under section 6225(b)(1)(A) except to the extent otherwise provided by the Secretary.

Section 202(b) of the TTCA amended several provisions relating to modifications of imputed underpayments. Sections 6225(c)(3), (c)(4)(A), and (c)(5)(A)(i), which previously referred to the ''portion of the imputed underpayment,'' were amended to refer to the ''portion of the adjustment.'' This amendment clarifies that modifications under sections 6225(c)(3), (c)(4), and (c)(5) result in disregarding the portion of the partnership adjustment affected by the modification, rather than the portion of the imputed underpayment. Section 202(c) of the TTCA also added section 6225(c)(9), which provides that the Secretary shall establish procedures under which the adjustments described in section 6225(a)(2)—adjustments that do not result in an imputed underpayment—may be modified in such manner as the Secretary determines appropriate.

Section 203 of the TTCA amended section 6225(c)(2) relating to the procedures for partners to take adjustments into account during modification. Section 6225(c)(2)(A) governs the filing of amended returns by partners. Section 6225(c)(2)(B) provides for an alternative procedure to the filing of amended returns. Section 6225(c)(2)(C) provides rules for adjustments that reallocate the distributive share of any item from one partner to another. Section 6225(c)(2)(D) provides that sections 6501 and 6511 shall not apply in certain situations related to amended returns and the alternative procedure to filing amended returns. Section 6225(c)(2)(E) provides that any adjustments to tax attributes that occur as a result of a modification under section 6225(c)(2) are binding on the partners and the partnership. Section 6225(c)(2)(F) provides rules for tiered structures, including defining the term ''relevant partner'' to mean any partner in the chain of ownership of any partnerships that are partners in the partnership requesting modification.

A. Proposed §§ 301.6225–1, 301.6225–2, and 301.6225–3

Proposed rules under §§ 301.6225–1, 301.6225–2, and 301.6225–3 were previously published in the **Federal Register** in the June 2017 NPRM (82 FR 27382–91), the November 2017 NPRM (82 FR 56776), and in the December 2017 NPRM (82 FR 60154) (collectively, former proposed §§ 301.6225–1, 301.6225–2, and 301.6225–3). For an explanation of the rules under former proposed §§ 301.6225–1, 301.6225–2, and 301.6225–3, see 82 FR 27350–58, 82 FR 56766–75, and 82 FR 60152–53.

Proposed § 301.6225–1 has been reorganized to clarify the process for determining an imputed underpayment. This reorganization, when compared to former proposed § 301.6225–1 (1) more clearly describes the steps necessary to determine an imputed underpayment and adjustments that do not result in an imputed underpayment; (2) consolidates rules regarding adjustments that do not result in an imputed underpayment; and (3) relocates rules regarding creditable expenditures to more clearly explain how to account for creditable expenditures in the determination of the imputed underpayment.

Proposed § 301.6225–1(b) addresses the calculation of the imputed underpayment. Due to the number of adjustments that could be made based on the definition of partnership-related item, the IRS will need to address circumstances in which multiple partnership-related items are adjusted to address a single issue or transaction in the administrative proceeding. Adjusting multiple partnership-related items that relate to the same issue or transaction could result in an imputed underpayment that double-counts some of the adjustments even though, if the partnership and partners had properly reported the item, one or more adjustments would have been subsumed by another item. To prevent double-counting the individual adjustments as inputs into the imputed underpayment, proposed § 301.6225–1(b)(4) provides that the IRS may treat adjustments that would otherwise be double-counted as zero for purposes of determining the imputed underpayment.

Proposed § 301.6225–1(c) describes the different groupings in which adjustments are placed for purposes of determining an imputed underpayment. These groupings are the reallocation grouping, the credit grouping, the creditable expenditure grouping, and the residual grouping. Proposed § 301.6225–1(c)(1) provides authority for the IRS to alter the manner in which adjustments are grouped to appropriately reflect the facts and circumstances.

Proposed § 301.6225–1(c)(2) defines the term ''reallocation adjustment'' and provides that in general reallocation adjustments are placed in the reallocation grouping. Under proposed § 301.6225–1(c)(3), however, reallocation adjustments to credits are placed in the credit grouping, and under § 301.6225–1(c)(4), reallocation adjustments to creditable expenditures are placed in the creditable expenditure grouping, similar to the rule under former proposed § 301.6225–1(d)(2)(iv). Proposed § 301.6225–1(c)(2)(ii) provides that each reallocation adjustment results in two separate adjustments—one positive adjustment and one negative adjustment. Proposed § 301.6225–1(c)(6) provides similar rules for recharacterization adjustments.

Proposed § 301.6225–1(c)(5)(ii) provides rules for how to account for adjustments to partnership-related items that are not allocated by the partnership to its partners under section 704(b). Proposed § 301.6225–1(d)(2)(iii)(B) provides that adjustments to such items, solely for purposes of determining an imputed underpayment, are treated as a positive adjustment to income to the extent appropriate. The Treasury Department and the IRS request comments regarding how to treat recharacterization and reallocation adjustments related to items that are not allocated under section 704(b).

To incorporate the additions of sections 6225(b)(3) and (b)(4), proposed § 301.6225–1(d)(1) provides that when the IRS determines a negative adjustment (as defined in proposed § 301.6225–1(d)(2)(ii)), all partnership adjustments are placed into subgroupings based on whether the adjusted items are required to be taken into account separately under section 702 and other provisions of the Code. Proposed § 301.6225–1(d)(1) provides authority for the IRS to alter the manner in which adjustments are subgrouped to appropriately reflect the facts and circumstances.

Proposed § 301.6225–1(d)(2) provides for the treatment of certain partnership adjustments and defines the terms negative adjustment and positive adjustment. A negative adjustment is defined as an adjustment that is a decrease in an item of income, treated as a decrease in an item of income, or that is an increase in an item of credit. A positive adjustment is an adjustment that is not a negative adjustment. Proposed § 301.6225–1(d)(3) requires that positive and negative adjustments resulting from reallocation adjustments and recharacterization adjustments be placed into separate subgroupings.

Proposed § 301.6225–1(e) provides rules for appropriately netting adjustments within each grouping or subgrouping and provides that adjustments are not netted between groupings or subgroupings. The statutory changes referencing section 702(a) and other provisions of the Code and the general inability to net negative adjustments result in restrictions on netting in these proposed rules that are broader than the restrictions described in former proposed § 301.6225–1. The examples in the proposed rules have been revised to reflect these broader restrictions on netting.

Proposed § 301.6225–1(f) provides rules related to determining whether adjustments are adjustments that do not result in an imputed underpayment. If the adjustments do not result in an imputed underpayment, such adjustments are taken into account in accordance with § 301.6225–3.

Proposed § 301.6225–1(g) provides the IRS may create multiple imputed underpayments for a particular tax year. Proposed § 301.6225–1(g)(2)(iii)(B) allows a particular adjustment that does not result in an imputed underpayment to be associated with a particular imputed underpayment. This rule ensures that adjustments that are appropriately associated with the imputed underpayment will be taken into account along with the other adjustments underlying the imputed underpayment if an election under section 6226 is made with respect to that imputed underpayment. For example, a reallocation or recharacterization adjustment generally results in more than one adjustment. In the case of a reallocation adjustment, there are adjustments that affect at least two partners. In a recharacterization adjustment, there is an adjustment to correct the characterization and an adjustment disallowing the incorrect characterization. As a result, if an adjustment that does not result in an imputed underpayment is due to a reallocation or recharacterization adjustment and one side of the adjustment is used to calculate a specific imputed underpayment, the other side of the adjustment, which is an adjustment that does not result in an imputed underpayment, is associated with that specific imputed underpayment.

The IRS may also determine that other adjustments that do not result in an imputed underpayment should be associated with a specific imputed underpayment. An adjustment that does not result in an imputed underpayment and that is not associated with a particular specific imputed underpayment is associated with the general imputed underpayment.

Proposed § 301.6225–2 provides guidance on procedures to modify the imputed underpayment. Former § 301.6225–2(b) provided that the effect of modification was determined by considering how the modification changed the relevant portion of the adjustment. This approach to modification is consistent with the amendments to section 6225(c). Accordingly, proposed § 301.6225–2(b)

reflects the rule that modification affects the portion of an adjustment.

Proposed § 301.6225–2(b)(3)(iv) provides rules on rate modification in the case of special allocations. Those rules generally mirror the statutory rule under section 6225(c)(4)(B)(ii). The rule in the statute is complex compared with other rate modifications in that they require a valuation analysis. The Treasury Department and the IRS request comments on ways to implement these rules efficiently.

Proposed § 301.6225–2(d)(2) provides rules regarding amended returns and the alternative procedure to filing amended returns. Proposed § 301.6225–2(d)(2) provides that a partnership may satisfy the requirements of amended return modification by submitting all the information required for amended return modification and the partners paying any amount that would be due if the partners had filed amended returns. The Treasury Department and the IRS request comments on how best to implement the alternative procedure to filing amended returns.

Former proposed § 301.6225–2(d)(2)(viii) provided that partners could raise a reasonable cause defense under section 6664(c) (or other partner-level defense as described in former proposed § 301.6226–3(i)(3)) with an amended return in modification. Proposed § 301.6225–(d)(2)(viii) now provides that such partner-level defenses should be raised through a claim for refund that is submitted outside of the modification process. This rule is similar to the current rule regarding partner-level defenses related to adjustments that are taken into account by partners under section 6226. See proposed § 301.6226–3(d)(3).

Section 6225(c)(6) grants the Secretary authority to ''by regulations or guidance provide for additional procedures to modify imputed underpayment amounts on the basis of such other factors as the Secretary determines are necessary and appropriate to carry out the purposes of this section.'' The Treasury Department and the IRS have elected to use this authority in two circumstances that were not included in former proposed § 301.6225–2. First, the Treasury Department and the IRS have concluded that the references to the adjustment year in section 6225(c)(5) make the implementation of section 6225(c)(5) unworkable. No partner would qualify as a specified partner until the adjustment year, but at any time during the administrative proceeding that is relevant to modification, the adjustment year does not yet exist. As a result, the only time this type of modification could be used would be in the case of an AAR because in that case, the adjustment year is the year in which the AAR is filed. In order for modification under section 6225(c)(5) to be administrable, proposed § 301.6225–2(d)(5)(iv) provides that a ''qualified relevant partner'' is a person that meets the definition of a specified partner but in a year that can be determined at the time modification is requested. The definition of a specified passive activity loss has also been changed to clarify that the years at issue do not have to be the adjustment year.

Second, the Treasury Department and the IRS are also exercising the authority under section 6225(c)(6) to add a modification for partnerships with partners entitled to benefits under an income tax treaty. Proposed § 301.6225–2(d)(9) allows modification if a relevant partner would have qualified for a reduction or exemption from tax with respect to a particular item under an income tax treaty with the United States. The Treasury Department and the IRS request comments on this type of modification.

Proposed § 301.6225–2(e) provides rules for modification of certain types of adjustments that do not result in an imputed underpayment (as defined in proposed § 301.6225–1(f)). Proposed § 301.6225–2(e) limits the ability to modify such adjustments to certain types of modification. The Treasury Department and the IRS request comments on whether the list of allowed modifications under proposed § 301.6225–2(e) is sufficient.

Lastly, proposed § 301.6225–2 adopts the term ''relevant partner'' to describe any direct or indirect partner in the partnership seeking modification. See section 6225(c)(2)(F) and proposed § 301.6225–2(a).

Proposed § 301.6225–3 provides rules regarding adjustments that do not result in in an imputed underpayment. The changes in the TTCA comport with former proposed § 301.6225–3, which required that the partnership take the adjustments that do not result in an imputed underpayment into account as separately stated or non-separately stated adjustments as appropriate.

B. Proposed § 301.6225–4

Proposed rules under § 301.6225–4 were previously published in the **Federal Register** (83 FR 4868–82) in the February 2018 NPRM (former proposed § 301.6225–4). For an explanation of the rules under former proposed § 301.6225–4, see 82 FR 4877.

Proposed § 301.6225–4 sets forth rules under which a partnership and its partners must adjust specified tax attributes to take into account partnership adjustments and the partnership's payment of an imputed underpayment. Changes have been made throughout former proposed § 301.6225–4 to conform to the changes to the definition of ''tax attribute'' under proposed § 301.6241–1(a)(10). See section 11.A of this preamble regarding the change to the definition of ''tax attribute.'' In addition, the definition of ''specified tax attributes'' in proposed § 301.6225–4(a)(2) now includes earnings and profits under section 312 in response to comments received concerning the effect of partnership adjustments on a corporate partner's earnings and profits.

4. Election for the Alternative to Payment of the Imputed Underpayment

Section 6226 provides an alternative to the general rule under section 6225(a)(1) that the partnership must pay an imputed underpayment. Under section 6226, the partnership may elect to have its reviewed year partners take into account adjustments made by the IRS and pay any tax due as a result of those adjustments. If this election is made, the reviewed year partners must pay any chapter 1 tax resulting from taking into account the adjustments, and the partnership is not required to pay the imputed underpayment.

Section 206(d) of TTCA amended section 6226(a) to clarify that if a partnership makes a valid election under section 6226 with respect to an imputed underpayment, no assessment of such imputed underpayment, levy, or proceeding in any court for the collection of such imputed underpayment shall be made against such partnership.

Section 206(e) of the TTCA amended section 6226(b)(1) to provide that when a partner takes into account the adjustments, the partner's chapter 1 tax is adjusted by the aggregate of the ''correction amounts'' determined under section 6226(b)(2). After amendment by the TTCA, the correction amounts under section 6226(b)(2) are defined as the amounts by which the partner's chapter 1 tax would increase ''or decrease'' for the partner's first affected year if the partner's share of the adjustments were taken into account for that year. The correction amounts are also the amount by which the partner's chapter 1 tax would increase ''or decrease'' by reason of the adjustment to tax attributes for any intervening years. See section 6226(b)(2).

Section 204(a) of the TTCA added to the Code section 6226(b)(4), which provides that a partnership or S corporation that receives a statement under section 6226(a)(2) must file a

partnership adjustment tracking report with the IRS and furnish statements under rules similar to the rules of section 6226(a)(2). If the partnership or S corporation fails to furnish such statements, the partnership or S corporation must compute and pay an imputed underpayment under rules similar to the rules of section 6225. A partnership that is a partner must file the partnership adjustment tracking report, and furnish statements or pay an imputed underpayment, notwithstanding any election out of the centralized partnership audit regime under section 6221(b) by the partnership for the tax year that includes the end of the reviewed year of the audited partnership. The term ''audited partnership'' means the partnership in the chain of ownership that originally made the election under section 6226. See section 6226(b)(4)(D).

A. Proposed §§ 301.6226–1, 301.6226–2, and 301.6226–3

Proposed rules under §§ 301.6226–1, 301.6226–2, and 301.6226–3 were previously published in the **Federal Register** in the June 2017 NPRM (82 FR 27391–97), the November 2017 NPRM (82 FR 56778–79), and the December 2017 NPRM (82 FR 60155–61) (collectively, former proposed §§ 301.6226–1, 301.6226–2, and 301.6226–3). For an explanation of the rules under former proposed §§ 301.6226–1, 301.6226–2, and 301.6226–3, see 82 FR 27358–66, 82 FR 56769–71, and 82 FR 60148–51.

Former proposed § 301.6226–1(b)(2) provided that if a partnership makes a valid election in accordance with proposed § 301.6226–1, the partnership is not liable for the imputed underpayment to which the election relates. To reflect the statutory change to section 6226(a), language has been added to proposed § 301.6226–1(b)(2) to clarify that if a partnership makes a valid election under section 6226 with respect to an imputed underpayment, the IRS may not assess such imputed underpayment, levy, or bring a proceeding in any court for the collection of that imputed underpayment against such partnership. A similar change has also been made to proposed § 301.6226–1(c)(2) (regarding invalid elections) to clarify that if a final determination is made that a purported election under section 6226 is invalid, the IRS may assess the imputed underpayment with respect to which the election was made against the partnership without regard to the limitations under section 6232(b).

Former proposed § 301.6226–3 provided that a reviewed year partner that is furnished a statement under section 6226(a)(2) is required to pay any additional chapter 1 tax (additional reporting year tax) that results from taking into account the partnership adjustments on that statement. As mentioned above in this section of the preamble, section 206(e) of the TTCA amended section 6226(b) to provide that decreases, as well as increases, in chapter 1 tax that result from taking into account partnership adjustments are used in computing a partner's additional reporting year tax. Section 206(e) of the TTCA also replaced the term ''adjustment amount'' with ''correction amount.'' Accordingly, proposed § 301.6226–3 now refers to ''correction amount'' instead of ''adjustment amount,'' as appropriate, and now provides that a reviewed year partner's chapter 1 tax for the reporting year may be increased or decreased by the additional reporting year tax. The additional reporting year tax is the sum of the correction amounts for the first affected year and any correction amounts for the intervening years. Under proposed § 301.6226–3(b)(2) and (3), the correction amounts are the amounts by which the partner's chapter 1 tax for the taxable year would be increased or decreased if the partner's taxable income for that year were recomputed by taking into account, in the case of the first affected year, the partner's share of the partnership adjustments reflected on the statement furnished to the partner or, in the case of any intervening year, any change to tax attributes of the partner resulting from the changes in the first affected year. A correction amount for the first affected year or any intervening year may be less than zero and may be used to offset any correction amounts from any other year in computing the additional reporting year tax. The examples under proposed § 301.6226–3(h) illustrate situations in which a correction amount may be less than zero.

Furthermore, the additional reporting year tax may be less than zero and may offset other taxes owed by the partner on the partner's reporting year return. Accordingly, any references to the additional reporting year tax as a ''liability'' have been removed from former proposed § 301.6226–3 to account for situations in which the additional reporting year tax is less than zero.

Section 6226(c)(2) provides that interest in the case of a section 6226 election is determined at the partner level, from the due date of the return for the taxable year to which the increase in chapter 1 tax is attributable, and at the underpayment rate under section 6621(a)(2) (substituting 5 percent for 3 percent). As discussed above in this section of the preamble, the TTCA amended section 6226(b) to provide that both increases and decreases in chapter 1 tax are used in computing a partner's additional reporting year tax. However, the TTCA did not similarly amend the reference to ''increases'' in section 6226(c)(2) with the result that interest only applies to the increases in the chapter 1 tax that would have resulted from taking into account the partnership adjustments under section 6226. No provision under the centralized partnership audit regime provides for interest in the case of a *decrease* in chapter 1 tax that would have resulted in the first affected year or any intervening year if the adjustments were taken into account in those years. Accordingly, proposed § 301.6226–3(c)(1) provides that interest on the correction amounts determined under proposed § 301.6226–3(b) is only calculated for taxable years for which there is a correction amount greater than zero, that is, taxable years for which there would have been an increase in chapter 1 tax if the adjustments were taken into account.

Proposed § 301.6226–3(c)(1) further provides that for purposes of calculating interest on the correction amounts, any correction amount that is less than zero does not offset any correction amount that is greater than zero. Although those amounts may offset when determining the additional reporting year tax (as described in proposed § 301.6226–3(b)), allowing the same offset for purposes of calculating interest is inconsistent with section 6226(c)(2), which provides that interest is determined with respect to any increase determined under section 6226(b)(2).

Proposed § 301.6226–3(d)(3) has also been clarified to provide that if a partner wants to raise a partner-level defense to any penalty, addition to tax, or additional amount, a partner must first pay the penalty, addition to tax, or additional amount and file a claim for refund for the reporting year in order to raise the defense.

As discussed above in this section of the preamble, section 204(a) of the TTCA amended section 6226(b) to provide that partnerships and S corporations that are direct or indirect partners in an audited partnership and that receive statements under 6226(a)(2) must file partnership adjustment tracking reports with the IRS and furnish statements to their owners under rules similar to section 6226. If no statements are furnished, the partnership or S corporation must

compute and pay an imputed underpayment.

Former proposed § 301.6226–3(e)(1) provided that a pass-through partner (as defined in proposed § 301.6241–1(a)(5)) that was furnished a statement described in proposed § 301.6226–2 (including a statement as described in former proposed § 301.6226–3(e)(3)) must take into account the adjustments reflected on that statement by either furnishing statements to its partners or by paying an amount calculated like an imputed underpayment. Any statements furnished under those provisions were treated as statements described in proposed § 301.6226–2, and any pass-through partner receiving a statement under former proposed § 301.6226–3(e)(3) was required to also take the adjustments reflected on the statement into account by furnishing statements to its own partners or paying an amount calculated like an imputed underpayment. See former proposed § 301.6226–3(e)(3)(i) and (iv).

Although the rules under former proposed § 301.6226–3(e) were largely consistent with the rules under section 6226(b)(4), some changes were needed to conform the two sets of rules. First, proposed § 301.6226–3(a)(1) now provides that the rules under proposed § 301.6226–3(a)(1) apply to a reviewed year partner except to the extent otherwise provided in proposed § 301.6226–3. Second, proposed § 301.6226–3(e) now includes a requirement that the pass-through partner must file a partnership adjustment tracking report. Third, proposed § 301.6226–3(e) provides a default rule that a pass-through partner must furnish statements to its own partners in accordance with proposed § 301.6226–3(e)(3). If a pass-through partner fails to furnish statements in accordance with proposed § 301.6226–3(e)(3), the pass-through partner must compute and pay an imputed underpayment. Additionally, language referring to a pass-through partner ''taking into account'' the adjustments under former proposed § 301.6226–3(e) was removed to more closely align with the statutory language in section 6226(b)(4). Fourth, proposed § 301.6226–3(e) defines and refers to the term ''audited partnership,'' which proposed § 301.6226–3(e)(1) defines as the partnership that made the election under § 301.6226–1. See section 6226(b)(4)(D). Lastly, proposed § 301.6226–3(e)(4) provides that the amount a pass-through partner must compute and pay, if it does not furnish statements to its partners, is an ''imputed underpayment.'' See section 6226(b)(4)(A)(ii)(II).

Because under proposed § 301.6226–3(e), pass-through partners compute and pay an ''imputed underpayment,'' rather than calculating correction amounts under proposed § 301.6226–3(b), references in former proposed § 301.6226–3(b) to amended returns filed by indirect partners as part of modification have been deleted. Pass-through partners computing an imputed underpayment under proposed § 301.6226–3(e) may account for modifications submitted by their indirect partners, but non-pass-through partners calculating correction amounts under proposed § 301.6226–3(b) cannot. Accordingly, the references in former proposed § 301.6226–3(b) to amended returns filed by indirect partners were removed.

To reflect the change to the definition of ''tax attribute'' under proposed § 301.6241–1(a)(10) (see section 11.A. of this preamble), proposed §§ 301.6226–2 and 301.6226–3 now only refer to the tax attributes of the partner. For example, proposed §§ 301.6226–2(e) and 301.6226–3(e)(3)(iii) no longer require that the audited partnership report any changes to *partnership* tax attributes on the statements furnished to its partners under section 6226(a)(2). Therefore, when a partner computes the partner's correction amount for any intervening year, the partner calculates the amount by which the partner's chapter 1 tax for any intervening year would increase or decrease if any tax attribute of that partner (for example, a net operating loss carryover or capital loss carryover) has been adjusted after taking into account the partner's share of the adjustments in the first affected year.

Finally, references to ''items'' or ''items of income, gain, loss, deduction, or credit'' throughout former §§ 301.6226–1, 6226–2, and 6226–3 have been replaced with references to ''partnership-related items.''

B. Revisions to the Regulations Under Section 6226 Unrelated to the TTCA Amendments

In addition to the changes needed to conform to the amendments by the TTCA, some additional changes have been made to former proposed §§ 301.6226–1, 6226–2, and 6226–3. First, proposed § 301.6226–1(b)(2) now provides that only those adjustments that do not result in an imputed underpayment which are associated with an imputed underpayment for which an election under section 6226 is made are included in the reviewed year partner's share of the partnership adjustments reported to the partner. Any adjustments that do not result in an imputed underpayment which are not associated with an imputed underpayment for which an election under section 6226 is made are taken into account under section 6225. This change was necessary to clarify which partnership adjustments are pushed out in the case of multiple imputed underpayments where the push out election is not made with respect to all imputed underpayments. See proposed § 301.6225–1(g) for rules regarding the treatment of adjustments that do not result in an imputed underpayment in the context of specific imputed underpayments.

Second, under proposed § 301.6226–1(c)(1), an election under section 6226 is only valid if all the provisions under proposed § 301.6226–1 (regarding making the election) and § 301.6226–2 (regarding the furnishing of statements) are satisfied, and an election made under section 6226 is valid until the IRS determines that the election is invalid. The rule that an election is valid until the IRS determines it is invalid was moved from former proposed § 301.6226–1(c)(2) to proposed § 301.6226–1(c)(1) to clarify that an election that does not fully satisfy the requirements of proposed §§ 301.6226–1 and 301.6226–2 is valid unless the IRS determines that the purported election is invalid. For example, if a partnership makes an election in accordance with proposed § 301.6226–1 but fails to furnish statements to its partners, that election is valid until the IRS determines otherwise.

In addition, the word ''final'' was removed from before the word ''determination'' in proposed § 301.6226–1(c)(2) when referring to a determination made by the IRS that a purported election under section 6226 is invalid. The removal of the word ''final'' clarifies that the IRS may determine that an election is invalid and assess and collect the imputed underpayment to which the purported election related without first being required to make a proposed or initial determination of invalidity. Although nothing in the regulations precludes the IRS from first notifying the partnership of a potential problem with an election before determining the election is invalid, proposed § 301.6226–1(c)(2) provides that the IRS may determine that an election is invalid even if the partnership has corrected the statements required to be filed and furnished in accordance with proposed § 301.6226–2(d)(3) and also provides that the IRS is not obligated to require the correction of any errors prior to determining an election is invalid.

Third, several changes were made to clarify that the partnership must provide correct information in order to make a valid election under section 6226 and in order for statements to be properly furnished either under proposed § 301.6226–2 or proposed § 301.6226–3(e)(3). Proposed § 301.6226–1(c)(4)(ii) requires the partnership to provide correct information in its election, and proposed § 301.6226–2(e) and proposed § 301.6226–3(e)(3)(iii) require that the statements filed and furnished with the IRS include correct information. Additionally, proposed § 301.6226–2(d)(3) provides that if the IRS cannot determine whether the statements filed and furnished by the partnership are correct because of a failure by the partnership to comply with any requirements (such as filing a partnership adjustment tracking report), the IRS may, but is not obligated to, require the partnership to provide additional information to substantiate the statements. Proposed § 301.6226–2(d)(2) extends the rules governing corrections of errors in statements to statements furnished by pass-through partners under proposed § 301.6226–3(e)(3) and to provide that, if consent of the IRS is required for a correction, that corrected statements may not be furnished until the IRS provides consent.

Fourth, duplicative language regarding the definition of the extended due date for the adjustment year of the audited partnership was removed from former proposed § 301.6226–3(e)(3)(ii) and (e)(4)(ii).

Fifth, in proposed § 301.6226–3(g), the word ''grantor'' has been added between the words ''wholly-owned'' and ''trusts'' to clarify that ''wholly-owned trusts'' means ''wholly-owned grantor trusts.''

Sixth, the phrase ''an entity described in § 301.7701–2(c)(2)(i)'' in former proposed § 301.6226–3(j) was changed to ''a wholly-owned entity disregarded as separate from its owner for Federal tax purposes in the reviewed year'' to conform to the definition of disregarded entity under proposed § 301.6241–1(a)(4).

Seventh, proposed § 301.6226–3(c)(2) now provides that interest on any penalties, additions to tax, or additional amounts is calculated from each applicable taxable year until the penalty, addition to tax, or additional amount is paid. Former proposed § 301.6226–3(c)(2) provided that interest was calculated from the first affected year. Under proposed § 301.6226–3(d)(2), partners calculate any penalties, additions to tax, or additional amounts that relate to the partnership adjustments at the partner level. Because the adjustments could create tax effects in more than just the first affected year (for example, as a result of changes to tax attributes in an intervening year), a penalty, addition to tax, or additional amount might likewise result in more than just the first affected year. Accordingly, proposed § 301.6226–3(c)(2) provides that interest on penalties, additions to tax, and additional amounts runs from the applicable taxable year (that is, the particular tax year to which the penalty, addition to tax, or additional amount relates).

Finally, certain errors were corrected in the examples under proposed § 301.6226–3(h). Examples 2 through 4 and 6 through 9 under former proposed § 301.6226–3(h) incorrectly listed the last day to file a petition under section 6234 as the date the adjustments became final, and examples 6 through 9 incorrectly referred to former proposed § 301.6226–1(b) as support for this rule. Under proposed § 301.6226–2(b), partnership adjustments become finally determined on the later of the expiration of the time to file a petition under section 6234 or, if a petition is filed under section 6234, the date when the court's decision becomes final. The examples under proposed § 301.6226–3(h) now reflect that the adjustments become final on the day after the last day to file a petition under section 6234 to be consistent with the rule under § 301.6226–2(b), and incorrect references to § 301.6226–1(b) in Examples 6 through 9 under former proposed § 301.6226–3(h) have been replaced with correct references to § 301.6226–2(b).

Proposed § 301.6226–4

Proposed rules under §§ 301.6226–4 were previously published in the **Federal Register** in the February 2018 NPRM (83 FR 4868) (former proposed § 301.6226–4). For an explanation of the rules under former proposed § 301.6226–4, see 83 FR 4874.

Proposed § 301.6226–4 sets forth rules for adjusting reviewed year partners' tax attributes to take into account partnership adjustments when a partnership makes an election under section 6226. To reflect the addition of section 6226(b)(4), proposed § 301.6226–3(e)(4) now provides that a reviewed year partner that is a pass-through partner must pay an imputed underpayment if the pass-through partner does not furnish statements. In addition, changes have been made throughout former proposed § 301.6226–4 to conform to the change to the definition of ''tax attribute'' under proposed § 301.6241–1(a)(10). See section 11.A of this preamble. These changes reflect that the adjustments to tax attributes taken into account by a partner should be consistent, regardless of whether the partner files an amended return during modification, participates in the alternative procedure to filing an amended return, or receives a statement under section 6226. Accordingly, the proposed regulations under section 6226 have been revised to refer only to the tax attributes of the partner in the intervening years. Additionally, clarifying changes were made in proposed § 301.6226–4(b) to conform to the terminology used in proposed § 301.6226–3. Lastly, an incorrect cross-reference in former proposed § 301.6226–4(c)(4)(iii) has been replaced with the correct cross-reference.

5. Administrative Adjustment Requests

Section 6227 provides a mechanism for a partnership to file an AAR to correct errors on a partnership return for a prior year. Prior to amendment by the TTCA, section 6227(a) provided that a partnership may file a request for administrative adjustment in the amount of one or more items of income, gain, loss, deduction, or credit of the partnership or any partnership taxable year. Section 201(c) of the TTCA amended section 6227(a) by striking ''items of income, gain, loss, deduction, or credit of the partnership'' and inserting ''partnership-related items.''

Prior to amendment by the TTCA, section 6227(b) provided that any adjustment requested in an AAR is taken into account for the partnership taxable year in which the AAR is made. Section 206(p) of the TTCA amended section 6227(b) by striking ''is made'' both places it appears and inserting ''is filed.''

Prior to amendment by the TTCA, section 6227(b)(1) provided that if an adjustment results in an imputed underpayment, the adjustment may be determined and taken into account by the partnership under rules similar to the rules under section 6225 relating to payment of the imputed underpayment by the partnership, except that the provisions under section 6225 pertaining to modification of the imputed underpayment based on amended returns by partners, the time for submitting information to the Secretary for purposes of modification, and approval by the Secretary of any modification do not apply.

Section 206(p) of the TTCA amended section 6227(b)(1) by striking the reference to ''paragraphs (2), (6), and (7)'' of section 6225(c) (relating to

modification) and inserting ''paragraphs (2), (7), and (9)'' of section 6225(c). As a result, section 6227(b)(1) provides that adjustments requested in an AAR are taken into account by the partnership under rules similar to section 6225 (except for sections 6225(c)(2), (7), and (9)). As amended by TTCA, section 6225(c)(2) provides rules allowing for amended returns and an alternative procedure to filing amended returns for purposes of modification, section 6225(c)(7) provides that information required to be submitted for purposes of modification be submitted within 270 days from the date on which the notice of a proposed partnership adjustment is mailed under section 6231, and section 6225(c)(9) provides for modification with respect to adjustments that do not result in an imputed underpayment.

Lastly, section 206(f) of the TTCA added section 6227(d) to provide that the Secretary shall issue regulations or other guidance which provide for the proper coordination of section 6227 and section 905(c).

A. Proposed §§ 301.6227–1, 301.6227–2, and 301.6227–3

Proposed rules under §§ 301.6227–1, 301.6227–2, and 301.6227–3 were previously published in the **Federal Register** (82 FR 27397–99) in the June 2017 NPRM, November 2017 NPRM (82 FR 56779), and December 2017 NPRM (82 FR 60161) (collectively, former proposed §§ 301.6227–1, 301.6227–2, and 301.6227–3). For an explanation of the rules under former proposed §§ 301.6227–1, 301.6227–2, and 301.6227–3, see 82 FR 27366–69, 82 FR 56769, and 82 FR 60151.

Former proposed § 301.6227–1(a) provided that a partner may not file an AAR except if the partner is doing so on behalf of the partnership in the partner's capacity as the partnership representative or if the partner is a partnership-partner filing an AAR under former proposed § 301.6227–3(c). Proposed § 301.6227–3(c), however, does not provide for the filing of an AAR by a partnership-partner. Rather, under proposed § 301.6227–3(c), a partnership-partner takes into account adjustments requested in an AAR by the partnership in which it is a partner by following the rules under proposed § 301.6226–3(e) (except to the extent otherwise provided). Proposed § 301.6227–1(a) therefore is changed to remove the reference to partnership-partners, and now only refers to partners filing AARs in their capacity as a partnership representative.

Proposed § 301.6227–2(a)(1) provides the rules for determining whether an imputed underpayment results from adjustments requested in an AAR by referring to the rules under proposed § 301.6225–1. Under proposed § 301.6227–2(a)(2), in the case of an AAR, a partnership may reduce an imputed underpayment as a result of certain modifications permitted under proposed § 301.6225–2. Under former proposed § 301.6227–2(a)(2), these modifications included modifications that relate to tax-exempt partners (proposed § 301.6225–2(d)(3)), rate modification (proposed § 301.6225–2(d)(4)), modification related to certain passive losses of publicly traded partnerships (proposed § 301.6225–2(d)(5)), modification applicable to qualified investment entities described in section 860 (proposed § 301.6225–2(d)(7)), and other modifications to the extent permitted under future IRS guidance (proposed § 301.6225–2(d)(10)). Proposed § 301.6227–2(a)(2) adopts this same list of modifications and adds modifications related to the composition of the groupings that factor into the calculation of the imputed underpayment (proposed § 301.6225–2(d)(6)(ii)) and modifications related to tax treaties (proposed § 301.6225–2(d)(9)).

Proposed § 301.6227–2(a)(2) provides that other types of modification, such as modification under proposed § 301.6225–2(d)(2) with respect to amended returns, including the alternative procedure to filing amended returns, and modification under proposed § 301.6225–2(d)(8) with respect to closing agreements, are not available in the case of an AAR. Modifications with respect to adjustments that do not result in an imputed underpayment also are also not available in the case of an AAR.

Former proposed § 301.6227–2(a)(2)(i) provided that a partnership did not need to seek IRS approval prior to modifying an imputed underpayment that results from adjustments requested in an AAR. Section 6227(b)(1) does not explicitly carve out section 6225(c)(8),which states that any modification to the imputed underpayment made under section 6225(c) shall be made only upon approval of such modification by the Secretary. Section 6227(b)(1) does provide, however, that partnerships take into account adjustments requested in an AAR under rules similar to the rules under section 6225. In proposing rules similar to the rules under section 6225 for the purposes of requesting an AAR and taking into account adjustments, the Treasury Department and the IRS have determined it is more efficient and beneficial for both the IRS and for partnerships to be able to apply modifications when filing an AAR without first securing approval of permitted modifications. Accordingly, although any modifications in connection with an AAR are subject to IRS approval, the rules under proposed § 301.6227–2(a)(2)(i) provide that the partnership is not required to obtain the approval from the IRS before applying modifications when calculating the amount of the imputed underpayment the partnership needs to pay when filing the AAR. Proposed § 301.6227–2(a)(2)(ii) also provides, however, that modifications to an imputed underpayment resulting from adjustments requested in an AAR may not be applied by the partnership if the AAR that is filed does not include notification to the IRS of the modification, a description of the effect of the modification on the imputed underpayment, an explanation of the basis for such modification, and all necessary documentation to support the partnership's entitlement to such modification.

Under proposed § 301.6227–3, a reviewed year partner that receives a statement described in proposed § 301.6227–1(d) must treat that statement as if it were provided under section 6226(a)(2). Former proposed § 301.6227–3(b)(1) also provided that the restriction in former proposed § 301.6226–3(b)(1)—that the correction amount for the first affected year and any intervening year cannot be less than zero—does not apply in the case of taking into account adjustments requested by the partnership in an AAR. Proposed § 301.6227–3(b)(1) no longer needs to address that restriction because the restriction in former proposed § 301.6226–3(b)(1) no longer exists. Therefore, the exception in former proposed § 301.6227–3(b)(1) has been eliminated. Additionally, the provision in former proposed § 301.6227–3(b)(2), stating that when the additional reporting tax results in being less than zero the partner may reduce his chapter 1 tax for the reporting year, is moved to proposed § 301.6227–3(b)(1).

Former proposed § 301.6227–1 included a reserved paragraph regarding notice of change to amounts of creditable foreign tax expenditures. Proposed § 301.6227–1 also reserves this same paragraph and does not contain rules to coordinate sections 6227 and 905(c). The Treasury Department and the IRS seek comments regarding the coordination of sections 6227 and 905(c) for consideration in future guidance.

Lastly, the reference to ''items of income, gain, loss, deduction, or credit of the partnership'' in former proposed § 301.6227–1(a) has been replaced with

a reference to ''partnership-related items.''

B. Revisions to the Regulations Under Section 6227 Unrelated to the TTCA Amendments

Proposed § 301.6227–1(a) now coordinates the rules regarding the filing of an AAR and the revocation of a designation of the partnership representative under § 301.6223–1. Former proposed § 301.6227–1(a) provided that the partnership may not file an AAR solely for the purpose of allowing the partnership to change the designation of a partnership representative. Proposed § 301.6227–1(a) now adds that when the partnership changes the designation of the partnership representative or the appointment of a designated individual in conjunction with the filing of an AAR, the change in designation or appointment is treated as occurring prior to the filing of the AAR.

Former proposed § 301.6227–1(b) provided that an AAR may not be filed after a notice of administrative proceeding (NAP) has been mailed. To account for situations in which the IRS mails a NAP, but then withdraws it, proposed § 301.6227–1(b) now provides that an AAR may not be filed after a NAP has been mailed, except when the NAP has been withdrawn under proposed § 301.6231–1(f).

Additions were also made in proposed § 301.6227–3(c) to clarify the rules for pass-through partners, unrelated to the changes made by the TTCA. First, proposed § 301.6227–3(c)(1) provides that when a pass-through partner takes into account adjustments requested in an AAR in accordance with proposed § 301.6226–3(e), the pass-through partner must provide the information described in proposed § 301.6227–3(c)(3) as opposed to the information in described in proposed § 301.6226–3(e)(3)(iii) when furnishing statements to its partners. Second, under proposed § 301.6227–3(c)(1), a pass-through partner that computes and pays an imputed underpayment in accordance with proposed § 301.6226–3(e)(4) may not take into account any modifications. Third, proposed § 301.6227–3(c)(4) provides that when a pass-through partner furnishes a statement to an affected partner under proposed § 301.6227–3(c), the affected partner must treat that statement as if it were a statement described in proposed § 301.6227–3(a) that was furnished to such affected partner.

6. Notices of Proceedings and Adjustments

Section 6231(a) provides that the Secretary shall mail to the partnership and to the partnership representative a notice of any administrative proceeding initiated at the partnership level, notice of any proposed partnership adjustment resulting from that proceeding (NOPPA), and notice of any final partnership adjustment (FPA). Prior to amendment by the TTCA, section 6231(a) also provided that any FPA shall be mailed no earlier than 270 days after the date on which the NOPPA is mailed. Such notices shall be sufficient if mailed to the last known address of the partnership and the partnership representative, even if the partnership has terminated its existence. See section 6231(a) flush language (prior to amendment by the TTCA).

Prior to amendment by the TTCA, the statute did not limit the period for the IRS to propose adjustments under the centralized partnership audit regime. Section 206(h) of the TTCA amended section 6231 to address this issue. As amended, section 6231(b)(1) provides that any NOPPA shall not be mailed later than the date determined under section 6235(a)(1), which is generally the date that is 3 years after the later of: (1) The date on which the partnership return for the taxable year was filed, (2) the return due date for the taxable year, or (3) the date on which the partnership filed an AAR with respect to the taxable year.

Section 206(h) of the TTCA makes a conforming amendment to section 6231(a) to reflect the addition of the period of limitations to made partnership adjustments. Prior to amendment, section 6231(a) provided that ''Such notices shall be sufficient if mailed to the last known address of the partnership representative or the partnership (even if the partnership has terminated its existence).'' The amendment replaced the words ''Such notices'' with ''Any notice of final partnership adjustment.''

Section 201(c) of the TTCA also makes a conforming amendment to section 6231(a) by striking the phrase ''all items of income, gain, loss, deduction, or credit of the partnership'' and inserting ''all partnership-related items.''

A. Proposed § 301.6231–1

Proposed rules under § 301.6231–1 were previously published in the **Federal Register** (82 FR 60161–62) in the December 2017 NPRM (former proposed § 301.6231–1). For an explanation of the rules under former proposed § 301.6231–1, see 82 FR 60151–52.

Although not required by statute, former proposed § 301.6231–1(b)(1) provided a period of limitations for making partnership adjustment. That section provided that a NOPPA may not be mailed after the expiration of the period described in section 6235(a)(1), including any extensions of that period and after applying any of the special rules in section 6235(c) (providing additional time for situations where no return is filed, fraud, and other specified reasons).

Former proposed § 301.6231–1(c) provided that NAPs, NOPPAs, and FPAs are sufficient if mailed to the last known address of the partnership and the partnership representative. As discussed above in this section of the preamble, section 6231(a) now provides that any FPA is sufficient if mailed to the last known address of the partnership and the partnership representative. The Treasury Department and the IRS have determined that while the last known address requirement under section 6231(a) only applies to a notice of final partnership adjustment, the IRS will also mail the NAP and the NOPPA to the last known address of the partnership and the partnership representative.

Accordingly, because the rules under former proposed § 301.6231–1(b)(1) and (c) are consistent with the statutory changes to section 6231(a), those rules are unchanged. The only change to former proposed § 301.6231–1 was to replace references to ''item of income, gain, loss, deduction, or credit'' and to a ''partner's distributive share'' in former proposed § 301.6231–1(a)(1) with a reference to ''partnership-related item''.

7. Assessment, Collection, and Payment of Imputed Underpayments

Section 6232(a) provides rules for the assessment, collection, and payment of imputed underpayments. Section 206(g) of the TTCA amended section 6232(a) to clarify that the assessment of any imputed underpayment is not subject to the deficiency procedures under subchapter B of chapter 63 of the Code and to clarify that in the case of an AAR, the underpayment may be assessed when the AAR is filed. See JCX–6–18, at 48.

Section 6232(b) provides limitations on the assessment of an imputed underpayment. Section 206(g) of the TTCA amended section 6232(b) to correct a reference to ''assessment of a deficiency'' to now refer to ''assessment of an imputed underpayment.'' Section 206(p) of the TTCA also amends section

6232(b) to strike the reference to ''this chapter'' and replace it with ''this subtitle (other than subchapter B of this chapter).''

Section 205 of the TTCA added a new subsection (f) to section 6232 to provide a mechanism for collection of tax due in the case of a failure of a partnership or S corporation to pay an imputed underpayment or specified similar amount. Under section 6232(f)(1), if any amount of any imputed underpayment to which section 6225 applies or any specified similar amount as defined in section 6232(f)(2) has not been paid by the date which is 10 days after the date on which the Secretary provides notice and demand for such payment, the Secretary may assess upon each partner of the partnership a tax equal to such partner's proportionate share of such amount.

Under section 6232(f)(2), the term ''specified similar amount'' means the amount determined under section 6226(b)(4)(ii)(II) and any amount assessed upon a partner under section 6232(f)(1)(B) that is a partnership or an S corporation. Section 206(g)(2)(B) of the TTCA amended section 6232(b) to provide that the limitations on assessment with respect to an imputed underpayment do not apply in the case of a specified similar amount defined in section 6232(f)(2).

The Treasury Department and the IRS are not proposing rules under section 6232(f) at this time. The Treasury Department and the IRS request comments with respect to section 6232(f), including the determination of a partner's proportionate share of the unpaid amount, for consideration with respect to future guidance.

A. Proposed § 301.6232–1

Proposed rules under § 301.6232–1 were previously published in the **Federal Register** (82 FR 60162–63) in the December 2017 NPRM (former proposed § 301.6232–1). For an explanation of the rules under former proposed §§ 301.6232–1, see 82 FR 60152.

Former proposed § 301.6232–1(a) provided that because the centralized partnership audit regime under subchapter C of chapter 63 applies to an assessment of an imputed underpayment, the deficiency procedures under subchapter B of chapter 63 do not apply. Former proposed § 301.6232–1(b) provided that the IRS may assess an underpayment reflected on an AAR on the date the AAR is filed. Former proposed § 301.6232–1(c) provided limitations on assessment of the imputed underpayment, except as otherwise provided in § 301.6232–1. Because the rules under former proposed § 301.6232–1(a) and (b) are consistent with the statutory changes to section 6232(a), those rules are unchanged.

Proposed § 301.6232–1(c) is generally the same as former proposed § 301.6232–1(c). However, changes were made to take into account section 206(g)(2)(B) of TTCA, providing that the limitations on assessment do not apply to specified similar amounts, and section 206(p) of TTCA, providing that the limitations on assessments under proposed § 301.6232–1(c) apply except as otherwise provided in subtitle F of the Code (other than deficiency procedures under subchapter B of chapter 63).

With respect to former proposed § 301.6232–1(d), the reference to ''items of income, gain, loss, deduction, or credit'' in former proposed § 301.6232–1(d)(1)(i) was replaced with a reference to ''partnership-related items.''

8. Interest and Penalties Related to Imputed Underpayments

Section 6233 provides rules related to interest and penalties with respect to imputed underpayments. Section 206(i) of the TTCA amended section 6233 by adding a new subsection (c), which provides a cross-reference to section 6603 for rules allowing deposits to suspend the running of interest on potential underpayments.

A. Proposed §§ 301.6233(a)–1 and 301.6233(b)–1

Proposed rules under §§ 301.6233(a)–1 and 301.6233(b)–1 were previously published in the **Federal Register** (82 FR 60163–65) in the December 2017 NPRM (former proposed §§ 301.6233(a)–1 and 301.6233(b)–1). For an explanation of the rules under former proposed §§ 301.6233(a)–1 and 301.6233(b)–1, see 82 FR 60152–53.

Proposed § 301.6233(a)–1 provides rules for determining interest and penalties from the reviewed year, and proposed § 301.6233(b)–1 provides rules for determining interest and penalties from the adjustment year. Neither former proposed § 301.6233(a)–1 nor former proposed § 301.6233(b)–1 provided rules regarding deposits to suspend the running of interest on underpayments. The Treasury Department and the IRS are not proposing rules regarding the interaction of the deposit rules under section 6603 and the interest rules under section 6233. However, the Treasury Department and the IRS request comments for consideration in future guidance regarding the interaction between section 6603 and the interest rules under section 6233.

Former proposed § 301.6233(a)–1(c)(2)(ii)(C) provided a definition of ''negative adjustment'' and defined that term through reference to ''items of income, gain, loss, deduction, or credit.'' Proposed § 301.6225–1 now uses the term ''negative adjustment'' and the phrase ''items of income, gain, loss, deduction, or credit'' has been removed from subchapter C of chapter 63. To reflect these changes, proposed § 301.6233(a)–1(c)(2)(ii)(C) now provides that a ''decreasing adjustment'' is ''an adjustment to a partnership-related item that resulted in a decrease to the imputed underpayment.'' Example 3 under proposed § 301.6233(a)–1(c)(3) also reflects changes to former proposed §§ 301.6225–1 and 301.6225–2.

Former proposed § 301.6233(a)–1(c)(2)(ii), regarding how to calculate the portion of the imputed underpayment to which a penalty applies, referred to ''non-credit partnership adjustments'' and ''credit adjustments.'' Under proposed § 301.6225–1(e)(3)(iii) certain adjustments to creditable expenditures are treated as an adjustment to a credit and may impact the calculation of the imputed underpayment. To properly account for such adjustments when determining the portion of an imputed underpayment subject to a penalty, the term ''non-credit partnership adjustment'' was changed to ''a partnership adjustment that is not an adjustment to a credit or treated as an adjustment to a credit,'' and the term ''credit adjustment'' changed to ''an adjustment to a credit or treated as an adjustment to a credit.''

Former proposed § 301.6233(a)–1(c)(2)(iii)(B), regarding the application of the substantial understatement penalty under section 6662(d)(1)(A)(i) to imputed underpayments, provided that taxable income meant the net ordinary business income or loss of the partnership. The reference to ''ordinary business'' failed to account for other sources of income of the partnership that are appropriate to consider for purposes of the substantial understatement penalty. Therefore, proposed § 301.6233(a)–1(c)(2)(iii)(B) now provides that for purposes of determining the amount of tax required to be shown on the return it is the net income or loss of the partnership that is treated as taxable income. See Page 5 of Form 1065, Return of Partnership Income.

Former proposed § 301.6233(a)–1(c)(2)(v), pertaining to reasonable cause and good faith defenses, provided that

partner-level defenses may not be raised in a proceeding of the partnership except as provided under the modification procedures pertaining to amended returns and partner closing agreements. For clarity, this provision has been moved to proposed § 301.6233(a)–1(c)(1). Furthermore, the provision allowing partner-level defenses to penalties to be raised under the modification procedures has been removed. A partner may raise a partner-level defense by filing a claim for refund under procedures existing outside of the centralized partnership audit regime or through an agreement with the IRS regarding an adjustment to a partnership-related item.

9. Judicial Review of Partnership Adjustments

Section 6234(a) provides that within 90 days after the date on which an FPA is mailed under section 6231 with respect to any partnership taxable year, the partnership may file a petition for readjustment for such taxable year with the Tax Court, the district court in which the partnership's principal place of business is located, or the Court of Federal Claims. Prior to amendment by the TTCA, section 6234(b)(1) provided that a petition for readjustment under section 6234 may be filed in a district court of the United States or the Court of Federal Claims only if the partnership filing the petition deposits with the Secretary, on or before the date the petition is filed, the amount of the imputed underpayment. Section 206(j) of the TTCA amended section 6234(b)(1) to clarify that the amount of the jurisdictional deposit that the partnership must make in order to file a readjustment petition in a district court or the Court of Federal Claims is the amount of (as of the date of the filing of the petition) the imputed underpayment, penalties, additions to tax, and additional amounts with respect to the imputed underpayment. See JCX–6–18, at 49.

A. Proposed § 301.6234–1

Proposed rules under § 301.6234–1 were previously published in the **Federal Register** (82 FR 60165–66) in the December 2017 NPRM (former proposed § 301.6234–1). For a further explanation of the rules under former proposed § 301.6234–1, see 82 FR 60153.

Former proposed § 301.6234–1(b) provided that a partnership may file a petition for a readjustment of any partnership adjustment in a district court or the Court of Federal Claims ''only if the partnership filing the petition deposits with the [IRS], on or before the date the petition is filed, the amount of any imputed underpayment resulting from the partnership adjustment.''

To reflect the amendment to section 6234(b)(1) made by section 206(j) of the TTCA regarding the amount of the deposit, proposed § 301.6234–1(b) now provides that amount required to be deposited is the amount (as of the date of the filing of the petition) of any imputed underpayment and any penalties, additions to tax, and additional amounts with respect to such imputed underpayment.

To account for the possibility that multiple imputed underpayments may be reflected in an FPA, proposed § 301.6234–1(b) also now provides that the partnership must only deposit the amount of any imputed underpayment to which the petition for readjustment relates and the amount of any penalties, additions to tax, and additional amounts with respect to such imputed underpayment.

10. Period of Limitations on Making Adjustments

Section 6235 provides the period of limitations on making adjustments under the centralized partnership audit regime. Under section 6235(a), the general rule is that no adjustment for any partnership taxable year may be made after the later of three specified dates. Section 206(k) of the TTCA amended section 6235(a) by inserting ''or section 905(c)'' after ''Except as otherwise provided in this section.'' The amendment makes clear that the period of limitations on making adjustments under the centralized partnership audit regime does not limit the period for notification of the Secretary and redetermination of tax under section 905(c) with respect to foreign tax redeterminations.

In addition, section 206(k) of the TTCA amended section 6235 by striking paragraph (d), which provided for a suspension of the period on making adjustments when the Secretary mails an FPA. That provision was similar to a provision that existed under TEFRA, but the provision has no effect on making adjustments under the centralized partnership audit regime. See JCX–6–18, at 49–50.

A. Proposed § 301.6235–1

Proposed rules under § 301.6235–1 were previously published in the **Federal Register** (82 FR 60166–67) in the December 2017 NPRM (former proposed § 301.6235–1). For an explanation of the rules under former proposed § 301.6235–1, see 82 FR 60153–54.

Proposed § 301.6235–1(a) now reflects the amendments to section 6235 to provide an exception for section 905(c) and to remove the reference to section 6235(d).

11. Definitions and Special Rules

A. Proposed § 301.6241–1

Proposed rules under § 301.6241–1 were previously published in the **Federal Register** (82 FR 27399–400) in the June 2017 NPRM (former proposed § 301.6241–1). For an explanation of the rules under former proposed § 301.6241–1, see 82 FR 27369.

Former proposed § 301.6241–1(a)(1) defined the term ''adjustment year'' to mean the partnership taxable year in which a decision of a court becomes final (if a petition is filed under section 6234), an AAR is made, or, in any other case, when an FPA is mailed (or if the partnership waives its right to an FPA, the year the waiver is executed by the IRS). Section 206(p) of the TTCA amended section 6227 to provide that an AAR is ''filed,'' as opposed to ''made.'' To reflect this amendment, proposed § 301.6241–1(a)(1) now provides that an AAR is ''filed'' and not ''made.''

Former proposed § 301.6241–1(a)(3) defined the term ''imputed underpayment'' as the amount determined under § 301.6225–1. Because an imputed underpayment may also be computed and paid pursuant to proposed § 301.6226–3(e)(4) (relating to pass-through partners) as well as under proposed § 301.6227–2 and § 301.6227–3(c) (relating to AARs), proposed § 301.6241–1(a)(3) now refers to imputed underpayments determined under those provisions. Proposed § 301.6241–1(a)(3) was also clarified to provide that an imputed underpayment calculated under section 6225 is calculated under section 6225 and the regulations thereunder.

Proposed § 301.6241–1(a)(4) now provides that the term ''indirect partner'' includes a person that holds an interest in the partnership through a wholly owned entity that is disregarded as separate from its owner for Federal income tax purposes, such as a disregarded entity or grantor trust. This change from the language in the former proposed regulations clarifies that a partnership may seek modification under proposed § 301.6225–2 based on indirect partners holding an interest through a disregarded entity or grantor trust.

Proposed § 301.6241–1(a)(6) now provides that the term ''partnership adjustment'' means any adjustment to a partnership-related item (as defined in

proposed § 301.6241–6), and such term includes a portion of a partnership adjustment.

Former proposed § 301.6241–1(a)(10) defined a tax attribute as anything that can affect, with respect to a partnership or partner, the amount or timing of an item of income, gain, loss, deduction, or credit or that can affect the amount of tax due in any taxable year. As discussed in section 4.A. of this preamble, section 203(a) of the TTCA amended section 6225 to provide an alternative procedure to filing amended returns during modification under which a partner agrees to take into account adjustments to the tax attributes ''of such partner''. Section 6225(c)(2)(B)(ii). To reflect the amendment to section 6225(c)(2)(B) regarding tax attributes of a partner, the phrase ''with respect to a partnership or a partner'' was removed from the definition of tax attribute under former proposed § 301.6241–1(a)(10). The reference to ''items of income, gain, loss, deduction, or credit'' in former proposed § 301.6241–1(a)(10) was also replaced with a reference to ''partnership-related item.''

B. Proposed § 301.6241–2

Proposed rules under § 301.6241–2 were previously published in the **Federal Register** (82 FR 27400) in the June 2017 NPRM (former proposed § 301.6241–2). Former proposed § 301.6241–2 provided for coordination between Title 11 of the United States Code, which deals with bankruptcy, and the centralized partnership audit regime. Because the amendments by the TTCA did not affect section 6241(6), the rules under former proposed § 301.6241–2 are unchanged. For an explanation of the rules under former proposed § 301.6241–2, see 82 FR 27369–70.

C. Proposed § 301.6241–3

Proposed rules under § 301.6241–3 were previously published in the **Federal Register** (82 FR 27400–02) in the June 2017 NPRM (former proposed § 301.6241–3). For an explanation of the rules under former proposed § 301.6241–3, see 82 FR 27370–71.

Former proposed § 301.6241–3(a)(3) provided that the rules requiring former partners to take into account adjustments of a partnership which the IRS determined had ceased to exist did not apply to the former partners of a partnership that had elected out of the centralized partnership audit regime under section 6221(b). Because under section 6226(b)(4) a partnership-partner that has elected out of the centralized partnership audit regime may be liable for an imputed underpayment in the case of a push out election, proposed § 301.6241–3(a)(3) now provides that the rules under proposed § 301.6241–3 apply to a partnership-partner and its former partners, regardless of whether the partnership-partner has elected out of the centralized partnership audit regime. Accordingly, under proposed § 301.6241–3(a)(3), the former partners of any partnership that may be liable for an imputed underpayment, including a partnership-partner that has elected out of the centralized partnership audit regime, will be required to take into account a partnership adjustment if the IRS determines that such partnership ceased to exist before the partnership adjustment had taken effect. Example 2 under proposed § 301.6241–3(f) illustrates this rule.

Former proposed § 301.6241–3(b)(2)(i) provided that the IRS will not determine that a partnership has ceased to exist solely because: (i) A partnership has technically terminated under section 708(b)(1)(B); (ii) the partnership has made a valid election under section 6226 and the regulations thereunder with respect to any imputed underpayment; or (iii) the partnership has not paid any amount the partnership is liable for under subchapter C of chapter 63. To reflect the amendment to section 708 by the Act to eliminate technical terminations, the reference to section 708(b)(1)(B) was removed from former proposed § 301.6241–3(b)(2)(i). In addition, a rule was added to former proposed § 301.6241–3(b)(2)(i) to provide that a partnership also does not cease to exist solely because it furnished statements in accordance with proposed § 301.6226–3(e)(3). This change clarifies that partnership-partners that properly furnish statements in accordance with proposed § 301.6226–3(e)(3) (and therefore are not liable for an imputed underpayment) are treated the same as an audited partnership who made a valid election under section 6226.

Additional clarifications were made to proposed § 301.6241–3. First, the phrase ''any amounts'' in former proposed § 301.6241–3(a)(2) was replaced with the phrase ''any unpaid amounts.'' This clarification was made to eliminate the implication that the partnership was not liable for the original amount due and to clarify that if the IRS determines that a partnership has ceased to exist, the partnership is no longer liable for any remaining unpaid amounts due under subchapter C of chapter 63, meaning that if the partnership had made a prior payment, the IRS can retain that payment. Second, former proposed § 301.6241–3(b)(2)(iii) provided that the IRS may not determine that a partnership has ceased to exist after the expiration of the period of limitations on collection. Proposed § 301.6241–3(b)(2)(iii) now provides that the period relevant to this determination is the period of limitations on collection with respect to the imputed underpayment that was assessed against the partnership that ceased to exist. Finally, prior references to section 708(b)(1)(A) in former proposed § 301.6241–3(b)(2), (d)(2), and (f) were changed to refer to section 708(b)(1) to reflect the amendment to section 708 made by the Act.

D. Proposed § 301.6241–4

Proposed rules under § 301.6241–4 were previously published in the **Federal Register** (82 FR 27402) in the June 2017 NPRM (former proposed § 301.6241–4). For an explanation of the rules under former proposed § 301.6241–4, see 82 FR 27371.

Former proposed § 301.6241–4 provided that payments made by a partnership under the centralized partnership audit regime, including payment of any imputed underpayment and any amount under proposed § 301.6226–3, were not deductible to the partnership. Because the payment amount for a partnership-partner in the case of a push out election is referred to as an imputed underpayment, reference to any amount under § 301.6226–3 in former proposed § 301.6241–4 became superfluous and thus was removed.

E. Proposed § 301.6241–5

Proposed rules under § 301.6241–5 were previously published in the **Federal Register** (82 FR 27402) in the June 2017 NPRM (former proposed § 301.6241–5). For an explanation of the rules under former proposed § 301.6241–5, see 82 FR 27371.

Former proposed § 301.6241–5 provided rules for extending the centralized partnership audit regime to entities filing partnership returns. References in former proposed § 301.6241–5(a) to ''items of income, gain, loss, deduction, or credit'' and ''partner's distributive share'' were replaced with a reference to ''partnership-related item.'' Proposed § 301.6241–5(c) now also reflects the fact that certain business arrangements, which may not be classified as entities, can file partnership returns to make an election under section 761(a). Under proposed § 301.6241–5(c), the centralized partnership audit regime does not apply in that case notwithstanding the filing of a partnership return.

12. Coordination With Other Chapters of the Code

Section 201(b) of the TTCA added section 6241(9) to the Code regarding the coordination of the centralized partnership audit regime with chapters of the Code other than chapter 1. Section 6241(9)(A) provides that the centralized partnership audit regime shall not apply with respect to any tax imposed (including any amount required to be deducted or withheld) under chapter 2, 2A, 3, or 4 of subtitle A of the Code, except that any partnership adjustment determined under the centralized partnership audit regime for purposes of chapter 1 shall be taken into account for purposes of determining any such tax to the extent that such adjustment is relevant to such determination. Section 6241(9)(B) provides that in the case of any tax imposed (including any amount required to be deducted or withheld) under chapters 3 and 4 of the Code, which is determined with respect to a partnership adjustment, such tax shall be so determined with respect to the reviewed year and shall be so imposed (or so required to be deducted or withheld) with respect to the adjustment year.

Section 201(b) also added section 6501(c)(12) to the Code regarding the statute of limitation on assessment of taxes under chapter 2 or 2A which are attributable to any partnership adjustment. Section 6501(c)(12) provides in the case of any partnership adjustment determined under the centralized partnership audit regime, the period for assessment of any tax imposed under chapter 2 or 2A of the Code which is attributable to such adjustment shall not expire before the date that is one year after one of two events. In the case of an adjustment pursuant to the decision of a court in a proceeding brought under section 6234, the period for assessment shall not expire before the date that is one year after the decision becomes final. In any other case, the period for assessment shall not expire before the date that is one year after 90 days after the date on which the FPA is mailed under section 6231.

A. Proposed § 301.6241–7

Former proposed § 301.6221(a)–1(d) provided that nothing in subchapter C of chapter 63 precluded the IRS from making any adjustment to an item of a partnership (as described in the prior version of § 301.6221(a)–1(b)) outside of the centralized partnership audit regime for purposes of determining tax imposed by provisions of the Code other than chapter 1. Accordingly, under former proposed § 301.6221(a)–1(d), the IRS was not precluded from examining a partnership's compliance with its obligations under chapters 3 and 4 (or any other chapter of the Code other than chapter 1) in a proceeding outside of the centralized partnership audit regime. Former proposed § 301.6221(a)–1(f) provided examples to illustrate this concept.

The rules contained in former proposed § 301.6221(a)–1(d), and the examples in former proposed § 301.6221(a)–1(f), are consistent with section 6241(9)(A). However, given that these concepts are now codified in section 6241, the rules and examples under former proposed § 301.6221(a)–1(d) and (f) are now under proposed § 301.6241–7(a)(1) and (2). References to ''items of income, gain, loss, deduction, or credit'' were replaced with references to ''partnership-related item'' as defined under proposed § 301.6241–6. Other editorial changes were made to reflect revisions to former proposed § 301.6221(a)–1.

Proposed § 301.6241–7(a)(1) provides that the centralized partnership audit regime does not apply with respect to any tax imposed (including any amount required to be deducted or withheld) under any chapter of the Code other than chapter 1, including chapter 2, 2A, 3, or 4 of the Code. Accordingly, for purposes of determining taxes under chapters of the Code other than chapter 1, the IRS may make adjustments to partnership-related items in proceedings not subject to the centralized partnership audit regime. However, to the extent an adjustment to a partnership-related item or a determination made under the centralized partnership audit regime is relevant in determining tax outside of chapter 1, such adjustment or determination must be taken into account in determining that non-chapter 1 tax. Proposed § 301.6241–7(a)(2) provides examples to illustrate these concepts.

Proposed § 301.6241–7(b) provides rules for coordinating the centralized partnership audit regime with chapters 3 and 4 of the Code. Proposed § 301.6241–7(b)(1) restates the rule in section 6241(9)(B) regarding the timing of withholding for tax imposed under chapters 3 and 4 that is determined with respect to a partnership adjustment. Proposed § 301.6241–7(b)(2) defines the terms chapter 3, chapter 4, and amount subject to withholding.

Former proposed §§ 301.6225–1(a)(4) and 301.6226–2(h) provided rules to coordinate the collection of tax in the case of partnership adjustments to amounts subject to withholding under chapters 3 and 4, including rules for when the partnership pays an imputed underpayment resulting from such an adjustment and rules for when the partnership makes the election under section 6226 with respect to such an imputed underpayment. These rules now fall within proposed § 301.6241–7(b)(3) and (b)(4). Proposed § 301.6241–7(b)(4) now provides that a partnership required to pay tax under chapter 3 or chapter 4 when it makes an election under section 6226 is required to pay the tax before the due date of the partnership return for the adjustment year (without regard to extension).

13. Other Amendments by the TTCA to the Centralized Partnership Audit Regime

Section 206(l) of the TTCA amended section 6241 by adding a new provision, section 6241(11), providing for the treatment of special enforcement matters. Under section 6241(11), in the case of partnership-related items which involve special enforcement matters, the Secretary may prescribe regulations pursuant to which the centralized partnership audit regime (or any portion thereof) does not apply to such items, and that such items are subject to special rules (including rules related to assessment and collection) as the Secretary determines to be necessary for the effective and efficient enforcement of the Code. For purposes of section 6241(11), the term ''special enforcement matters'' means: (1) Failure to comply with the requirements of section 6226(b)(4)(A)(ii) (regarding the requirement for a pass-through partner to furnish statements or compute and pay an imputed underpayment); (2) assessments under section 6851 (relating to termination assessments of income tax) or section 6861 (relating to jeopardy assessments of income, estate, gift, and certain excise taxes); (3) criminal investigations; (4) indirect methods of proof of income; (5) foreign partners or partnerships; and (6) other matters that the Secretary determines by regulation present special enforcement considerations. Rules under this provision may be provided in future guidance. The Treasury Department and the IRS are considering proposing rules under section 6241(11)(B)(vi) (dealing with other matters that present special enforcement considerations) which allow certain partnership-related items reported solely by persons other than the partnership to be adjusted outside the centralized partnership audit regime. The Treasury Department and the IRS request comments on this provision, including whether there are

any additional special enforcement considerations that should be addressed through regulations.

Section 206(m) of the TTCA amended section 6241 by adding a new provision, section 6241(12), to clarify that a U.S. shareholder of a controlled foreign corporation (CFC) which is a partner of a partnership shall be treated as a partner of such partnership for purposes of the centralized partnership audit regime. The U.S. shareholder's distributive share of the partnership is the U.S. shareholder's pro rata share of the CFC's Subpart F income determined under rules similar to section 951(a)(2). Similarly, a taxpayer that makes a Qualified Electing Fund (QEF) election with respect to a passive foreign investment company (PFIC) that is a partner in a partnership shall be treated as a partner of such partnership. In this case, a taxpayer's distributive share of the partnership is the taxpayer's pro rata share of the PFIC's ordinary earnings and net capital gain determined under rules similar to section 1293(b). Consequently, in both circumstances, the U.S. shareholder of a CFC and the taxpayer of a PFIC will be treated as the adjustment year partner or reviewed year partner under the centralized partnership audit regime, where applicable. Regulatory authority was also given to issue regulations or other guidance as necessary or appropriate to carry out the purpose of the provision, including regulations which apply the rule in similar circumstances or with respect to similarly situated persons. Consequently, in both circumstances, the U.S. shareholder of a CFC and the taxpayer of a PFIC will be treated as the adjustment year partner or reviewed year partner under proposed §§ 301.6241–1(a)(2) and 301.6241–1(a)(9) where applicable.

Special Analyses

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

Because the proposed regulations would not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply.

Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Statement of Availability of IRS Documents

IRS Revenue Procedures, Revenue Rulings, Notices, and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *www.irs.gov.*

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic and written comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request.

A public hearing has been scheduled for October 9, 2018, beginning at 10 a.m. in the Auditorium of the Internal Revenue Building, 1111 Constitution Avenue NW, Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For more information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the time to be devoted to each topic by October 1, 2018. Submit a signed paper or electronic copy of the outline as prescribed in this preamble under the **ADDRESSES** heading. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these proposed regulations are Jennifer M. Black, Joy E. Gerdy-Zogby, Steven L. Karon, and Brittany Harrison of the Associate Chief Counsel (Procedure and Administration). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Withdrawal of Notices of Proposed Rulemaking and Partial Withdrawal of Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, the notices of proposed rulemaking (REG–119337–17, REG–120232–17, REG–120233–17, and REG–118067–17) that were published in the **Federal Register** on November 30, 2017 (82 FR 56765), December 19, 2017 (82 FR 27071), and February 2, 2018 (83 FR 4868) are withdrawn. Also under the authority of 26 U.S.C. 7805, 301.6221(a)–1, 301.6222–1, 301.6225–1, 301.6225–2, 301.6225–3, 301.6225–4, 301.6226–1, 301.6226–2, 301.6226–3, 301.6226–4, 301.6227–1, 301.6227–2, 301.6227–3 of the notice of proposed rulemaking (REG–136118–15) published in the **Federal Register** on June 14, 2017 (82 FR 27334) is withdrawn.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAX

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.704–1 is amended by:

■ 1. Adding paragraph (b)(1)(viii).

■ 2. Adding a sentence to the end of paragraph (b)(2)(iii)(*a*).

■ 3. Adding paragraphs (b)(2)(iii)(*f*), (b)(2)(iv)(*i*)(*4*), and (b)(4)(xi) through (xv).

The additions read as follows:

§ 1.704–1 Partner's distributive share.

* * * * *

(b) * * *

(1) * * *

(viii) *Items relating to a final determination under the centralized partnership audit regime*—(*a*) *In general.* Certain items of income, gain, loss, deduction or credit may result from a final determination under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) (relating to the centralized partnership audit regime). Special rules

under section 704(b) and § 1.704–1(b) apply to these items that take into account that the item relates to the reviewed year (as defined in § 301.6241–1(a)(8) of this chapter) but occurs in the adjustment year (as defined in § 301.6241–1(a)(1) of this chapter). See paragraphs (b)(2)(iii)(*a*) and (*f*), (b)(2)(iv)(*i*)(*4*), and (b)(4)(xi) through (xv) of this section.

(*b*) *Successors*—(*1*) *In general.* In the case of a transfer or liquidation of a partnership interest subsequent to a reviewed year, a successor has the meaning provided in paragraph (b)(1)(viii)(*b*) of this section. In the case of a subsequent transfer by a successor of a partnership interest, the principles of paragraph (b)(1)(viii)(*b*) of this section will also apply to the new successor.

(*2*) *Identifiable transferee partner.* Except as otherwise provided in paragraph (b)(1)(viii)(*b*)(*3*) of this section, in the case of a transfer of all or part of a partnership interest during or subsequent to the reviewed year, a successor is the partner to which the reviewed year transferor partner's capital account carried over (or would carry over if the partnership maintained capital accounts) under paragraph (b)(2)(iv)(*l*) of this section (an identifiable transferee partner).

(*3*) *Unidentifiable transferee partner.* If, after exercising reasonable diligence, the partnership cannot determine an identifiable transferee partner under paragraph (b)(1)(viii)(*b*)(*2*) of this section, each partner in the adjustment year that is not an identifiable transferee partner and was not a partner in the reviewed year, (an unidentifiable transferee partner) is a successor to the extent of the proportion of its interest in the partnership to the total interests of unidentifiable transferee partners in the partnership (considering all facts and circumstances).

(*4*) *Liquidation of partnership interest.* In the case of a liquidation of a partner's entire interest in the partnership during or subsequent to the reviewed year, the successors to the liquidated partner are certain adjustment year partners (as defined in § 301.6241–1(a)(2) of this chapter) as provided in this paragraph (b)(1)(viii)(*b*)(*4*). The determination of the extent to which the adjustment year partners are treated as successors under this section must be made in a manner that reflects the extent to which the adjustment year partners' interests in the partnership increased as a result of the liquidating distribution (considering all facts and circumstances).

(2) * * *

(iii) * * *

(*a*) * * * Notwithstanding any other sentence of this paragraph (b)(2)(iii)(*a*), an allocation of any of the following will be substantial only if the allocation is described in paragraph (b)(2)(iii)(*f*) of this section: an expenditure for any payment required to be made by a partnership under subchapter C of chapter 63 (relating to the centralized partnership audit regime), adjustments reflected on a statement furnished to a pass-through partner (as defined in § 301.6241–1(a)(5) of this chapter) under § 301.6226–3(e)(4) of this chapter, or interest, penalties, additions to tax, or additional amounts described in section 6233.

* * * * *

(*f*) *Certain expenditures under the centralized partnership audit regime*—(*1*) *In general.* The economic effect of an allocation of an expenditure for any payment required to be made by a partnership under subchapter C of chapter 63 (as described in § 301.6241–4(a) of this chapter) is substantial only if the expenditure is allocated in the manner described in this paragraph (b)(2)(iii)(*f*). For partnerships with allocations that do not satisfy paragraph (b)(2)(ii) of this section, see paragraph (b)(4)(xi) of this section.

(*2*) *Expenditures for imputed underpayments or similar amounts.* Except as otherwise provided, an expenditure for an imputed underpayment, as defined in § 301.6241–1(a)(3) of this chapter, is allocated to the reviewed year partner (or its successor, as defined in paragraph (b)(1)(viii)(*b*) of this section) in proportion to the allocation of the notional item (as described in § 301.6225–4(b) of this chapter) to which the expenditure relates, taking into account modifications under § 301.6225–2 of this chapter attributable to that partner.

(*3*) *Interest, penalties, additions to tax, or additional amounts described in section 6233.* An expenditure for interest, penalties, additions to tax, or additional amounts as determined under section 6233 (or penalties and interest described in § 301.6226–3(e)(4)(iv) of this chapter) is allocated to the reviewed year partner (or its successor, as defined in paragraph (b)(1)(viii)(*b*) of this section) in proportion to the allocation of the portion of the imputed underpayment with respect to which the penalty applies or related notional item to which it relates (whichever is appropriate), taking into account modifications under § 301.6225–2 of this chapter attributable to that partner.

(*4*) *Imputed underpayments unrelated to notional items.* In the case of an imputed underpayment that results from a partnership adjustment for which no notional items are created under § 301.6225–4(b)(2) of this chapter, the expenditure must be allocated to the reviewed year partner (or its successor, as defined in paragraph (b)(1)(viii)(*b*) of this section) that would have borne the economic benefit or burden of the partnership adjustment if the partnership and its partners had originally reported in a manner consistent with the partnership adjustment that resulted in the imputed underpayment with respect to the reviewed year.

(iv) * * *

(*i*) * * *

(*4*) *Certain expenditures under the centralized partnership audit regime.* Notwithstanding paragraph (b)(2)(iv)(*i*)(*1*) of this section, the economic effect of an allocation of an expenditure for any payment required to be made by a partnership under subchapter C of chapter 63 (as described in § 301.6241–4(a) of this chapter) is substantial only if the expenditure is allocated in the manner described in paragraph (b)(2)(iii)(*f*) of this section. For partnerships with allocations that do not satisfy paragraph (b)(2)(ii) of this section, see paragraph (b)(4)(xii) of this section.

* * * * *

(4) * * *

(xi) *Notional items under the centralized partnership audit regime.* An allocation of a notional item (as described in § 301.6225–4(b)(3) of this chapter) does not have substantial economic effect within the meaning of paragraph (b)(2) of this section. However, the allocation of a notional item of income or gain described in § 301.6225–4(b)(3)(ii) and (iv) of this chapter, or expense or loss described in § 301.6225–4(b)(3)(iii) and (v) of this chapter, will be deemed to be in accordance with the partners' interests in the partnership if the notional item is allocated in the manner in which the corresponding actual item would have been allocated in the reviewed year under the rules of this section, treating successors (as defined in paragraph (b)(1)(viii)(*b*) of this section) as reviewed year partners. Additionally, the allocation of a notional item of expense or loss described in § 301.6225–4(b)(3)(iv) of this chapter, or a notional item of income or gain described in § 301.6225–4(b)(3)(v) of this chapter, will be deemed to be in accordance with the partners' interests in the partnership if the notional item is allocated to the reviewed year partners (or their successors as defined in paragraph (b)(1)(viii)(*b*) of this section) in the

manner in which the excess item was allocated in the reviewed year.

(xii) *Certain section 705(a)(2)(B) expenditures under the centralized partnership audit regime.* An allocation of an expenditure for any payment required to be made by a partnership under subchapter C of chapter 63 (relating to the centralized partnership audit regime and as described in § 301.6241–4(a) of this chapter) will be deemed to be in accordance with the partners' interests in the partnership, as provided in paragraph (b)(3) of this section, only if the expenditure is allocated in the manner described in paragraph (b)(2)(iii)(*f*) of this section and if the partners' distribution rights are reduced by the partners' shares of the imputed underpayment.

(xiii) *Partnership adjustments that do not result in an imputed underpayment under the centralized partnership audit regime.* An allocation of an item arising from a partnership adjustment that does not result in an imputed underpayment (as defined in § 301.6225–1(f) of this chapter) does not have substantial economic effect within the meaning of paragraph (b)(2) of this section. However, the allocation of such an item will be deemed to be in accordance with the partners' interests in the partnership if allocated in the manner in which the item would have been allocated in the reviewed year under the rules of this section, treating successors as defined in paragraph (b)(1)(viii)(*b*) of this section as reviewed year partners.

(xiv) *Partnership adjustments subject to an election under section 6226.* An allocation of an item arising from a partnership adjustment that results in an imputed underpayment for which an election is made under § 301.6226–1 of this chapter does not have substantial economic effect within the meaning of paragraph (b)(2) of this section. However, the allocation of such an item will be deemed to be in accordance with the partners' interests in the partnership if allocated in the adjustment year (as defined in § 301.6241–1(a)(1) of this chapter) in the manner in which the item would have been allocated under the rules of this section (or otherwise taken into account under subtitle A of the Code) in the reviewed year (as defined in § 301.6241–1(a)(8) of this chapter), followed by any intervening years (as defined in § 301.6226–3(b)(3) of this chapter), concluding with the reporting year (as defined in § 301.6226–3(a) of this chapter).

(xv) *Substantial economic effect under sections 168(h) and 514(c)(9)(E)(i)(ll).* An allocation described in paragraphs (b)(4)(xi) through (xiv) of this section will be deemed to have substantial economic effect for purposes of sections 168(h) and 514(c)(9)(E)(i)(ll) if the allocation is deemed to be in accordance with the partners' interests in the partnership under the applicable rules set forth in paragraphs (b)(4)(xi) through (xiv) of this section.

* * * * *

■ **Par. 3.** Section 1.705–1 is amended by adding paragraph (a)(10) to read as follows:

§ 1.705–1 Determination of basis of partner's interest.

(a) * * *

(10) For rules relating to determining the adjusted basis of a partner's interest in a partnership following a final determination under subchapter C of chapter 63 of the Internal Revenue Code (relating to the centralized partnership audit regime), see §§ 301.6225–4 and 301.6226–4 of this chapter.

* * * * *

■ **Par. 4.** Section 1.706–4 is amended by redesignating paragraphs (e)(2)(viii) through (xi) as paragraphs (e)(2)(ix) through (xii), respectively, and adding a new paragraph (e)(2)(viii) to read as follows:

§ 1.706–4 Determination of distributive share when a partner's interest varies.

* * * * *

(e) * * *

(2) * * *

(viii) Any item arising from a final determination under subchapter C of chapter 63 of the Internal Revenue Code (relating to the centralized partnership audit regime) with respect to a partnership adjustment resulting in an imputed underpayment for which no election is made under § 301.6226–1 of this chapter or for which a pass-through partner (as defined in § 301.6241–1(a)(5)) pays an imputed underpayment under § 301.6226–3(e)(4).

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 5.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 6.** Section 301.6221(a)–1 is added to read as follows:

§ 301.6221(a)–1 Determination at partnership level.

(a) *In general.* Except as otherwise provided under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) and the regulations thereunder, any adjustment to a partnership-related item (as defined in § 301.6241–6) is determined, any tax imposed by chapter 1 of subtitle A of the Internal Revenue Code (Code) attributable thereto is assessed and collected, and the applicability of any penalty, addition to tax, or additional amount that relates to an adjustment to any partnership-related item is determined at the partnership level under subchapter C of chapter 63. Any consideration necessary to make a determination at the partnership level under subchapter C of chapter 63, including the period of limitations on making partnership adjustments under section 6235 or facts necessary to calculate an imputed underpayment under section 6225, is also made at the partnership level except as otherwise provided under subchapter C of chapter 63 and the regulations thereunder. For rules relating to assessment and collection in a proceeding involving inconsistent treatment of a partnership-related item, see § 301.6222–1; in the case of modification under section 6225(c), see § 301.6225–2; in the case of an election under section 6226, see § 301.6226–3. For rules relating to tax imposed (including any amount required to be deducted or withheld) by chapter 2, 2A, 3 or 4 of subtitle A of the Code, see section 6241(9) and § 301.6241–7. For rules relating to special enforcement matters, see § 301.6241–8.

(b) *Applicability date*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 7.** Section 301.6222–1 is added to read as follows:

§ 301.6222–1 Partner's return must be consistent with partnership return.

(a) *Consistent treatment of partnership-related items*—(1) *In general.* The treatment of partnership-related items (as defined in § 301.6241–6) on a partner's return must be consistent with the treatment of such items on the partnership return in all respects, including the amount, timing, and characterization of such items. A partner has not satisfied the requirement of this paragraph (a) if the treatment of the partnership-related item on the partner's return is consistent with how such item was treated on a schedule or other information furnished to the partner by the partnership but inconsistent with the treatment of the item on the partnership return actually

filed. For rules relating to the election to be treated as having reported the inconsistency where the partner treats a partnership-related item consistently with an incorrect schedule or other information furnished by the partnership, see paragraph (d) of this section.

(2) *Partner that is a partnership.* The rules of this section apply to a partnership-partner (as defined in § 301.6241–1(a)(7)) regardless of whether the partnership-partner has made an election under section 6221(b) to elect out of the provisions of subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63). Accordingly, unless the requirements of paragraph (c) of this section are satisfied, a partnership-partner must treat partnership-related items of a partnership in which it is a partner consistent with the treatment of such items on the partnership return filed by the partnership in which it is a partner.

(3) *Partnership does not file a return.* A partner's treatment of a partnership-related item attributable to a partnership that does not file a return is per se inconsistent, unless the partner files a notice of inconsistent treatment under paragraph (c) of this section.

(4) *Treatment of items on a partnership return.* For purposes of this section, the treatment of a partnership-related item on a partnership return includes—

(i) The treatment of such item on the partnership's return of partnership income filed with the IRS under section 6031, and any amendment or supplement thereto, including an administrative adjustment request (AAR) filed pursuant to section 6227 and the regulations thereunder; and

(ii) The treatment of such item on any statement, schedule or list, and any amendment or supplement thereto, filed by the partnership with the Internal Revenue Service (IRS), including any statements filed pursuant to section 6226 and the regulations thereunder.

(5) *Examples.* The following examples illustrate the rules of this paragraph (a). For purposes of these examples, each partnership is subject to the provisions of subchapter C of chapter 63, and each partnership and its partners are calendar year taxpayers, unless otherwise stated.

Example 1. B is a partner in Partnership during 2018 and 2019. Both B and Partnership are calendar year taxpayers. In December 2018, Partnership receives an advance payment for services to be performed in 2019 and reports this amount as income on its partnership return for 2018. B includes its distributive share of income from the advance payment on B's income tax return for 2019 and not on B's income tax return for 2018. B did not file a notice of inconsistent treatment with respect to the advanced payment. B's treatment of the income attributable to Partnership is inconsistent with the treatment of that item by Partnership on its partnership return.

Example 2. C is a partner in Partnership during 2018. Partnership incurred start-up costs before it was actively engaged in its business. Partnership capitalized these costs on its 2018 partnership return. C deducted his distributive share of the start-up costs on C's 2018 income tax return. C's treatment of the start-up costs is inconsistent with the treatment of that item by Partnership on its partnership return.

Example 3. D is a partner in Partnership during 2018. Partnership reports a loss of $100,000 on its partnership return for 2018. On the 2018 Schedule K–1 attached to the partnership return, Partnership reports $5,000 as D's distributive share of that loss. On the 2018 Schedule K–1 furnished to D, however, Partnership reports $15,000 as D's distributive share of the loss. D reports the $15,000 loss on D's 2018 income tax return. D has not satisfied the requirements of paragraph (a) of this section because D reported D's distributive share of the loss in a manner that is inconsistent with how D's distributive share of the loss was reported on the 2018 partnership return actually filed. See, however, paragraph (d) of this section for the election to be treated as having reported the inconsistency where the partner treats an item consistently with an incorrect schedule.

Example 4. D was a partner in Partnership during 2018. Partnership reports a loss of $100,000 on its partnership return for 2018. In 2020, Partnership files an AAR under section 6227 reporting that the amount of the loss on its 2018 partnership return is $90,000, rather than $100,000 as originally reported. Pursuant to section 6227 and the regulations thereunder, Partnership elects to have its partners take the adjustment into account, and furnishes D a statement showing D's share of the reduced loss for 2018. D fails to take his share of the reduced loss for 2018 into account in accordance with section 6227 and the regulations thereunder. D has not satisfied the requirements of paragraph (a) of this section because D has not taken into account his share of the loss in a manner consistent with how Partnership treated such items on the partnership return actually filed.

Example 5. E was a partner in Partnership during 2018. In 2021, Partnership receives a notice of final partnership adjustment in an administrative proceeding under subchapter C of chapter 63 with respect to Partnership's 2018 taxable year. Partnership properly elects the application of section 6226 and furnishes to E a statement of E's share of adjustments with respect to Partnership's 2018 taxable year. E fails to take his share of the adjustments into account in accordance with section 6226 and the regulations thereunder. E has not satisfied the requirements of paragraph (a) of this section because E has not taken into account his share of adjustments with respect to Partnership's 2018 taxable year in a manner consistent with how Partnership treated such items on the partnership return actually filed.

Example 6. In 2018, E is a partner in Partnership. E is a partnership-partner with a 2018 taxable year that ends on the same day as Partnership's 2018 taxable year. E has filed a valid election under section 6221(b) in effect with respect to E's 2018 partnership taxable year. Notwithstanding E's election under section 6221(b) for its 2018 taxable year, E is subject to section 6222 for taxable year 2018. E must treat, on its 2018 partnership return, any items attributable to E's interest in Partnership in a manner that is consistent with the treatment of those items on the 2018 partnership return actually filed by Partnership.

(b) *Effect of inconsistent treatment*—(1) *Determination of underpayment of tax resulting from inconsistent treatment.* If a partner fails to satisfy the requirements of paragraph (a) of this section, unless the partner provides notice in accordance with paragraph (c) of this section, the IRS may adjust the inconsistently reported partnership-related item on the partner's return to make it consistent with the treatment of such item on the partnership return and determine the underpayment of tax that results from that adjustment. For purposes of this section, the underpayment of tax is the amount by which the correct tax, as determined by making the partner's return consistent with the partnership return, exceeds the tax shown on the partner's return.

(2) *Assessment and collection of tax.* The IRS may assess and collect any underpayment of tax resulting from an adjustment described in paragraph (b)(1) of this section in the same manner as if the underpayment of tax was on account of a mathematical or clerical error appearing on the partner's return, except that the procedures under section 6213(b)(2) for requesting abatement of an assessment do not apply.

(3) *Effect when partner is a partnership.* If the partner is itself a partnership (a partnership-partner), any adjustment on account of such partnership-partner's failure to satisfy the requirements of paragraph (a) of this section will be treated as an adjustment on account of a mathematical or clerical error under section 6213(b), except that the procedures under section 6213(b)(2) for requesting abatement of an assessment do not apply. See section 6232(d)(1)(B) and § 301.6232–1(d).

(4) *Examples.* The following examples illustrate the rules of this paragraph (b).

Example 1. D, an individual, is a partner in Partnership. D and Partnership are both calendar year taxpayers and Partnership does not have an election under section 6221(b) in effect for its 2018 taxable year. On its partnership return for taxable year 2018,

Partnership reports $100,000 in ordinary income. On the Schedule K–1 attached to the partnership return, as well as on the Schedule K–1 furnished to D, Partnership reports $15,000 as D's distributive share of the $100,000 in ordinary income. D reports only $5,000 of the $15,000 of ordinary income on his 2018 income tax return. The IRS may determine the amount of tax that results from adjusting the ordinary income attributable to D's interest in Partnership reported on D's 2018 income tax return from $5,000 to $15,000 and assess that resulting underpayment in tax as if it was on account of a mathematical or clerical error appearing on D's return. D may not request an abatement of that assessment under section 6213(b).

Example 2. F was a partner in Partnership during 2018. In 2021, Partnership receives a notice of final partnership adjustment in an administrative proceeding under subchapter C of chapter 63 with respect to Partnership's 2018 taxable year. Partnership properly elects the application of section 6226 and files with the IRS a statement of F's share of adjustments with respect to Partnership's 2018 taxable year. F fails to report one adjustment, F's share of a decrease in the amount of losses for 2018, on F's return as required by section 6226 and the regulations thereunder. The IRS may determine the amount of tax that results from adjusting the decrease in the amount of losses on F's return to be consistent with the amount included on the section 6226 statement filed with the IRS and may assess the resulting underpayment in tax as if it was on account of a mathematical or clerical error appearing on F's return. F may not request an abatement of that assessment under section 6213(b).

(c) *Notification to the IRS when items attributable to a partnership are treated inconsistently*—(1) *In general.* Paragraphs (a) and (b) of this section (regarding the consistent treatment of partnership-related items and the effect of inconsistent treatment) do not apply to partnership-related items identified as inconsistent (or that may be inconsistent) in a statement that the partner provides to the IRS according to the forms, instructions, and other guidance prescribed by the IRS. Instead, the procedures in paragraph (c)(3) of this section apply. A statement does not identify an inconsistency for purposes of this paragraph (c) unless it is attached to the partner's return on which the partnership-related item is treated inconsistently.

(2) *Coordination with section 6223.* Paragraph (c)(1) of this section is not applicable to a partnership-related item the treatment of which is binding on the partner because of actions taken by the partnership under subchapter C of chapter 63 or because of a final decision in a proceeding with respect to the partnership under subchapter C of chapter 63. Accordingly, the provisions of paragraph (c)(1) of this section do not apply with respect to the partner's treatment of a partnership-related item reflected on an AAR under section 6227 or a statement under section 6226 filed by the partnership with the IRS to which the partner is bound under section 6223. Therefore, if the partner's treatment of a partnership-related item reflected on an AAR or statement described in section 6226 is not consistent with the treatment of the partnership to which the partner is bound under section 6223, the provisions of section 6222(c) and paragraph (c)(1) of this section do not apply with respect to such item, and any resulting underpayment may be assessed and collected in accordance with paragraph (b)(2) of this section.

(3) *Partner protected only to extent of notification.* A partner who reports the inconsistent treatment of a partnership-related item is not subject to paragraphs (a) and (b) of this section only with respect to those items identified in the statement described in paragraph (c)(1) of this section. Thus, if a partner notifying the IRS with respect to one partnership-related item does not report the inconsistent treatment of another partnership-related item, the IRS may determine the amount of tax that results from adjusting the unidentified, inconsistently reported item on the partner's return to make it consistent with the treatment of such item on the partnership return, and assess the resulting underpayment of tax in accordance with paragraph (b)(2) of this section.

(4) *Adjustment after notification*—(i) *In general.* If a partner notifies the IRS of the inconsistent treatment of a partnership-related item in accordance with paragraph (c)(1) of this section, and the IRS disagrees with the inconsistent treatment, the IRS may adjust the identified, inconsistently reported item in a proceeding with respect to the partner. Nothing in this paragraph (c)(4)(i) precludes the IRS from also conducting a proceeding with respect to the partnership.

(ii) *Adjustments in partner proceeding.* In a proceeding with respect to a partner described in paragraph (c)(4)(i) of this section, the IRS may adjust any identified, inconsistently reported partnership-related item to make the item consistent with the treatment of that item on the partnership return or determine that the correct treatment of such item differs from the treatment on the partnership return and instead adjust the item to reflect the correct treatment, notwithstanding the treatment of that item on the partnership return. The IRS may also adjust any item on the partner's return, including items that are not partnership-related items. Any final decision with respect to an inconsistent position in a proceeding to which the partnership is not a party is not binding on the partnership.

(5) *Examples.* The following examples illustrate the rules of this paragraph (c). For purposes of these examples, each partnership is subject to the provisions of subchapter C of chapter 63, and each partnership and partner is a calendar year taxpayer, unless otherwise stated.

Example 1. B is a partner in Partnership during 2018. B treats a deduction and a capital gain attributable to Partnership on B's 2018 income tax return in a manner that is inconsistent with the treatment of those items by Partnership on its 2018 partnership return. B reports the inconsistent treatment of the deduction in accordance with paragraph (c)(1) of this section, but not the inconsistent treatment of the gain. Because B did not notify the IRS of the inconsistent treatment of the gain in accordance with paragraph (c)(1) of this section, the IRS may determine the amount of tax that results from adjusting the gain reported on B's 2018 income tax return in order to make the treatment of that gain consistent with how the gain was treated on Partnership's partnership return. Pursuant to paragraph (c)(3) of this section, the IRS may assess and collect the underpayment of tax resulting from the adjustment to the gain as if it was on account of a mathematical or clerical error appearing on B's return.

Example 2. On its 2018 partnership return, Partnership treats partner E's distributive share of ordinary loss attributable to Partnership as $8,000. E, however, claims an ordinary loss of $9,000 as attributable to Partnership on its 2018 income tax return and notifies the IRS of the inconsistent treatment in accordance with paragraph (c)(1) of this section. As a result of the notice of inconsistent treatment, the IRS conducts a separate proceeding under subchapter B of chapter 63 of the Internal Revenue Code with respect to E's 2018 income tax return, a proceeding to which Partnership is not a party. During the proceeding, the IRS determines that the proper amount of E's distributive share of the ordinary loss from Partnership is $3,000. During the same proceeding, the IRS also determines that E overstated a charitable contribution deduction in the amount of $2,500 on its 2018 income tax return. The determination of the adjustment of E's share of ordinary loss is not binding on Partnership. The charitable contribution deduction is not attributable to Partnership or to another partnership subject to the provisions of subchapter C of chapter 63. The IRS may determine the amount of tax that results from adjusting the $9,000 ordinary loss deduction to $3,000 and from adjusting the charitable contribution deduction. Pursuant to paragraph (c)(4)(ii) of this section, the IRS is not limited to only adjusting the ordinary loss of $9,000, as originally reported on E's partner return, to $8,000, as originally reported by Partnership on its partnership return, nor is the IRS prohibited from adjusting the charitable

contribution deduction in the proceeding with respect to E.

(d) *Partner receiving incorrect information*—(1) *In general.* A partner is treated as having complied with section 6222(c)(1)(B) and paragraph (c)(1) of this section with respect to a partnership-related item if the partner—

(i) Demonstrates that the treatment of such item on the partner's return is consistent with the treatment of that item on the statement, schedule, or other form prescribed by the IRS and furnished to the partner by the partnership, and

(ii) The partner makes an election in accordance with paragraph (d)(2) of this section.

(2) *Time and manner of making election*—(i) *In general.* An election under paragraph (d) of this section must be filed in writing with the IRS office set forth in the notice that notified the partner of the inconsistency no later than 60 days after the date of such notice.

(ii) *Contents of election.* The election described in paragraph (d)(2)(i) of this section must be—

(A) Clearly identified as an election under section 6222(c)(2)(B);

(B) Signed by the partner making the election;

(C) Accompanied by a copy of the statement, schedule, or other form furnished to the partner by the partnership and a copy of the IRS notice that notified the partner of the inconsistency; and

(D) Include any other information required in forms, instructions, or other guidance prescribed by the IRS.

(iii) *Treatment of partnership-related item is unclear.* Generally, the requirement described in paragraph (d)(2)(ii)(C) of this section will be satisfied by attaching a copy of the statement, schedule, or other form furnished to the partner by the partnership to the election (in addition to a copy of the IRS notice that notified the partner of the inconsistency). However, if it is not clear from the statement, schedule, or other form furnished by the partnership that the partner's treatment of the partnership-related item on the partner's return is consistent, the election must also include an explanation of how the treatment of such item on the statement, schedule, or other form furnished by the partnership is consistent with the treatment of the item on the partner's return, including with respect to the characterization, timing, and amount of such item.

(3) *Example.* The following example illustrates the rules of this paragraph (d). For purposes of this example, the partnership is subject to subchapter C of chapter 63 and the partnership and its partners are calendar year taxpayers.

Example. E is a partner in Partnership for 2018. On its 2018 partnership return, Partnership reports that E's distributive share of ordinary income attributable to Partnership is $1,000. Partnership furnishes to E a Schedule K–1 for 2018 showing $500 as E's distributive share of ordinary income. E reports $500 of ordinary income attributable to Partnership on its 2018 income tax return consistent with the Schedule K–1 furnished to E. The IRS notifies E that E's treatment of the ordinary income attributable to Partnership on its 2018 income tax return is inconsistent with how Partnership treated the ordinary income allocated to E on its 2018 partnership return. Within 60 days of receiving the notice from the IRS of the inconsistency, E files an election with the IRS in accordance with paragraph (d)(2) of this section. Because E made a valid election under section 6222(c)(2)(B) and paragraph (d)(1) of this section, E is treated as having notified the IRS of the inconsistency with respect to the ordinary income attributable to Partnership under paragraph (c)(1) of this section.

(e) *Applicability date*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par 8.** Section 301.6225–1 is added to read as follows:

§ 301.6225–1 Partnership Adjustment by the Internal Revenue Service.

(a) *Imputed underpayment based on partnership adjustments*—(1) *In general.* In the case of any partnership adjustments (as defined in § 301.6241–1(a)(6)) by the Internal Revenue Service (IRS), if the adjustments result in an imputed underpayment (as determined in accordance with paragraph (b) of this section), the partnership must pay an amount equal to such imputed underpayment in accordance with paragraph (a)(2) of this section. If the adjustments do not result in an imputed underpayment (as described in paragraph (f) of this section), such adjustments must be taken into account by the partnership in the adjustment year (as defined in § 301.6241–1(a)(1)) in accordance with § 301.6225–3. Partnership adjustments may result in more than one imputed underpayment pursuant to paragraph (g) of this section. Each imputed underpayment determined under this section is based solely on partnership adjustments with respect to a single taxable year.

(2) *Partnership pays the imputed underpayment.* An imputed underpayment (determined in accordance with paragraph (b) of this section and included in a notice of final partnership adjustment (FPA) under section 6231(a)(3)) must be paid by the partnership in the same manner as if the imputed underpayment were a tax imposed for the adjustment year in accordance with § 301.6232–1. The FPA will include the amount of any imputed underpayment, as modified under § 301.6225–2 if applicable, unless the partnership waives its right to such FPA under section 6232(d)(2). See § 301.6232–1(d)(2). For the alternative to payment of the imputed underpayment by the partnership, see § 301.6226–1. If a partnership pays an imputed underpayment, the partnership's expenditure for the imputed underpayment is taken into account by the partnership in accordance with § 301.6241–4. For interest and penalties with respect to an imputed underpayment, see section 6233.

(3) *Imputed underpayment set forth in notice of proposed partnership adjustment.* An imputed underpayment set forth in a notice of proposed partnership adjustment (NOPPA) under section 6231(a)(2) is determined in accordance with paragraph (b) of this section without regard to any modification under § 301.6225–2. Modifications under § 301.6225–2, if allowed by the IRS, may change the amount of an imputed underpayment set forth in the NOPPA and determined in accordance with paragraph (b) of this section. Only the partnership adjustments set forth in a NOPPA are taken into account for purposes of determining an imputed underpayment under this section and any modification under § 301.6225–2.

(b) *Determination of an imputed underpayment*—(1) *In general.* In the case of any partnership adjustment by the IRS, an imputed underpayment is determined by—

(i) Grouping the partnership adjustments in accordance with paragraph (c) of this section and, if appropriate, subgrouping such adjustments in accordance with paragraph (d) of this section;

(ii) Netting the adjustments in accordance with paragraph (e) of this section;

(iii) Calculating the total netted partnership adjustment in accordance with paragraph (b)(2) of this section;

(iv) Multiplying the total netted partnership adjustment by the highest rate of Federal income tax in effect for

the reviewed year under section 1 or 11; and

(v) Increasing or decreasing the product that results under paragraph (b)(1)(iv) of this section by—

(A) Any amounts treated under paragraph (e)(3)(ii) of this section as net positive adjustments (as defined in paragraph (e)(4)(i) of this section); and

(B) Any net negative adjustments (as defined in paragraph (e)(4)(ii) of this section), except net negative adjustments resulting from reallocation adjustments to credits as described in paragraph (d)(3)(ii) of this section and creditable tax expenditures described in paragraph (e)(3)(iii) of this section.

(2) *Calculation of the total netted partnership adjustment.* For purposes of determining an imputed underpayment under paragraph (b)(1) of this section, the *total netted partnership adjustment* is the sum of all net positive adjustments in the reallocation grouping described in paragraph (c)(2) of this section and the residual grouping described in paragraph (c)(5) of this section.

(3) *Adjustments to items for which tax has been collected under chapters 3 and 4.* A partnership adjustment is disregarded for purposes of calculating the total netted partnership adjustment under paragraph (b)(2) of this section to the extent that the IRS has collected the tax required to be withheld under chapter 3 or chapter 4 (as defined in § 301.6241–7(b)(2)(ii) and (iii)) that is attributable to the partnership adjustment. See § 301.6241–7(b)(3) for rules that apply when a partnership pays an imputed underpayment that includes a partnership adjustment to an amount subject to withholding (as defined in § 301.6241–7(b)(2)(i)) under chapter 3 or chapter 4 for which such tax has not yet been collected.

(4) *Treatment of adjustment as zero for purposes of calculating the imputed underpayment.* If the effect of a partnership adjustment under chapter 1 of subtitle A of the Internal Revenue Code (Code) to any person is reflected in another adjustment taken into account under this section, the IRS may treat an adjustment as zero solely for purposes of calculating the imputed underpayment.

(c) *Grouping of partnership adjustments*—(1) *In general.* To determine an imputed underpayment under paragraph (b) of this section, partnership adjustments are placed into one of four groupings. These groupings are the reallocation grouping described in paragraph (c)(2) of this section, the credit grouping described in paragraph (c)(3) of this section, the creditable expenditure grouping described in paragraph (c)(4) of this section, and the residual grouping described in paragraph (c)(5) of this section. Adjustments in groupings may be placed in subgroupings, as appropriate, in accordance with paragraph (d) of this section. The IRS may, in its discretion, group adjustments in a manner other than the manner described in this paragraph (c) when such grouping would appropriately reflect the facts and circumstances. For requests to modify the groupings, see § 301.6225–2(d)(6).

(2) *Reallocation grouping*—(i) *In general.* Any adjustment that allocates or reallocates a partnership-related item to and from a particular partner or partners is a *reallocation adjustment.* Except in the case of an adjustment to a credit (as described in paragraph (c)(3) of this section) or to a creditable expenditure (as described in paragraph (c)(4) of this section), reallocation adjustments are placed in the reallocation grouping. Adjustments that reallocate a credit to and from a particular partner or partners are placed in the credit grouping (see paragraph (c)(3) of this section), and adjustments that reallocate a creditable expenditure to and from a particular partner or partners are placed in the creditable expenditure grouping (see paragraph (c)(4) of this section).

(ii) *Each reallocation adjustment results in at least two separate adjustments.* Each reallocation adjustment generally results in at least two separate adjustments. One adjustment reverses the effect of the improper allocation of a partnership-related item, and the other adjustment effectuates the proper allocation of the partnership-related item. Generally, a reallocation adjustment results in one positive adjustment (as defined in paragraph (d)(2)(iii) of this section) and one negative adjustment (as defined in paragraph (d)(2)(ii) of this section).

(3) *Credit grouping.* Each adjustment to a partnership-related item that is reported or could be reported by a partnership as a credit on the partnership's return, including a reallocation adjustment, is placed in the credit grouping.

(4) *Creditable expenditure grouping*—(i) *In general.* Each adjustment to a creditable expenditure, including a reallocation adjustment to a creditable expenditure, is placed in the creditable expenditure grouping.

(ii) *Adjustment to a creditable expenditure*—(A) *In general.* For purposes of this section, an adjustment to a partnership-related item is treated as an adjustment to a creditable expenditure if any person could take the item that is adjusted (or item as adjusted if the item was not originally reported by the partnership) as a credit. See § 1.704–1(b)(4)(ii) of this chapter. For instance, if the adjustment is a reduction of qualified research expenses, the adjustment is to a creditable expenditure for purposes of this section because any person allocated the qualified research expenses by the partnership could claim a credit with respect to their allocable portion of such expenses under section 41, rather than a deduction under section 174.

(B) *Creditable foreign tax expenditures.* The creditable expenditure grouping includes each adjustment to a creditable foreign tax expenditure (CFTE) as defined in § 1.704–1(b)(4)(viii)(*b*) of this chapter, including any reallocation adjustment to a CFTE.

(5) *Residual grouping*—(i) *In general.* Any adjustment to a partnership-related item not described in paragraph (c)(2), (3), or (4) of this section is placed in the residual grouping.

(ii) *Adjustments to partnership-related items that are not allocated under section 704(b).* The residual grouping includes any adjustment to a partnership-related item that derives from an item that would not have been required to be allocated by the partnership to a reviewed year partner under section 704(b).

(6) *Recharacterization adjustments*—(i) *Recharacterization adjustment defined.* An adjustment that changes the character of a partnership-related item is a recharacterization adjustment. For instance, an adjustment that changes a loss from ordinary to capital or from active to passive is a recharacterization adjustment.

(ii) *Grouping recharacterization adjustments.* A recharacterization adjustment is placed in the appropriate grouping as described in paragraphs (c)(2) through (5) of this section.

(iii) *Recharacterization adjustments result in two partnership adjustments.* In general, a recharacterization adjustment results in at least two separate adjustments in the appropriate grouping under paragraph (c)(6)(ii) of this section. One adjustment reverses the improper characterization of the partnership-related item, and the other adjustment effectuates the proper characterization of the partnership-related item. A recharacterization adjustment results in two adjustments regardless of whether the amount of the partnership-related item is being adjusted. Generally, recharacterization adjustments result in one positive

adjustment and one negative adjustment.

(d) *Subgroupings*—(1) *In general.* If any partnership adjustment within any grouping described in paragraph (c) of this section is a negative adjustment, the adjustments within that grouping are subgrouped in accordance with this paragraph (d). If all partnership adjustments within the groupings are positive adjustments, this paragraph (d) does not apply, and no adjustment within the groupings is subgrouped in accordance with this paragraph (d). The IRS may, in its discretion, subgroup adjustments in a manner other than the manner described in this paragraph (d) when such subgrouping would appropriately reflect the facts and circumstances. For requests to modify the subgroupings, see § 301.6225–2(d)(6).

(2) *Definition of negative adjustments and positive adjustments*—(i) *In general.* For purposes of this section, partnership adjustments made by the IRS are treated as follows:

(A) An increase in an item of gain is treated as an increase in an item of income;

(B) A decrease in an item of gain is treated as a decrease in an item of income;

(C) An increase in an item of loss or deduction is treated as a decrease in an item of income; and

(D) A decrease in an item of loss or deduction is treated as an increase in an item of income.

(ii) *Negative adjustment.* A *negative adjustment* is any adjustment that is a decrease in an item of income, a partnership adjustment treated under paragraph (d)(2)(i) of this section as a decrease in an item of income, or an increase in an item of credit.

(iii) *Positive adjustment*—(A) *In general.* A *positive adjustment* is any adjustment that is not a negative adjustment as defined in paragraph (d)(2)(ii) of this section.

(B) *Treatment of adjustments that cannot be allocated under section 704(b).* For purposes of determining an imputed underpayment under this section, an adjustment described in paragraph (c)(5)(ii) of this section that could result in an increase in income or decrease in a loss, deduction, or credit for any person without regard to any particular person's specific circumstances is treated as a positive adjustment to income to the extent appropriate.

(3) *Subgrouping rules*—(i) *In general.* Except as otherwise provided in this paragraph (d)(3), an adjustment is subgrouped according to how the adjustment would be required to be taken into account separately under section 702(a) or any other provision of the Code or regulations applicable to the adjusted partnership-related item. For purposes of creating subgroupings under this section, if any adjustment could be subject to any preference, limitation, or restriction under the Code (or not allowed, in whole or in part, against ordinary income) if taken into account by any person, the adjustment is placed in a separate subgrouping from all other adjustments within the grouping. A negative adjustment that is not otherwise required to be placed in its own subgrouping under this paragraph (d)(3) must be placed in the same subgrouping as another adjustment if the negative adjustment and the other adjustment would have been properly netted at the partnership level and such netted amount would have been required to be allocated to the partners of the partnership as a single partnership-related item for purposes of section 702(a) or other provision of the Code and regulations.

(ii) *Subgrouping reallocation adjustments*—(A) *Reallocation adjustments in the reallocation grouping.* Each positive adjustment and each negative adjustment resulting from a reallocation adjustment as described in paragraph (c)(2)(ii) of this section is placed in its own separate subgrouping within the reallocation grouping. For instance, if the reallocation adjustment reallocates a deduction from one partner to another partner, the decrease in the deduction (positive adjustment) allocated to the first partner is placed in a subgrouping within the reallocation grouping separate from the increase in the deduction (negative adjustment) allocated to the second partner. If a particular partner or group of partners has two or more reallocation adjustments allocable to such partner or group, such adjustments may be subgrouped in accordance with paragraph (d)(3)(i) of this section and netted in accordance with paragraph (e) of this section.

(B) *Reallocation adjustments in the credit grouping.* In the case of a reallocation adjustment to a credit, which is placed in the credit grouping pursuant to paragraph (c)(3) of this section, the decrease in credits allocable to one partner or group of partners is treated as a positive adjustment, and the increase in credits allocable to another partner or group of partners is treated as a negative adjustments. Each positive adjustment and each negative adjustment resulting from a reallocation adjustment to credits is placed in its own separate subgrouping within the credit grouping.

(iii) *Subgroupings within the creditable expenditure grouping*—(A) *In general.* Each adjustment in the creditable expenditure grouping described in paragraph (c)(4) of this section is subgrouped in accordance with this paragraph (d)(3)(iii).

(B) *Subgroupings for adjustments to CFTEs.* Each adjustment to a CFTE is subgrouped based on the separate category of income to which the CFTE relates in accordance with section 904(d) and the regulations thereunder, and to account for any different allocation of the CFTE between partners. Two or more adjustments to CFTEs are included within the same subgrouping only if each adjustment relates to CFTEs in the same separate category, and each adjusted partnership-related item would be allocated to the partners in the same ratio had those items been properly reflected on the partnership return for the reviewed year.

(C) *Other creditable expenditures.* [Reserved]

(iv) *Subgrouping recharacterization adjustments.* Each positive adjustment and each negative adjustment resulting from a recharacterization adjustment as described in paragraph (c)(6) of this section is placed in its own separate subgrouping within the residual grouping. If a particular partner or group of partners has two or more recharacterization adjustments allocable to such partner or group, such adjustments may be subgrouped in accordance with paragraph (d)(3)(i) of this section and netted in accordance with paragraph (e) of this section.

(e) *Netting adjustments within each grouping or subgrouping*—(1) *In general.* All adjustments within a subgrouping determined in accordance with paragraph (d) of this section are netted in accordance with this paragraph (e) to determine whether there is a net positive adjustment (as defined in paragraph (e)(4)(i) of this section) or net negative adjustment (as defined in paragraph (e)(4)(ii) of this section) for that subgrouping. If paragraph (d) of this section does not apply because a grouping only includes positive adjustments, all adjustments in that grouping are netted in accordance with this paragraph (e). For purposes of this paragraph (e), netting means summing all adjustments together within each grouping or subgrouping, as appropriate.

(2) *Limitations on netting adjustments.* Positive adjustments and negative adjustments may only be netted against each other if they are in the same grouping or subgrouping in accordance with the rules in paragraphs

(c) and (d) of this section. An adjustment in one grouping or subgrouping may not be netted against an adjustment in any other grouping or subgrouping. Adjustments from one taxable year may not be netted against adjustments from another taxable year.

(3) *Results of netting adjustments within groupings or subgroupings*—(i) *Groupings other than the credit and creditable expenditure groupings.* Except as described in paragraphs (e)(3)(ii) and (iii) of this section, each net positive adjustment (as defined in paragraph (e)(4)(i) of this section) with respect to a particular grouping or subgrouping that results after netting the adjustments in accordance with this paragraph (e) is included in the calculation of the total netted partnership adjustment under paragraph (b)(2) of this section. Each net negative adjustment (as defined in paragraph (e)(4)(ii) of this section) with respect to a grouping or subgrouping that results after netting the adjustments in accordance with this paragraph (e) is excluded from the calculation of the total netted partnership adjustment under paragraph (b)(2) of this section. Adjustments underlying a net negative adjustment described in the preceding sentence are adjustments that do not result in an imputed underpayment (as described in paragraph (f) of this section).

(ii) *Credit grouping.* Any net positive adjustment or net negative adjustment in the credit grouping (including any such adjustment with respect to a subgrouping within the credit grouping) is excluded from the calculation of the total netted partnership adjustment. A net positive adjustment or net negative adjustment described in this paragraph (e)(3)(ii) is taken into account under paragraph (b)(1)(v) of this section, except for negative adjustments to credits resulting from a reallocation adjustment that were placed in a separate subgrouping pursuant to paragraph (d)(3)(ii)(B) of this section. A negative adjustment to a credit placed in its separate subgrouping under paragraph (d)(3)(ii)(B) of this section is treated as an adjustment that does not result in an imputed underpayment in accordance with paragraph (f)(1)(i) of this section.

(iii) *Treatment of creditable expenditures*—(A) *Creditable foreign tax expenditures.* A net decrease to a CFTE in any CFTE subgrouping (as described in paragraph (d)(3)(iii)(B) of this section) is treated as a net positive adjustment described in paragraph (e)(3)(ii) of this section. A net increase to a CFTE in any CFTE subgrouping is treated as a net negative adjustment described in paragraph (e)(3)(i) of this section.

(B) *Other creditable expenditures.* [Reserved]

(4) *Net positive adjustment and net negative adjustment defined*—(i) *Net positive adjustment.* A *net positive adjustment* means an amount that is greater than zero which results from netting adjustments within a grouping or subgrouping in accordance with this paragraph (e). A net positive adjustment includes a positive adjustment that was not netted with any other adjustment. A net positive adjustment includes a net decrease in an item of credit.

(ii) *Net negative adjustment.* A *net negative adjustment* means any amount which results from netting adjustments within a grouping or subgrouping in accordance with this paragraph (e) that is not a net positive adjustment (as defined in paragraph (e)(4)(i) of this section). A net negative adjustment includes a negative adjustment that was not netted with any other adjustment.

(f) *Partnership adjustments that do not result in an imputed underpayment*—(1) *In general.* Except as otherwise provided in paragraph (e) of this section, a partnership adjustment does not result in an imputed underpayment if—

(i) After grouping, subgrouping, and netting the adjustments as described in paragraphs (c), (d), and (e) of this section, the result of netting with respect to any grouping or subgrouping that includes a particular partnership adjustment is a net negative adjustment (as described in paragraph (e)(4)(ii) of this section); or

(ii) The calculation under paragraph (b)(1) of this section results in an amount that is zero or less than zero.

(2) *Treatment of an adjustment that does not result in an imputed underpayment.* Any adjustment that does not result in an imputed underpayment (as described in paragraph (b)(2) of this section) is taken into account by the partnership in the adjustment year in accordance with § 301.6225–3. If the partnership makes an election pursuant to section 6226 with respect to an imputed underpayment, the adjustments that do not result in that imputed underpayment that are associated with that imputed underpayment (as described in paragraph (g)(2)(iii)(B) of this section) are taken into account by the reviewed year partners in accordance with § 301.6226–3.

(g) *Multiple imputed underpayments in a single administrative proceeding*—(1) *In general.* The IRS, in its discretion, may determine that partnership adjustments for the same partnership taxable year result in more than one imputed underpayment. The determination of whether there is more than one imputed underpayment for any partnership taxable year, and if so, which partnership adjustments are taken into account to calculate any particular imputed underpayment is based on the facts and circumstances and nature of the partnership adjustments. See § 301.6225–2(d)(6) for modification of the number and composition of imputed underpayments.

(2) *Types of imputed underpayments*—(i) *In general.* There are two types of imputed underpayments: A general imputed underpayment (described in paragraph (d)(2)(ii) of this section) and a specific imputed underpayment (described in paragraph (d)(2)(iii) of this section). Each type of imputed underpayment is separately calculated in accordance with this section.

(ii) *General imputed underpayment.* The general imputed underpayment is calculated based on all adjustments (other than adjustments that do not result in an imputed underpayment under paragraph (f) of this section) that are not taken into account to determine a specific imputed underpayment under paragraph (g)(2)(iii) of this section. There is only one general imputed underpayment in any administrative proceeding. If there is one imputed underpayment in an administrative proceeding, it is a general imputed underpayment and may take into account adjustments described in paragraph (g)(2)(iii) of this section, if any, and all adjustments that do not result in that general imputed underpayment (as described in paragraph (e) of this section) are associated with that general imputed underpayment.

(iii) *Specific imputed underpayment*—(A) *In general.* The IRS may, in its discretion, designate a specific imputed underpayment with respect to adjustments to a partnership-related item or items that were allocated to one partner or a group of partners that had the same or similar characteristics or that participated in the same or similar transaction or on such other basis as the IRS determines properly reflects the facts and circumstances. The IRS may designate more than one specific imputed underpayment with respect to any partnership taxable year. For instance, in a single partnership taxable year there may be a specific imputed underpayment with respect to adjustments related to a transaction affecting some, but not all, partners of the partnership (such as adjustments

that are specially allocated to certain partners) and a second specific imputed underpayment with respect to adjustments resulting from a reallocation of a distributive share of income from one partner to another partner. The IRS may, in its discretion, determine that partnership adjustments that could be taken into account to calculate one or more specific imputed underpayments under this paragraph (g)(2)(iii)(A) for a partnership taxable year are more appropriately taken into account in determining the general imputed underpayment for such taxable year. For instance, the IRS may determine that it is more appropriate to calculate only the general imputed underpayment if, when calculating the specific imputed underpayment requested by the partnership, there is an increase in the number of the partnership adjustments that after grouping and netting result in net negative adjustments and are disregarded in calculating the specific imputed underpayment.

(B) *Adjustments that do not result in an imputed underpayment associated with a specific imputed underpayment.* If the IRS designates a specific imputed underpayment, the IRS will designate which adjustments that do not result in an imputed underpayment, if any, are appropriate to associate with that specific imputed underpayment. If the adjustments underlying that specific imputed underpayment are reallocation adjustments or recharacterization adjustments, the net negative adjustment that resulted from the reallocation or recharacterization is associated with the specific imputed underpayment. Any adjustments that do not result in an imputed underpayment that are not associated with a specific imputed underpayment under this paragraph (d)(2)(iii)(B) are associated with the general imputed underpayment.

(h) *Examples.* The following examples illustrate the rules of this section. For purposes of these examples, each partnership is subject to the provisions of subchapter C of chapter 63 of the Code, each partnership and its partners are calendar year taxpayers, all partners are U.S. persons (unless otherwise stated), the highest rate of income tax in effect for all taxpayers is 40 percent for all relevant periods, and no partnership requests modification under § 301.6225–2.

Example 1. Partnership reports on its 2019 partnership return $100 of ordinary income and an ordinary deduction of <$70>. The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year and determines that ordinary income was $105 instead of $100 ($5 adjustment) and that the ordinary deduction was <$80> instead of <$70> (<$10> adjustment). Pursuant to paragraph (c) of this section, the adjustments are both in the residual grouping. The <$10> adjustment to the ordinary deduction would result in a decrease in the imputed underpayment if netted with the $5 adjustment to ordinary income. Because the <$10> adjustment to the ordinary deduction might be limited if taken into account by any person, it is grouped in a separate subgrouping from the $5 adjustment to ordinary income. The total netted partnership adjustment is $5, which results in an imputed underpayment of $2. The <$10> adjustment to the ordinary deduction is a net negative amount and is an adjustment that does not result in an imputed underpayment which is taken into account by Partnership in the adjustment year in accordance with § 301.6225–3.

Example 2. The facts are the same as *Example 1* of this paragraph (h), except that the <$10> adjustment would not be limited if taken into account by any of its partners (direct or indirect). The IRS may, in its discretion, group the $5 adjustment and the <$10> adjustment together in the residual grouping. As a result, the $5 and the <$10> adjustments are netted under paragraph (e) of this section. Such netting results in a net negative adjustment (as defined under paragraph (e)(4)(ii)) in the residual grouping of <$5> under paragraph (e) of this section. Pursuant to paragraph (f) of this section, the <$5> net negative adjustment is an adjustment that does not result in an imputed underpayment. Therefore, since the only net adjustment is an adjustment that does not result in an imputed underpayment, there is no imputed underpayment.

Example 3. Partnership reports on its 2019 partnership return ordinary income of $300, long-term capital gain of $125, long-term capital loss of <$75>, a depreciation deduction of <$100>, and a tax credit that can be claimed by the partnership of $5. In an administrative proceeding with respect to Partnership's 2019 taxable year, the IRS determines that ordinary income is $500 ($200 adjustment), long-term capital gain is $200 ($75 adjustment), long-term capital loss is <$25> ($50 adjustment), the depreciation deduction is <$70> ($30 adjustment), and the tax credit is $3 ($2 adjustment). Pursuant to paragraph (c) of this section, the tax credit is in the credit grouping under paragraph (c)(3) of this section. The remaining adjustments are part of the residual grouping under paragraph (c)(5) of this section. Pursuant to paragraph (d)(2) of this section, all of the adjustments in the residual grouping are positive adjustments. Because there are no negative adjustments, there is no need for further subgrouping within the residual grouping. Under paragraph (b)(2), the adjustments in the residual grouping are summed for a total netted partnership adjustment of $355. Under paragraph (b)(1)(iv) of this section, the total netted partnership adjustment is multiplied by 40 percent (highest tax rate in effect), which results in $142. Under paragraph (b)(1)(iv) of this section, the $142 is increased by the $2 credit adjustment, resulting in an imputed underpayment of $144.

Example 4. Partnership reported on its 2019 partnership return long-term capital gain of $125 and long-term capital loss of <$75>. In an administrative proceeding with respect to Partnership's 2019 taxable year, the IRS determines the long-term capital gain should have been reported as ordinary income of $125. There are no other adjustments for the 2019 taxable year. This recharacterization adjustment results in two adjustments in the residual grouping pursuant to paragraph (c)(6) of this section: an increase in ordinary income of $125 ($125 adjustment) as well as a decrease of long-term capital gain of $125 (<$125> adjustment). The decrease in long-term capital gain is a negative adjustment under paragraph (d)(2)(ii) of this section and the increase in ordinary income is a positive adjustment under paragraph (d)(2)(iii) of this section. Under paragraph (d)(3)(i) of this section, the adjustment to long-term capital gain is placed in a subgrouping separate from the adjustment to ordinary income because the reduction of long-term capital gain is required to be taken into account separately pursuant to section 702(a). The $125 decrease in long-term capital gain is a net negative adjustment in the long-term capital subgrouping and as a result is an adjustment that does not result in an imputed underpayment under paragraph (f) of this section. The $125 increase in ordinary income results in a net positive adjustment under paragraph (e)(4)(i) of this section. Because the ordinary subgrouping is the only subgrouping resulting in a net positive adjustment, $125 is the total netted partnership adjustment under paragraph (b)(2) of this section. Under paragraph (b)(1)(iv) of this section, $125 is multiplied by 40 percent resulting in an imputed underpayment of $50.

Example 5. Partnership reported a $100 deduction for certain expenses on its 2019 partnership return and an additional $100 deduction with respect to the same type of expenses on its 2020 partnership return. The IRS initiates an administrative proceeding with respect to Partnership's 2019 and 2020 taxable years and determines that Partnership improperly accelerated accrual of a portion of the expenses with respect to the deduction in 2019 that should have been taken into account in 2020. Therefore, for taxable year 2019, the IRS determines that Partnership should have reported a deduction of $75 with respect to the expenses ($25 adjustment in the 2019 residual grouping). For 2020, the IRS determines that Partnership should have reported a deduction of $125 with respect to these expenses (<$25> adjustment in the 2020 residual grouping). There are no other adjustments for the 2019 and 2020 partnership taxable years. Pursuant to paragraph (e)(2) of this section, the adjustments for 2019 and 2020 are not netted with each other. The 2019 adjustment of $25 is the only adjustment for that year and a net positive adjustment under paragraph (e)(4)(i) of this section, and therefore the total netted partnership adjustment for 2019 is $25 pursuant to paragraph (b)(2) of this section. The $25 total netted partnership adjustment is multiplied by 40 percent resulting in an imputed underpayment of $10 for

Partnership's 2019 taxable year. The $25 increase in the deduction for 2020 a net negative adjustment under paragraph (e)(4)(ii) of this section is an adjustment that does not result in an imputed underpayment for that year. Therefore, there is no imputed underpayment for 2020.

Example 6. On its partnership return for the 2020 taxable year, Partnership reported ordinary income of $100 and a capital gain of $50. Partnership had four equal partners during the 2020 tax year, all of whom were individuals. On its partnership return for the 2020 tax year, the capital gain was allocated to partner E and the ordinary income was allocated to all partners based on their interests in Partnership. In an administrative proceeding with respect to Partnership's 2020 taxable year, the IRS determines that for 2020 the capital gain allocated to E should have been $75 instead of $50 and that Partnership should have recognized an additional $10 in ordinary income. In the NOPPA mailed by the IRS, the IRS may determine pursuant to paragraph (g) of this section that there is a general imputed underpayment with respect to the increase in ordinary income and a specific imputed underpayment with respect to the increase in capital gain specially allocated to E.

Example 7. On its partnership return for the 2020 taxable year, Partnership reported a recourse liability of $100. During an administrative proceeding with respect to Partnership's 2020 taxable year, the IRS determines that the $100 recourse liability should have been reported as a $100 nonrecourse liability. Under paragraph (d)(2)(iii)(B), the adjustment to the character of the liability results in a $100 increase in income because such recharacterization of a liability could result in up to $100 in taxable income if taken into account by any person. The $100 increase in income is a positive adjustment in the residual grouping under paragraph (c)(5)(ii) of this section. There are no other adjustments for the 2020 partnership taxable year. The $100 positive adjustment is treated as a net positive adjustment under paragraph (e)(4)(i) of this section, and the total netted partnership adjustment under paragraph (b)(2) of this section is $100. Pursuant to paragraph (b)(1) of this section, the total netted partnership adjustment is multiplied by 40 percent for an imputed underpayment of $40.

Example 8. Partnership reports on its 2019 partnership return $400 of CFTEs in the general category under section 904(d). The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year and determines that the amount of CFTEs was $300 instead of $400 (<$100> adjustment to CFTEs). No other adjustments are made for the 2019 taxable year. The <$100> adjustment to CFTEs is placed in the creditable expenditure grouping described in paragraph (c)(4) of this section. Pursuant to paragraph (e)(3)(iii) of this section, the decrease to CFTEs in the creditable expenditure grouping is treated as a positive adjustment to (decrease in) credits in the credit grouping under paragraph (c)(3) of this section. Because no other adjustments have been made, the $100 decrease in credits produces an imputed underpayment of $100 under paragraph (b)(1) of this section.

Example 9. Partnership reports on its 2019 partnership return $400 of CFTEs in the passive category under section 904(d). The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year and determines that the CFTEs reported by Partnership were general category instead of passive category CFTEs. No other adjustments are made. Under the rules in paragraph (c)(6) of this section, an adjustment to the category of a CFTE is treated as two separate adjustments: An increase to general category CFTEs of $400 and a decrease to passive category CFTEs of $400. Both adjustments are included in the creditable expenditure grouping under paragraph (c)(4) of this section, but they are included in separate subgroupings. Therefore, the two amounts do not net. Instead, the $400 increase to CFTEs in the general category subgrouping is treated as a net negative adjustment under paragraph (e)(3)(iii)(A) of this section and is an adjustment that does not result in an imputed underpayment under paragraph (f) of this section. The decrease to CFTEs in the passive category subgrouping of the creditable expenditure grouping results in a decrease in CFTEs. Therefore, pursuant to paragraph (e)(3)(iii)(A) of this section, it is treated as a decrease in credits in the credit grouping under paragraph (c)(3) of this section, which results in an imputed underpayment of $400 under paragraph (b)(1) of this section.

Example 10. Partnership has two partners, A and B. Under the partnership agreement, $100 of the CFTE is specially allocated to A for the 2019 taxable year. The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year and determines that $100 of CFTE should be reallocated from A to B. Because the adjustment reallocates a creditable expenditure, paragraph (c)(4) of this section provides that it is included in the creditable expenditure grouping rather than the reallocation grouping. The partnership adjustment is a <$100> adjustment to general category CFTE allocable to A and an increase of $100 to general category CFTE allocable to B. Pursuant to paragraph (d)(3)(iii) of this section, the <$100> adjustment to general category CFTE and the increase of $100 to general category CFTE are included in separate subgroupings in the creditable expenditure grouping. The $100 increase in general category CFTEs, B-allocation subgrouping, is a net negative adjustment, which does not result in an imputed underpayment and is therefore taken into account by the partnership in the adjustment year in accordance with § 301.6225–3. The net decrease to CFTEs in the general-category, A-allocation subgrouping, is treated as a decrease to credits in the credit grouping under paragraph (c)(3) of this section, resulting in an imputed underpayment of $100 under paragraph (b)(1) of this section.

Example 11. Partnership has two partners, A and B. Partnership owns two entities, DE1 and DE2, that are disregarded as separate from their owner for Federal tax purposes and are operating in and paying taxes to foreign jurisdictions. The partnership agreement provides that all items from DE1 and DE2 are allocable to A and B in the following manner. Items related to DE1: To A 75% and to B 25%. Items related to DE2: To A 25% and to B 75%. On Partnership's 2018 return, Partnership reports CFTEs in the general category of $300, $100 with respect to DE1 and $200 with respect to DE2. Partnership allocates the $300 of CFTEs $125 and $175 to A and B respectively. During an administrative proceeding with respect to Partnership's 2018 taxable year, the IRS determines that Partnership understated the amount of creditable foreign tax paid by DE2 by $40 and overstated the amount of creditable foreign tax paid by DE1 by $80. No other adjustments are made. Because the two adjustments each relate to CFTEs that are subject to different allocations, the two adjustments are in different subgroupings under paragraph (d)(3)(iii)(B) of this section. The adjustment reducing the CFTEs related to DE1 results in a decrease in CFTEs within that subgrouping and under paragraph (e)(3)(iii)(A) of this section is treated as a decrease in credits in the credit grouping under paragraph (c)(3) of this section and results in an imputed underpayment of $80 under paragraph (b)(1) of this section. The increase of $40 of general category CFTE related to the DE2 subgrouping results in an increase in CFTEs within that subgrouping and is treated as a net negative adjustment, which does not result in an imputed underpayment and is taken into account in the adjustment year in accordance with § 301.6225–3.

(i) *Applicability date*—(1) *In general.* Except as provided in paragraph (i)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22T is in effect.

■ **Par. 9.** Section 301.6225–2 is added to read as follows:

§ 301.6225–2 Modification of Imputed Underpayment.

(a) *Partnership may request modification of an imputed underpayment.* A partnership that has received a notice of proposed partnership adjustment (NOPPA) under section 6231(a)(2) from the Internal Revenue Service (IRS) may request modification of a proposed imputed underpayment set forth in the NOPPA in accordance with this section and any forms, instructions, and other guidance prescribed by the IRS. The effect of modification on a proposed imputed underpayment is described in paragraph (b) of this section. Unless otherwise described in paragraph (d) of this section, a partnership may request any type of modification of an imputed underpayment described in paragraph (d) of this section in the time and manner described in paragraph (c) of

this section. A partnership may request modification with respect to a partnership adjustment (as defined in § 301.6241–1(a)(6)) that does not result in an imputed underpayment (as described in § 301.6225–1(f)(1)(ii)) as described in paragraph (e) of this section. Only the partnership representative may request modification under this section. See section 6223 and § 301.6223–2 for rules regarding the binding authority of the partnership representative. For purposes of this section, the term relevant partner means any person for whom modification is requested by the partnership that is—

(1) A reviewed year partner (as defined in § 301.6241–1(a)(9)), including any pass-through partner (as defined in § 301.6241–1(a)(5)), except for any reviewed year partner that is a wholly-owned entity disregarded as separate from its owner for Federal tax purposes, or

(2) An indirect partner (as defined in § 301.6241–1(a)(4)) except for any indirect partner that is a wholly-owned entity disregarded as separate from its owner for Federal tax purposes.

(b) *Effect of modification*—(1) *In general.* A modification of an imputed underpayment under this section that is approved by the IRS may result in an increase or decrease in the amount of an imputed underpayment set forth in the NOPPA. A modification under this section has no effect on the amount of any partnership adjustment determined under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63). See paragraph (e) of this section for the effect of modification on adjustments that do not result in an imputed underpayment. A modification may increase or decrease an imputed underpayment by affecting the extent to which adjustments factor into the determination of the imputed underpayment (as described in paragraph (b)(2) of this section), the tax rate that is applied in calculating the imputed underpayment (as described in paragraph (b)(3) of this section), and the number and composition of imputed underpayments, including the placement of adjustments in groupings and subgroupings (if applicable) (as described in paragraph (b)(4) of this section), as well as to the extent of other modifications allowed under rules provided in forms, instructions, or other guidance prescribed by the IRS (as described in paragraph (b)(5) of this section). If a partnership requests more than one modification under this section, modifications are taken into account in the following order:

(i) Modifications that affect the extent to which an adjustment factors into the determination of the imputed underpayment under paragraph (b)(2) of this section;

(ii) Modification of the number and composition of imputed underpayments under paragraph (b)(4) of this section;

(iii) Modifications that affect the tax rate under paragraph (b)(3) of this section.

(2) *Modifications that affect partnership adjustments for purposes of determining the imputed underpayment.* If the IRS approves modification with respect to a partnership adjustment, such partnership adjustment is excluded from the determination of the imputed underpayment as determined under § 301.6225–1(b). This paragraph (b)(2) applies to modifications under—

(i) Paragraph (d)(2) of this section (amended returns and the alternative procedure to filing amended returns);

(ii) Paragraph (d)(3) of this section (tax exempt status);

(iii) Paragraph (d)(5) of this section (specified passive activity losses);

(iv) Paragraph (d)(7) of this section (qualified investment entities);

(v) Paragraph (d)(8) of this section (closing agreements), if applicable;

(vi) Paragraph (d)(9) of this section (tax treaty modifications), if applicable; and

(vii) Paragraph (d)(10) of this section (other modifications), if applicable.

(3) *Modifications that affect the tax rate*—(i) *In general.* If the IRS approves a modification with respect to the tax rate applied to a partnership adjustment, such modification results in a reduction in tax rate applied to the total netted partnership adjustment with respect to the partnership adjustments in accordance with this paragraph (b)(3). A modification of the tax rate does not affect how the partnership adjustment factors into the calculation of the total netted partnership adjustment. This paragraph (b)(3) applies to modifications under—

(A) Paragraph (d)(4) of this section (rate modification);

(B) Paragraph (d)(8) of this section (closing agreements), if applicable;

(C) Paragraph (d)(9) of this section (tax treaty modifications), if applicable; and

(D) Paragraph (d)(10) of this section (other modifications), if applicable.

(ii) *Determination of the imputed underpayment in the case of rate modification.* Except as described in paragraph (b)(3)(iv) of this section, in the case of an approved modification described under paragraph (b)(3)(i) of this section, the imputed underpayment is the sum of the total netted partnership adjustment consisting of the net positive adjustments not subject to rate reduction under paragraph (b)(3)(i) of this section (taking into account any approved modifications under paragraph (b)(2) of the section), plus the *rate-modified netted partnership adjustment* determined under paragraph (b)(3)(iii) of this section, reduced or increased by any adjustments to credits (taking into account any modifications under paragraph (b)(4) of this section). The total netted partnership adjustment not subject to rate reduction under paragraph (b)(3)(i) of this section (taking into account any approved modifications under paragraph (b)(2) of the section) is determined by multiplying the partnership adjustments included in the total netted partnership adjustment that are not subject to rate modification under paragraph (b)(3)(i) of this section (including any partnership adjustment that remains after applying paragraph (b)(3)(iii) of this section) by the highest tax rate (as described in § 301.6225–1(b)(1)(iv)).

(iii) *Calculation of rate-modified netted partnership adjustment in the case of a rate modification.* The *rate-modified netted partnership adjustment* is determined as follows—

(A) Determine each relevant partner's distributive share of the partnership adjustments subject to an approved modification under paragraph (b)(3)(i) of this section based on how each adjustment subject to rate modification would be properly allocated under section 702 to such relevant partner in the reviewed year (as defined in § 301.6241–1(a)(8)).

(B) Multiply each partnership adjustment determined under paragraph (b)(3)(iii)(A) of this section by the tax rate applicable to such adjustment based on the approved modification described under paragraph (b)(3)(i) of this section.

(C) Add all of the amounts calculated under paragraph (b)(3)(iii)(B) of this section with respect to each partnership adjustment subject to an approved modification described under paragraph (b)(3)(i) of this section.

(iv) *Rate modification in the case of special allocations.* If an imputed underpayment results from adjustments to more than one partnership-related item and any relevant partner for whom modification described under paragraph (b)(3)(i) of this section is approved has a distributive share of such items that is not the same with respect to all such items, the imputed underpayment as modified based on the modification types described under paragraph (b)(3)(i) of this section is determined as described in paragraphs (b)(3)(ii) and (iii) of this section except that each relevant partner's distributive share is

determined based on the amount of net gain or loss to the partner that would have resulted if the partnership had sold all of its assets at their fair market value as of the close of the reviewed year appropriately adjusted to reflect any approved modification under paragraphs (d)(2) and (3) and (d)(5) through (10) of this section with respect to any relevant partner. Upon request by the IRS, the partnership may be required to provide the relevant partners' capital account calculation through the end of the reviewed year, a calculation of asset liquidation gain or loss, and any other information necessary to determine whether rate modification is appropriate, consistent with the rules of paragraph (c)(2) of this section.

(4) *Modification of the number and composition of imputed underpayments.* Once approved by the IRS, a modification under paragraph (d)(6) of this section affects the manner in which adjustments are placed into groupings and subgroupings (as described in § 301.6225–1(c) and (d)) or whether the IRS designates one or more specific imputed underpayments (as described in § 301.6225–1(g)). If the IRS approves a request for modification under this paragraph (b)(4), the imputed underpayment and any specific imputed underpayment affected by or resulting from the modification is determined according to the rules of § 301.6225–1 subject to any other modifications approved by the IRS under this section.

(5) *Other modifications.* The effect of other modifications described in paragraph (d)(10) of this section, including the order that such modification will be taken into account for purposes of paragraph (b)(1) of this section, may be set forth in forms, instructions, or other guidance prescribed by the IRS.

(c) *Time, form, and manner for requesting modification*—(1) *In general.* In addition to the requirements described in paragraph (d) of this section, a request for modification under this section must be submitted in accordance with, and include the information required by, the forms, instructions, and other guidance prescribed by the IRS. The partnership representative must submit any request for modification and all relevant information (including information required under paragraphs (c)(2) and paragraph (d) of this section) to the IRS within the time described in paragraph (c)(3) of this section. The IRS will notify the partnership representative in writing of the approval or denial, in whole or in part, of any request for modification. A request for modification, including a request by the IRS for information related to a request for modification, and the determination by the IRS to approve or not approve all or a portion of a request for modification, is part of the administrative proceeding with respect to the partnership under subchapter C of chapter 63 and does not constitute an examination, inspection, or other administrative proceeding with respect to any other person for purposes of section 7605(b).

(2) *Partnership must substantiate facts supporting a request for modification*—(i) *In general.* A partnership requesting modification under this section must substantiate the facts supporting such a request to the satisfaction of the IRS. The documents and other information necessary to substantiate a particular request for modification are based on the facts and circumstances of each request, as well as the type of modification requested under paragraph (d) of this section, and may include tax returns, partnership operating documents, certifications in the form and manner required with respect to the particular modification, and any other information necessary to support the requested modification. The IRS may, in forms, instructions, or other guidance, set forth procedures with respect to information and documents supporting the modification, including procedures to require particular documents or other information to substantiate a particular type of modification, the manner for submitting documents and other information to the IRS, and recordkeeping requirements. The IRS will deny a request for modification if a partnership fails to provide information the IRS determines is necessary to substantiate a request for modification within the time restrictions described in paragraph (c) of this section.

(ii) *Information to be furnished for any modification request.* In the case of any modification request, the partnership representative must furnish to the IRS a detailed description of the partnership's structure, allocations, ownership, and ownership changes, its relevant partners for each taxable year relevant to the request for modification, as well as the partnership agreement as defined in § 1.704–1(b)(2)(ii)(h) of this chapter for each taxable year relevant to the modification request. In the case of any modification request with respect to a relevant partner that is an indirect partner, the partnership representative must provide to the IRS any information that the IRS may require relevant to any pass-through partner through which the relevant partner holds its interest in the partnership. For instance, if the partnership requests modification with respect to an amended return filed by a relevant partner pursuant to paragraph (d)(2) of this section, the partnership representative may be required to provide to the IRS information that would have been required to have been filed by pass-through partners through which the relevant partner holds its interest in the partnership as if those pass-through partners had also filed their own amended returns.

(3) *Time for submitting modification request and information*—(i) *Modification request.* Unless the IRS grants an extension of time, all information required under this section with respect to a request for modification must be submitted to the IRS in the form and manner prescribed by the IRS on or before 270 days after the date the NOPPA is mailed.

(ii) *Extension of the 270-day period.* The IRS may, in its discretion, grant a request for extension of the 270-day period described in paragraph (c)(3)(i) of this section provided the partnership submits such request to the IRS, in the form and manner prescribed by forms, instructions, or other guidance, before expiration of such period, as extended by any prior extension granted under this paragraph (c)(3)(ii).

(iii) *Expiration of the 270-day period by agreement.* The 270-day period described in paragraph (c)(3)(i) of this section (including any extensions under paragraph (c)(3)(ii) of this section) expires as of the date the partnership and the IRS agree, in writing, to waive the 270-day period after the mailing of the NOPPA and before the IRS may issue a notice of final partnership adjustment. See section 6231(b)(2)(A); § 301.6231–1(b)(2).

(4) *Approval of modification by the IRS.* Notification of approval will be provided to the partnership only after receipt of all relevant information (including any supplemental information required by the IRS) and all necessary payments with respect to the particular modification requested before expiration of the 270-day period in paragraph (c)(3)(i) of this section plus any extension granted by the IRS under paragraph (c)(3)(ii) of this section.

(d) *Types of modification*—(1) *In general.* Except as otherwise described in this section, a partnership may request one type of modification or more than one type of modification described in paragraph (d) of this section.

(2) *Amended returns by partners*—(i) *In general.* A partnership may request a modification of an imputed underpayment based on an amended return filed by a relevant partner provided all of the partnership

adjustments properly allocable to such relevant partner are taken into account and any amount due is paid in accordance with this paragraph (d)(2) of this section. Only adjustments to partnership-related items or adjustments to a relevant partner's tax attributes affected by adjustments to partnership-related items may be taken into account on an amended return under paragraph (d)(2) of this section. A partnership may request a modification for purposes of this paragraph (d)(2) by submitting a modification request based on the alternative procedure to filing amended returns as described in paragraph (d)(2)(x) of this section. The partnership may not request an additional modification of any imputed underpayment for a partnership taxable year under this section with respect to any relevant partner that files an amended return (or utilizes the alternative procedure to filing amended returns) under paragraph (d)(2) of this section or with respect to any partnership adjustment allocated to such relevant partner.

(ii) *Requirements for approval of a modification request based on amended return.* Except as otherwise provided under alternative procedures described in paragraph (d)(2)(x) of this section, an amended return modification request under this paragraph (d)(2) will not be approved unless the provisions of this paragraph (d)(2)(ii) are satisfied.

(A) *Full payment required.* An amended return modification request under paragraph (d)(2) of this section will not be approved unless the relevant partner filing the amended return has paid all tax, penalties, additions to tax, additional amounts, and interest due as a result of taking into account the adjustments in the first affected year (as defined in § 301.6226–3(b)(2)) and all modification years (as described in paragraph (d)(2)(ii)(B) of this section) at the time such return is filed with the IRS.

(B) *Amended returns for all relevant taxable years must be filed.* Modification under paragraph (d)(2) of this section will not be approved by the IRS unless a relevant partner files an amended return for the first affected year and any modification year. A *modification year* is any taxable year with respect to which any tax attribute (as defined in § 301.6241–1(a)(10)) of the relevant partner is affected by reason of taking into account the relevant partner's distributive share of all partnership adjustments in the first affected year. A modification year may be a taxable year before or after the first affected year, depending on the effect on the relevant partner's tax attributes of taking into account the relevant partner's distributive share of the partnership adjustments in the first affected year.

(C) *Amended returns for partnership adjustments that reallocate distributive shares.* Except as described in this paragraph (d)(2)(ii)(C), in the case of a partnership adjustment that reallocates the distributive share of any partnership-related item from one partner to another, a modification under paragraph (d)(2) of this section will be approved only if all partners affected by such adjustment file amended returns in accordance with paragraph (d)(2) of this section and all such returns are approved by the IRS for modification purposes. The IRS may determine that the requirements of this paragraph (d)(2)(ii)(C) are satisfied even if not all relevant partners affected by such adjustment file amended returns provided the remaining relevant partners affected by the reallocation take into account their distributive share of the adjustment through other modifications approved by the IRS (including the alternative procedures to filing amended returns under paragraph (d)(2)(x) of this section) or if a pass-through partner takes into account the relevant adjustments in accordance with paragraph (d)(2)(vi) of this section. For instance, in the case of an adjustment that reallocates a loss from one partner to another, the IRS may determine that the requirements of this paragraph (d)(2)(ii)(C) have been satisfied if one affected relevant partner files an amended return taking into account the adjustment and the other affected relevant partner signs a closing agreement with the IRS taking into account the adjustments.

(iii) *Form and manner for filing amended returns.* A relevant partner must file all amended returns required for modification under paragraph (d)(2) of this section with the IRS in accordance with forms, instructions, and other guidance prescribed by the IRS. Except as otherwise provided under alternative procedures described in paragraph (d)(2)(x) of this section, the IRS will not approve modification under paragraph (d)(2) of this section unless prior to the expiration of the 270-day period described in paragraph (c)(3) of this section, the partnership representative provides to the IRS, in the form and manner prescribed by the IRS, an affidavit from each relevant partner signed under penalties of perjury by such partner stating that all of the amended returns required to be filed under paragraph (d)(2) of this section has been filed (including the date on which such amended returns were filed) and that the full amount of tax, penalties, additions to tax, additional amounts, and interest was paid (including the date on which such amounts were paid).

(iv) *Period of limitations.* Generally, the period of limitations under sections 6501 and 6511 do not apply to an amended return filed under this paragraph (d)(2) provided the amended return otherwise meets the requirements of paragraph (d)(2) of this section.

(v) *Amended returns in the case of adjustments allocated through certain pass-through partners.* A request for modification related to an amended return of a relevant partner that is an indirect partner holding its interest in the partnership through a pass-through partner that could be subject to tax under chapter 1 on the partnership adjustments that are properly allocated to such pass-through partner will not be approved unless the partnership—

(A) Establishes that the pass-through partner is not subject to chapter 1 tax on the adjustments that are properly allocated to such pass-through partner; or

(B) Requests modification with respect to the adjustments resulting in chapter 1 tax for the pass-through partner, including full payment of such chapter 1 tax for the first affected year and all modification years under paragraph (d)(2) of this section or in accordance with forms, instructions, or other guidance prescribed by the IRS.

(vi) *Amended returns in the case of pass-through partners*—(A) *Pass-through partners may file amended returns.* A relevant partner that is a pass-through partner, including a partnership-partner (as defined in § 301.6241–1(a)(7)) that has a valid election under section 6221(b) in effect for a partnership taxable year, may, in accordance with forms, instructions, and other guidance provided by the IRS and solely for purposes of modification under paragraph (d)(2) of this section, take into account its share of the partnership adjustments and determine and pay an amount calculated in the same manner as the amount computed under § 301.6226–3(e)(4)(iii) subject to paragraph (d)(2)(vi)(B) of this section.

(B) *Modifications with respect to upper-tier partners of the pass-through partner.* In accordance with forms, instructions, and other guidance provided by the IRS, for purposes of determining and calculating the amount a pass-through partner must pay under paragraph (d)(2)(vi)(A) of this section, the pass-through partner may take into account modifications with respect to its direct and indirect partners to the extent that such modifications are

requested by the partnership requesting modification and approved by the IRS under this section.

(vii) *Limitations on amended returns*—(A) *In general.* A relevant partner may not file an amended return with respect to partnership adjustments or with respect to an imputed underpayment except as described in paragraph (d)(2) of this section.

(B) *Further amended returns restricted.* If a relevant partner files an amended return under paragraph (d)(2) of this section, such partner may not file a subsequent amended return without the permission of the IRS.

(viii) *Penalties.* The applicability of any penalties, additions to tax, or additional amounts that relate to an adjustment to a partnership-related item is determined at the partnership level in accordance with section 6221(a). However, the amount of penalties, additions to tax, and additional amounts a relevant partner must pay under paragraph (d)(2)(ii)(A) of this section for the first affected year and for any modification year is based on the underpayment or understatement of tax, if any, reflected on the amended return filed by the relevant partner under this paragraph (d)(2). For instance, if after taking into account the adjustments, the return of the relevant partner for the first affected year or any modification year reflects an underpayment or an understatement that falls below the applicable threshold for the imposition of a penalty under section 6662(d), no penalty would be due from that relevant partner for such year. A relevant partner may raise a partner-level defense (as described in § 301.6226–3(d)(3)) by first paying the penalty, addition to tax, or additional amount with the amended return filed under this paragraph (d)(2) and then filing a claim for refund in accordance with forms, instructions, and other guidance.

(ix) *Effect on tax attributes binding.* Any adjustments to the tax attributes of any relevant partner which are affected by modification under paragraph (d)(2) of this section are binding on the relevant partner with respect to the first affected year and all modification years (as defined in paragraph (d)(2)(ii)(B) of this section). A failure to adjust any tax attribute in accordance with this paragraph (d)(2)(ix) is a failure to treat a partnership-related item in a manner which is consistent with the treatment of such item on the partnership return within the meaning of section 6222. The provisions of section 6222(c) and § 301.6222–1(c) (regarding notification of inconsistent treatment) do not apply with respect to tax attributes under this paragraph (d)(2)(ix).

(x) *Alternative procedure to filing amended returns*—(A) *In general.* A partnership may satisfy the requirements of paragraph (d)(2) of this section by submitting on behalf of a relevant partner, in accordance with forms, instructions, and other guidance provided by the IRS, all information and payment of any tax, penalties, additions to tax, additional amounts, and interest that would be required to be provided if the relevant partner were filing an amended return under paragraph (d)(2) of this section, except as otherwise provided in relevant forms, instructions, and other guidance provided by the IRS. A relevant partner for which the partnership seeks modification under this paragraph (d)(2)(x) must agree to take into account, in accordance with forms, instructions, and other guidance provided by the IRS, adjustments to any tax attributes of such relevant partner. A modification request submitted in accordance with the alternative procedure under this paragraph (d)(2)(x) is not a claim for refund with respect to any person.

(B) *Modifications with respect to reallocation adjustments.* A submission made in accordance with this paragraph (d)(2)(x) with respect to any relevant partner is treated as if such relevant partner filed an amended return for purposes of paragraph (d)(2)(ii)(C) of this section (regarding the requirement that all relevant partners affected by a reallocation must file an amended return to be eligible to for the modification under paragraph (d)(2) of this section) provided the submission is with respect to the first affected year and all modification years of such relevant partner as required under paragraph (d)(2) of this section.

(3) *Tax-exempt partners*—(i) *In general.* A partnership may request modification of an imputed underpayment with respect to partnership adjustments that the partnership demonstrates to the satisfaction of the IRS are allocable to a relevant partner that would not owe tax by reason of its status as a tax-exempt entity (as defined in paragraph (d)(3)(ii) of this section) in the reviewed year (tax-exempt partner).

(ii) *Definition of tax-exempt entity.* For purposes of paragraph (d)(3) of this section, the term *tax-exempt entity* means a person or entity defined in section 168(h)(2)(A), (C), or (D).

(iii) *Modification limited to portion of partnership adjustments for which tax-exempt partner not subject to tax.* Only the portion of the partnership adjustments properly allocated to a tax-exempt partner with respect to which the partner would not be subject to tax for the reviewed year (tax-exempt portion) may form the basis of a modification of the imputed underpayment under paragraph (d)(3) of this section. A modification under paragraph (d)(3) of this section will not be approved by the IRS unless the partnership provides documentation in accordance with paragraph (c)(2) of this section to support the tax-exempt partner's status and the tax-exempt portion of the partnership adjustment allocable to the tax-exempt partner.

(4) *Modification based on a rate of tax lower than the highest applicable tax rate.* A partnership may request modification based on a lower rate of tax for the reviewed year with respect to adjustments that are attributable to a relevant partner that is a C corporation and adjustments with respect to capital gains or qualified dividends that are attributable to a relevant partner who is an individual. In no event may the lower rate determined under the preceding sentence be less than the highest rate in effect for the reviewed year with respect to the type of income and taxpayer. For instance, with respect to adjustments that are attributable to a C corporation, the highest rate in effect for the reviewed year with respect to all C corporations would apply to that adjustment, regardless of the rate that would apply to the C corporation based on the amount of that C corporation's taxable income. For purposes of this paragraph (d)(4), an S corporation is treated as an individual.

(5) *Certain passive losses of publicly traded partnerships*—(i) *In general.* In the case of a publicly traded partnership (as defined in section 469(k)(2)) that is a relevant partner, the imputed underpayment is determined without regard to the adjustment that the partnership demonstrates would be reduced by a specified passive activity loss (as defined in paragraph (d)(5)(ii) of this section) which is allocable to a specified partner (as defined in paragraph (d)(5)(iii) of this section) or qualified relevant partner (as defined in paragraph (d)(5)(iv) of this section).

(ii) *Specified passive activity loss.* A specified passive activity loss carryover amount for any specified partner or qualified relevant partner of a publicly traded partnership is the lesser of the section 469(k) passive activity loss of that partner which is separately determined with respect to such partnership—

(A) At the end of the first affected year (affected year loss); or

(B) At the end of either—

(*1*) The specified partner's taxable year in which or with which the adjustment year (as defined in

§ 301.6241–1(a)(1)) of the partnership ends, reduced to the extent any such partner has utilized any portion of its affected year loss to offset income or gain relating to the ownership or disposition of its interest in such publicly traded partnership during either the adjustment year or any other year; or

(*2*) The most recent year for which the publicly traded partnership has filed a return under section 6031.

(iii) *Specified partner.* A specified partner is a person that for each taxable year beginning with the first affected year through the person's taxable year in which or with which the partnership adjustment year ends satisfies the following three requirements—

(A) The person is a partner of a publicly traded partnership;

(B) The person is an individual, estate, trust, closely held C corporation, or personal service corporation; and

(C) The person has a specified passive activity loss with respect to the publicly traded partnership.

(iv) *Qualified relevant partner.* A qualified relevant partner is a relevant partner that meets the three requirements to be a specified partner (as described in paragraphs (d)(5)(iii)(A), (B), and (C) of this section) for each year beginning with the first affected year through described in paragraph (d)(5)(ii)(*B*)(*2*) of this section.

(v) *Partner notification requirement to reduce passive losses.* If the IRS approves a modification request under paragraph (d)(5) of this section, the partnership must report, in accordance with forms, instructions, or other guidance prescribed by the IRS, to each specified partner the amount of that specified partner's reduction of its suspended passive loss carryovers at the end of the adjustment year to take into account the amount of any passive losses applied in connection with such modification request. In the case of a qualified relevant partner, the partnership must report, in accordance with forms, instructions, or other guidance prescribed by the IRS, to each qualified relevant partner the amount of that qualified relevant partner's reduction of its suspended passive loss carryovers at the end of the taxable year for which the partnership's next return is due to be filed under section 6031 to be taken into account by the qualified relevant partner on the partner's return for the year that includes the end of the partnership's taxable year for which the partnership's next return is due to be filed under section 6031. The reduction in suspended passive loss carryovers as reported to a specified partner under this paragraph (d)(5)(v) is a determination of the partnership under subchapter C of chapter 63 and is binding on the specified partners under section 6223 and the regulations thereunder.

(6) *Modification of the number and composition of imputed underpayments*—(i) *In general.* A partnership may request modification of the number or composition of any imputed underpayment included in the NOPPA by requesting that the IRS include one or more partnership adjustments in a particular grouping or subgrouping (as described in § 301.6225–1(c) and (d)) or specific imputed underpayments (as described in § 301.6225–1(g)) different from the grouping, subgrouping, or imputed underpayment set forth in the NOPPA. For example, a partnership may request under this paragraph (d)(6) that one or more partnership adjustments taken into account to determine a general imputed underpayment set forth in the NOPPA be taken into account to determine a specific imputed underpayment.

(ii) *Request for particular treatment regarding limitations or restrictions.* A modification request under paragraph (d)(6) of this section includes a request that one or more partnership adjustments be treated as if no limitations or restrictions under § 301.6225–1(d) apply and as a result such adjustments may be subgrouped with other adjustments.

(7) *Partnerships with partners that are ''qualified investment entities'' described in section 860*–(i) *In general.* A partnership may request a modification of an imputed underpayment based on the partnership adjustments allocated to a relevant partner where the modification is based on deficiency dividends distributed as described in section 860(f) by a relevant partner that is a qualified investment entity (QIE) under section 860(b) (which includes both a regulated investment company (RIC) and a real estate investment trust (REIT)). Modification under this paragraph (d)(7) is available only to the extent that the deficiency dividends take into account adjustments described in § 301.6225–1 that are also adjustments within the meaning of section 860(d)(1) or (d)(2) (whichever applies).

(ii) *Documentation of deficiency dividend.* The partnership must provide documentation in accordance with paragraph (c) of this section of the ''determination'' described in section 860(e). Under section 860(e)(2), § 1.860–2(b)(1)(i) of this chapter, and paragraph (d)(8) of this section, a closing agreement entered into by the QIE partner pursuant to section 7121 and paragraph (d)(8) of this section is a determination described in section 860(e), and the date of the determination is the date in which the closing agreement is approved by the IRS. In addition, under section 860(e)(4), a determination also includes a Form 8927, *Determination Under Section 860(e)(4) by a Qualified Investment Entity,* properly completed and filed by the RIC or REIT pursuant to section 860(e)(4). To establish the date of the determination under section 860(e)(4) and the amount of deficiency dividends actually paid, the partnership must provide a copy of Form 976, *Claim for Deficiency Dividends Deductions by a Personal Holding Company, Regulated Investment Company, or Real Estate Investment Trust* (Form 976), properly completed by or on behalf of the QIE pursuant to section 860(g), together with a copy of each of the required attachments for Form 976.

(8) *Closing agreements.* A partnership may request modification based on a closing agreement entered into by the IRS and the partnership or any relevant partner, or both if appropriate, pursuant to section 7121. If modification under this paragraph (d)(8) is approved by the IRS, any partnership adjustment that is taken into account under such closing agreement and for which any required payment under the closing agreement is made will not be taken into account in determining the imputed underpayment under § 301.6225–1. Generally, the IRS will not approve any additional modification under this section with respect to a relevant partner to which a modification under this paragraph (d)(8) has been approved.

(9) *Tax treaty modifications.* A partnership may request a modification under this paragraph (d)(9) with respect to a relevant partner's distributive share of an adjustment to a partnership-related item if the relevant partner—

(i) Was a foreign person who would have qualified, under an income tax treaty with the United States, for a reduction or exemption from tax with respect to such partnership-related item in the reviewed year;

(ii) Would have derived the item (within the meaning of § 1.894–1(d) of this chapter) had it been taken into account properly in the partnership's reviewed year return; and

(iii) Is not otherwise prevented under the income tax treaty with the United States from claiming such reduction or exemption with respect to the reviewed year at the time the modification under this paragraph (d)(9) is requested.

(10) *Other modifications.* A partnership may request a modification not otherwise described in paragraph (d)

of this section, and the IRS will determine whether such modification is accurate and appropriate in accordance with paragraph (c)(4) of this section. Additional types of modifications and the documentation necessary to substantiate such modifications may be set forth in forms, instructions, or other guidance prescribed by the IRS.

(e) *Modification of adjustments that do not result in an imputed underpayment.* A partnership may request modification of adjustments that do not result in an imputed underpayment (as described in § 301.6225–1(f)(1)(ii)) using modifications described in paragraph (d)(2) of this section (amended returns and the alternative procedure to filing amended returns), paragraph (d)(6) of this section (number and composition of the imputed underpayment), paragraph (d)(8) of this section (closing agreements), or, if applicable, paragraph (d)(10) of this section (other modifications).

(f) *Examples.* The following examples illustrate the rules of this section. For purposes of these examples, each partnership is subject to the provisions of subchapter C of chapter 63, each partnership and its relevant partners are calendar year taxpayers, all relevant partners are U.S. persons (unless otherwise stated), the highest rate of income tax in effect for all taxpayers is 40 percent for all relevant periods, and no partnership requests modification under this section except as provided in the example.

Example 1. Partnership has two partners during its 2019 partnership taxable year: P and S. P is a partnership, and S is an S Corporation. P has four partners during its 2019 partnership taxable year: A, C, T and DE. A is an individual, C is a C Corporation, T is a trust, and DE is a wholly-owned entity disregarded as separate from its owner for Federal tax purposes. The owner of DE is B, an individual. T has two beneficiaries during its 2019 taxable year: F and G, both individuals. S has 3 shareholders during its 2019 taxable year: H, I, and J, all individuals. For purposes of this section, if Partnership requests modification with respect to A, B, C, F, G, H, I, and J, those persons are all relevant partners (as defined in paragraph (a) of this section). P, S, and DE are not relevant partners (as defined in paragraph (a) of this section) because DE is a wholly-owned entity disregarded as separate from its owner for Federal tax purposes and modification was not requested with respect to P and S.

Example 2. The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year. The IRS mails a NOPPA to Partnership for the 2019 partnership taxable year proposing a single partnership adjustment increasing ordinary income by $100, resulting in a $40 imputed underpayment ($100 multiplied by the 40 percent tax rate). Partner A, an individual, held a 20 percent interest in Partnership during 2019. Partnership timely requests modification under paragraph (d)(2) of this section based on A's filing an amended return for the 2019 taxable year taking into account $20 of the partnership adjustment and paying the tax and interest due attributable to A's share of the increased income and the tax rate applicable to A for the 2019 tax year. No tax attribute in any other taxable year of A is affected by A's taking into account A's share of the partnership adjustment for 2019. In accordance with paragraph (d)(2)(iii) of this section, Partnership's partnership representative provides the IRS with documentation demonstrating that A filed the 2019 return and paid all tax and interest due. The IRS approves the modification and, in accordance with paragraph (b)(2) of this section, the $20 increase in ordinary income allocable to A is not included in the calculation of the total netted partnership adjustment (determined in accordance with § 301.6225–1). Partnership's total netted partnership adjustment is reduced to $80 ($100 adjustment less $20 taken into account by A), and the imputed underpayment is reduced to $32 (total netted partnership adjustment of $80 after modification multiplied by 40 percent).

Example 3. The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year. Partnership has two equal partners during its entire 2019 taxable year: An individual, A, and a partnership-partner, B. During all of 2019, B has two equal partners: A tax-exempt entity, C, and an individual, D. The IRS mails a NOPPA to Partnership for its 2019 taxable year proposing a single partnership adjustment increasing Partnership's ordinary income by $100, resulting in a $40 imputed underpayment ($100 total netted partnership adjustment multiplied by 40 percent). Partnership timely requests modification under paragraph (d)(3) of this section with respect to B's partner, C, a tax-exempt entity. In accordance with paragraph (d)(3)(iii) of this section, Partnership's partnership representative provides the IRS with documentation substantiating to the IRS's satisfaction that C held a 25 percent indirect interest in Partnership through its interest in B during the 2019 taxable year, that C was a tax-exempt entity defined in paragraph (d)(3)(ii) of this section during the 2019 taxable year, and that C was not subject to tax with respect to its entire distributive share of the partnership adjustment allocated to B (which is $25 (50 percent × 50 percent × $100)). The IRS approves the modification and, in accordance with paragraph (b)(2) of this section, the $25 increase in ordinary income allocated to C, through B, is not included in the calculation of the total netted partnership adjustment (determined in accordance with § 301.6225–1). Partnership's total netted partnership adjustment is reduced to $75 ($100 adjustment less C's share of the adjustment, $25), and the imputed underpayment is reduced to $30 (total netted partnership adjustment of $75, after modification, multiplied by 40 percent).

Example 4. The facts are the same as in *Example 3* of this paragraph (f), except $10 of the $25 of the adjustment allocated to C is unrelated business taxable income (UBTI) as defined in section 512 because it is debt-financed income within the meaning of section 514 (no section 512 UBTI modifications apply) with respect to which C would be subject to tax if taken into account by C. As a result, the modification under paragraph (d)(3) of this section with respect to C relates only to $15 of the $25 of ordinary income allocated to C that is not UBTI. Therefore, only a modification of $15 ($25 less $10) of the total $100 partnership adjustment may be approved by the IRS under paragraph (d)(3) of this section and, in accordance with paragraph (b)(2) of this section, excluded when determining the imputed underpayment for Partnership's 2019 taxable year. The total netted partnership adjustment (determined in accordance with § 301.6225–1) is reduced to $85 ($100 less $15), and the imputed underpayment is reduced to $34 (total netted partnership adjustment of $85, after modification, multiplied by 40 percent).

Example 5. The facts are the same as in *Example 3* of this paragraph (f), except that Partnership also timely requests modification under paragraph (d)(2) with respect to an amended return filed by B, and, in accordance with (d)(2)(iii) of this section, Partnership's partnership representative provides the IRS with documentation demonstrating that B filed the 2019 return and paid all tax and interest due. B reports 50 percent of the partnership adjustments ($50) on its amended return, and B calculates an amount under paragraph (d)(2)(vi)(A) of this section and § 301.6226–3(e)(4)(iii) that, pursuant to paragraph (d)(2)(vi)(B) of this section, takes into account the modification under paragraph (d)(3) approved by the IRS with respect to B's partner C, a tax-exempt entity. B makes a payment pursuant to paragraph (d)(2)(ii)(A) of this section, and the IRS approves the requested modification. Partnership's total netted partnership adjustment is reduced by $50 (the amount taken into account by B). Partnership's total netted partnership adjustment (determined in accordance with § 301.6225–1) is $50, and the imputed underpayment, after modification, is $20.

Example 6. The facts are the same as in *Example 3* of this paragraph (f), except that in addition to the modification with respect to tax-exempt entity C, which reduced the imputed underpayment by excluding from the determination of the imputed underpayment $25 of the $100 partnership adjustment reflected in the NOPPA, Partnership timely requests modification under paragraph (d)(2) of this section with respect to an amended return filed by individual D, and, in accordance with (d)(2)(iii) of this section, Partnership's partnership representative provides the IRS with documentation demonstrating that D filed the 2019 return and paid all tax and interest due. D's amended return for D's 2019 taxable year takes into account D's share of the partnership adjustment (50 percent of B's 50 percent interest in Partnership, or $25) and D paid the tax and interest due as a result of taking into account D's share of the partnership adjustment in accordance with

paragraph (d)(2) of this section. No tax attribute in any other taxable year of D is affected by D taking into account D's share of the partnership adjustment for 2019. The IRS approves the modification and the $25 increase in ordinary income allocable to D is not included in the calculation of the total netted partnership adjustment (determined in accordance with § 301.6225–1). As a result, Partnership's total netted partnership adjustment is $50 ($100, less $25 allocable to C, less $25 taken into account by D), and the imputed underpayment, after modification, is $20.

Example 7. The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year. All of Partnership's partners during its 2019 taxable year are individuals. The IRS mails a NOPPA to Partnership for the 2019 taxable year proposing three partnership adjustments. The first partnership adjustment is an increase to ordinary income of $75 for 2019. The second partnership adjustment is an increase in the depreciation deduction allowed for 2019 of $25, which under § 301.6225–1(d)(2)(i) is treated as a $25 decrease in income. The third adjustment is an increase in long-term capital gain of $10 for 2019. In accordance with § 301.6225–1, the total netted partnership adjustment is $85 ($75 increase in ordinary income + $10 increase in long-term capital gain), resulting in an imputed underpayment of $34 ($85 multiplied by 40 percent). The $25 decrease in income as a result of the increase in depreciation is an adjustment that does not result in an imputed underpayment under § 301.6225–1(f). Under the partnership agreement in effect for Partnership's 2019 taxable year, the long-term capital gain and the increase in depreciation is specially allocated to B and the increase in ordinary income is specially allocated to A. Partnership requests a modification under paragraph (d)(6) of this section to determine a specific imputed underpayment with respect to the $75 adjustment to ordinary income allocated to A. The specific imputed underpayment is with respect to $75 of the increase in income specially allocated to A and the general imputed underpayment is with respect to $10 of the increase in capital gain and the $25 increase in depreciation deduction specially allocated to B. If the modification is approved by the IRS, the specific imputed underpayment is $30 ($75 multiplied by 40 percent), the general imputed underpayment is $4 ($10 multiplied by 40 percent), and the increase in depreciation of $25 remains an adjustment that does not result in an imputed underpayment under § 301.6225–1(f) and is associated with the general imputed underpayment.

Example 8. Partnership has two reviewed year partners, C1 and C2, both of which are C corporations. The IRS mails to Partnership a NOPPA with two adjustments, both based on rental real estate activity. The first adjustment is an increase of rental real estate income of $100 attributable to Property A. The second adjustment is an increase of rental real estate loss of $30 attributable to Property B. The Partnership did not treat the leasing arrangement with respect to Property A and Property B as an appropriate economic unit for purposes of section 469. If the $100 increase in income attributable to Property A and the $30 increase in loss attributable to Property B were included in the same subgrouping and netted, then taking the $30 increase in loss into account would result in a decrease in the amount of the imputed underpayment. Also, the $30 increased loss might be limited or restricted if taken into account by any person under the passive activity rules under section 469. For instance, under section 469, rental activities of the two properties could be treated as two activities, which could limit a partner's ability to claim the loss. In addition to the potential limitations under section 469, there are other potential limitations that might apply if the $30 loss were taken into account by any person. Therefore, in accordance with § 301.6225–1(d), the two adjustments are placed in separate subgroupings within the residual grouping, the total netted partnership adjustment is $100, the imputed underpayment is $40 ($100 × 40 percent), and the $30 increase in loss is an adjustment that does not result in an imputed underpayment under § 301.6225–1(f). Partnership requests modification under paragraph (d)(6) of this section, substantiating to the satisfaction of the IRS that C1 and C2 are publicly traded C corporations, and therefore, the passive activity loss limitations under section 469 of the Code do not apply. Partnership also substantiates to the satisfaction of the IRS that no other limitation or restriction applies that would prevent the grouping of the $100 with the $30 loss. The IRS approves Partnership's modification request and places the $100 of income and the $30 loss into the subgrouping in the residual grouping under the rules described in § 301.6225–1(c)(5). Under § 301.6225–1(e), because the two adjustments are in one subgrouping, they are netted together, resulting in a total netted partnership adjustment of $70 ($100 plus <$30>) and an imputed underpayment of $28 ($70 × 40 percent). After modification, there are not adjustments treated as an adjustment that does not result in an imputed underpayment under § 301.6225–1(f) because the $30 loss is now netted with the $100 of income.

(g) *Applicability date*—(1) *In general.* Except as provided in paragraph (g)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015, and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 10.** Section 301.6225–3 is added to read as follows:

§ 301.6225–3 Treatment of partnership adjustments that do not result in an imputed underpayment.

(a) *In general.* Partnership adjustments (as defined in § 301.6241–1(a)(6)) that do not result in an imputed underpayment (as described in § 301.6225–1(f)) are taken into account by a partnership in the adjustment year (as defined in § 301.6241–1(a)(1)) in accordance with paragraph (b) of this section.

(b) *Treatment of adjustments by the partnership*—(1) *In general.* Except as described in paragraphs (b)(2) through (5) of this section, a partnership adjustment that does not result in an imputed underpayment is taken into account as a reduction in non-separately stated income or as an increase in non-separately stated loss for the adjustment year depending on whether the adjustment is to a partnership-related item that is an item of income or loss.

(2) *Separately stated items.* In the case of a partnership adjustment to partnership-related item that is required to be separately stated under section 702, the adjustment is taken into account by the partnership in the adjustment year as a reduction in such separately stated item or as an increase in such separately stated item depending on whether the adjustment is a reduction or an increase to the separately stated item.

(3) *Credits.* In the case of an adjustment to a partnership-related item that is reported or could be reported by a partnership as a credit on the partnership's return for the reviewed year (as defined in § 301.6241–1(a)(8)), the adjustment is taken into account by the partnership in the adjustment year as a separately stated item.

(4) *Reallocation adjustments.* A partnership adjustment that reallocates a partnership-related item to or from a particular partner or partners that also does not result in an imputed underpayment pursuant to § 301.6225–1(f) is taken into account by the partnership in the adjustment year as a separately stated item or a non-separately stated item, as required by section 702. The portion of an adjustment allocated under this paragraph (b)(4) is allocated to adjustment year partners (as defined in § 301.6241–1(a)(2)) who are also reviewed year partners (as defined in § 301.6241–1(a)(9)) with respect to whom the amount was reallocated.

(5) *Adjustments taken into account by partners as part of the modification process.* If, as part of modification under § 301.6225–2, a relevant partner (as defined in § 301.6225–2(a)) takes into account a partnership adjustment that would not result in an imputed underpayment, and the IRS approves the modification, such partnership adjustment is not taken into account by the partnership in the adjustment year in accordance with § 301.6225–1(a).

(6) *Effect of election under section 6226.* If a partnership makes a valid election under § 301.6226–1 with respect to an imputed underpayment, a partnership adjustment that does not result in an imputed underpayment and that is associated with such imputed underpayment as described in § 301.6225–1(g) is taken into account by the reviewed year partners in accordance with § 301.6226–3 and is not taken into account under this section.

(c) *Treatment of adjustment year partners.* The rules under subchapter K with respect to the treatment of partners apply in the case of adjustments taken into account by the partnership under this section.

(d) *Applicability date*—(1) *In general.* Except as provided in paragraph (d)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 11.** Section 301.6225–4 is added to read as follows:

§ 301.6225–4 Effect of a partnership adjustment on specified tax attributes of partnerships and their partners.

(a) *Adjustments to specified tax attributes*—(1) *In general.* When there is a partnership adjustment (as defined in § 301.6241–1(a)(6)), the partnership and its adjustment year partners (as defined in § 301.6241–1(a)(2)) generally must adjust their specified tax attributes (as defined in paragraph (a)(2) of this section) in accordance with the rules in this section. For a partnership adjustment that results in an imputed underpayment (as defined in § 301.6241–1(a)(3)), specified tax attributes are generally adjusted by making appropriate adjustments to the book value and basis of partnership property under paragraph (b)(2) of this section, creating notional items based on the partnership adjustment under paragraph (b)(3) of this section, allocating those notional items as described in paragraph (b)(5) of this section, and determining the effect of those notional items for the partnership and its reviewed year partners (as defined in § 301.6241–1(a)(9)) or their successors (as defined in § 1.704–1(b)(1)(viii)(*b*) of this chapter) under paragraph (b)(6) of this section. Paragraph (c) of this section describes how to treat an expenditure for any payment required to be made by a partnership under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) including any imputed underpayment. Paragraph (d) of this section describes adjustments to tax attributes of a partnership and its partners in the case of a partnership adjustment that does not result in an imputed underpayment (as described in § 301.6225–1(f)).

(2) *Specified tax attributes.* Specified tax attributes are the tax basis and book value of a partnership's property, amounts determined under section 704(c), adjustment year partners' bases in their partnership interests, adjustment year partners' capital accounts determined and maintained in accordance with § 1.704–1(b)(2) of this chapter, and earnings and profits under section 312.

(3) *Timing.* Adjustments to specified tax attributes under this section are made in the adjustment year (as defined in § 301.6241–1(a)(1)). Thus, to the extent that an adjustment to a specified tax attribute under this section is reflected on a federal tax return, the partnership adjustment is generally first reflected on any return filed with respect to the adjustment year.

(4) *Effect of other sections.* The determination of specified tax attributes under this section is not conclusive as to tax attributes of a partnership or its partners determined under other sections of the Internal Revenue Code (Code), including the subchapter C of chapter 63. For example, a partnership that files an administrative adjustment request (AAR) under section 6227 adjusts partnership tax attributes as appropriate. Further, to the extent a partner or partnership appropriately adjusted its tax attributes prior to a final determination under subchapter C of chapter 63 with respect to a partnership adjustment (for example, in the context of an amended return modification described in § 301.6225–2(d)(2), the alternative procedure to filing amended returns as described in § 301.6225–2(d)(2)(x), or a closing agreement described in § 301.6225–2(d)(8)), those tax attributes are not adjusted under this section. Similarly, to the extent a partner filed a return inconsistent with the treatment of items on a partnership return, a reviewed year partner (or its successor) does not adjust its tax attributes to the extent the partner's prior return was consistent with the partnership adjustment. For the rules regarding consistent treatment by partners, see § 301.6222–1.

(5) *Election under section 6226*—(i) *In general.* Except as otherwise provided in paragraph (a)(5)(ii) of this section, tax attributes of a partnership and its partners are adjusted for a partnership adjustment that results in an imputed underpayment with respect to which an election is made under § 301.6226–1 in accordance with § 301.6226–4, and not the rules of this section.

(ii) *Pass-through partners and indirect partners.* A pass-through partner (as defined in § 301.6241–1(a)(5)) that is a partnership and pays an imputed underpayment under § 301.6226–3(e)(4) treats its share of each partnership adjustment reflected on the relevant statement as a partnership adjustment described in paragraph (a)(1) of this section, treats the imputed underpayment under § 301.6226–3(e)(4)(iii) as an imputed underpayment determined under § 301.6225–1 for purposes of § 1.704–1(b)(2)(iii)(*a*) and (*f*) of this chapter, treats items arising from an adjustment that does not result in an imputed underpayment as an item under paragraph (d) of this section, and finally treats amounts with respect to any penalties, additions to tax, and additional amounts and interest computed as an amount described in § 1.704–1(b)(2)(iii)(*f*)(*3*) of this chapter.

(6) *Reflection of economic arrangement.* This section and the rules in § 1.704–1(b)(1)(viii), (b)(2)(iii)(*a*) and (*f*), (b)(2)(iv)(*i*)(*4*), and (b)(4)(xi), (xii), (xiii), (xiv), and (xv) of this chapter must be interpreted in a manner that reflects the economic arrangement of the parties and the principles of subchapter K of the Code, taking into account the rules of the centralized partnership audit regime.

(b) *Adjusting specified tax attributes in the case of a partnership adjustment that results in an imputed underpayment*—(1) *In general.* This paragraph (b) applies with respect to each partnership adjustment that was taken into account in the determination of the imputed underpayment under § 301.6225–1, except to the extent partner or partnership tax attributes were already adjusted as part of the partnership adjustment.

(2) *Book value and basis of partnership property.* Partnership-level specified tax attributes must be adjusted under this paragraph (b)(2). Specifically, the partnership must make appropriate adjustments to the book value and basis of property to take into account any partnership adjustment. No adjustments are made with respect to property that was held by the partnership in the reviewed year but is no longer held by the partnership in the adjustment year. Amounts determined under section 704(c) must also be adjusted to take into account the partnership adjustment.

(3) *Creation of notional items based on partnership adjustment*—(i) *In general.* In order to give appropriate effect to each partnership adjustment for

partner-level specified tax attributes, notional items are created with respect to each partnership adjustment, except as provided in paragraph (b)(4) of this section.

(ii) *Increase in income or gain.* In the case of a partnership adjustment that is an increase to income or gain, a notional item of income or gain is created in an amount equal to the partnership adjustment.

(iii) *Increase in expense or loss.* In the case of a partnership adjustment that is an increase to an expense or a loss, a notional item of an expense or loss is created in an amount equal to the partnership adjustment.

(iv) *Decrease in income or gain.* In the case of a partnership adjustment that is a decrease to income or gain, a notional item of expense or loss is created in an amount equal to the partnership adjustment.

(v) *Decrease in expense or loss.* In the case of a partnership adjustment that is a decrease to an expense or to a loss, a notional item of income or gain is created in an amount equal to the partnership adjustment.

(vi) *Credits.* If a partnership adjustment reflects a net increase or net decrease in credits as determined in accordance with § 301.6225–1, the partnership may have one or more notional items of income, gain, loss, or deduction that reflects the change in the item that gives rise to the credit, and those items are treated as items in paragraph (b)(3)(ii), (iii), (iv), or (v) of this section. For example, if a partnership adjustment is to a credit, a notional item of deduction may be created when appropriate. See section 280C.

(4) *Situations in which notional items are not created*—(i) *In general.* In the case of a partnership adjustment described in this paragraph (b)(4), or when the creation of a notional item would duplicate a specified tax attribute or an actual item already taken into account, notional items are not created. Nevertheless, in these situations specified tax attributes are adjusted for the partnership and its reviewed year partners or their successors (as defined in § 1.704–1(b)(i)(viii)(*b*) of this chapter) in a manner that is consistent with how the partnership adjustment would have been taken into account under the partnership agreement in effect for the reviewed year taking into account all facts and circumstances. See § 1.704–1(b)(2)(iii)(*f*)(*4*) of this chapter for rules for allocating the expenditure for an imputed underpayment in these circumstances.

(ii) *Adjustments for non-section 704(b) items.* Notional items are not created for a partnership adjustment that does not derive from items that would have been allocated in the reviewed year under section 704(b). See paragraph (e) of this section, *Example 5.*

(iii) *Section 705(a)(2)(B) expenditures.* Notional items are not created for a partnership adjustment that is a change of an item of deduction to a section 705(a)(2)(B) expenditure.

(iv) *Tax-exempt income.* Notional items are not created for a partnership adjustment to an item of income of a partnership exempt from tax under subtitle A of the Code.

(5) *Allocation of the notional items.* Notional items are allocated to the reviewed year partners or their successors under § 1.704–1(b)(4)(xi) of this chapter.

(6) *Effect of notional items*—(i) *In general.* The partnership creates notional items of income, gain, loss, deduction, or credit in order to make appropriate adjustments to specified tax attributes. See paragraph (e), *Example 1* of this section.

(ii) *Partner capital accounts.* For purposes of capital accounts determined and maintained in accordance with § 1.704–1(b)(2) of this chapter, a notional item of income, gain, loss, deduction or credit is treated as an item of income, gain, loss, deduction or credit (including for purposes of determining book value). Similar adjustments may be appropriate for partnerships that do not determine and maintain capital accounts in accordance with § 1.704–1(b)(2) of this chapter.

(iii) *Partner's basis in its interest*—(A) *In general.* Except as otherwise provided, the basis of a partner's interest in a partnership is adjusted (but not below zero) to reflect any notional item allocated to the partner by treating the notional item as an item described in section 705(a).

(B) *Special basis rules.* The basis of a partner's interest in a partnership is not adjusted for any notional items allocated to the partner—

(*1*) When a partner that is not a tax-exempt entity (as defined in § 301.6225–2(d)(3)(ii)) is a successor under § 1.704–1(b)(1)(viii)(*b*) of this chapter to a reviewed year tax-exempt partner, to the extent that the IRS approved a modification under § 301.6225–2 because the tax-exempt partner was not subject to tax; or

(*2*) When the notional item would be allocated to a successor that is related (within the meaning of sections 267(b) or 707(b)) to the reviewed year partner, the successor acquired its interest from the reviewed year partner in a transaction (or series of transactions) in which not all gain or loss is recognized during an administrative adjustment proceeding with respect to the partnership's reviewed year under subchapter C of chapter 63, and a principal purpose of the interest transfer (or transfers) was to shift the economic burden of the imputed underpayment among the related parties.

(c) *Determining a partner's share of an expenditure for any payment required to be made by a partnership under subchapter C of chapter 63.* Payment by a partnership of any amount required to be paid under subchapter C of chapter 63 as described in § 301.6241–4(a) is treated as an expenditure described in section 705(a)(2)(B). Rules for determining whether the economic effect of an allocation of these expenses is substantial are provided in § 1.704–1(b)(2)(iii)(*f*) of this chapter and rules for determining whether an allocation of these expenses is deemed to be in accordance with the partners' interests in the partnership are provided in § 1.704–1(b)(4)(xii) of this chapter.

(d) *Adjusting tax attributes for a partnership adjustment that does not result in an imputed underpayment.* The rules under subchapter K of the Code apply in the case of a partnership adjustment that does not result in an imputed underpayment. See § 301.6225–3(c). Accordingly, tax attributes (as defined in § 301.6241–1(a)(10)) of a partnership and its partners are adjusted under those rules. An item arising from a partnership adjustment that does not result in an imputed underpayment (as defined in § 301.6225–1(f)) is allocated under § 1.704–1(b)(4)(xiii) of this chapter.

(e) *Examples.* The following examples illustrate the rules of this section. For purposes of these examples, unless otherwise stated, Partnership is subject to the provisions of subchapter C of chapter 63, Partnership and its partners are calendar year taxpayers, all partners are U.S. persons, and the highest rate of income tax in effect for all taxpayers is 20 percent for all relevant periods.

Example 1. (i) In 2019, A, B, and C are individuals that form Partnership. A contributes Whiteacre, which is unimproved land with an adjusted basis of $400 and a fair market value of $1,000, and B and C each contribute $1,000 in cash. The partnership agreement provides that all income, gain, loss, and deduction will be allocated in equal ⅓ shares among the partners. The partnership agreement also provides that the partners' capital accounts will be determined and maintained in accordance with § 1.704–1(b)(2)(iv) of this chapter, distributions in liquidation of the partnership (or any partner's interest) will be made in accordance with the partners' positive capital account balances, and any partner with a deficit

balance in his capital account following the liquidation of his interest must restore that deficit to the partnership (as provided in § 1.704–1(b)(2)(ii)(*b*)(*2*) and (*3*) of this chapter).

(ii) Upon formation, Partnership has the following assets and capital accounts:

	Partnership basis	Book	Value		Outside basis	Book	Value
Cash	$2,000	$2,000	$2,000	A	$400	$1,000	$1,000
Whiteacre	400	1,000	1,000	B	1,000	1,000	1,000
				C	1,000	1,000	1,000
Totals	2,400	3,000	3,000		2,400	3,000	3,000

(iii) In 2019, Partnership makes a $120 payment for Asset that it treats as a deductible expense on its partnership return.

	Partnership basis	Book	Value		Outside basis	Book	Value
Cash	$1,880	$1,880	$1,880	A	$360	$960	$1,000
Whiteacre	400	1,000	1,000	B	960	960	1,000
Asset	0	0	120	C	960	960	1,000
Totals	2,280	2,880	3,000		2,280	2,880	3,000

(iv) Partnership does not file an AAR for 2020. In 2021 (the adjustment year) it is finally determined that Partnership's $120 expenditure was not allowed as a deduction in 2019 (the reviewed year), but rather was the acquisition of an asset for which cost recovery deductions are unavailable. Accordingly, the IRS makes a partnership adjustment that disallows the entire $120 deduction, which results in an imputed underpayment of $48 ($120 × 40 percent). Partnership did not request modification under § 301.6225–2. Partnership pays the $48 imputed underpayment.

(v) Partnership first determines its tax attribute adjustments resulting from the partnership adjustment by applying paragraph (b) of this section. Pursuant to paragraph (b)(2) of this section, Partnership must re-state the basis and book value of Asset to $120. Further, pursuant to paragraph (b)(3)(v) of this section, a $120 notional item of income is created. The $120 item of notional income is allocated in equal shares ($40) to A, B, and C in 2021 under § 1.704–1(b)(4)(xi) of this chapter. Accordingly, in 2021 Partnership increases the capital accounts of A, B, and C by $40 each, and increases A, B, and C's outside bases by $40 each under paragraph (b)(6)(ii) and (iii) of this section, respectively.

(vi) As described in paragraph (c) of this section, Partnership's payment of the $48 imputed underpayment is treated as an expenditure described in section 705(a)(2)(B) under § 301.6241–4. Under § 1.704–1(b)(4)(xii) of this chapter, Partnership determines each partner's properly allocable share of this expenditure in 2021 by allocating the expenditure in proportion to the allocations of the notional item to which the expenditure relates. Accordingly, each of A, B, and C have a properly allocable share of $16 each, which is the same proportion (⅓ each) in which A, B, and C share the $120 item of notional income. Thus, A, B and C's capital accounts are each decreased by $16 in 2021 and A, B and C's outside bases are each decreased by $16 in 2021. The allocation of the expenditure under the partnership agreement has economic effect under § 1.704–1(b)(2)(ii) of this chapter and, because the allocation of the expenditure is determined in accordance with § 1.704–1(b)(2)(iii)(*f*) of this chapter, the economic effect of these allocations is deemed to be substantial.

(vii) The payment is also reflected by a $48 decrease in partnership cash for book purposes under § 1.704–1(b)(4)(ii) of this chapter. Therefore, in 2021, A's basis in Partnership is $384 and his capital account is $984. B and C each have a basis and capital account of $984.

	Partnership basis	Book	Value		Outside basis	Book	Value
Cash	$1,832	$1,832	$1,832	A	$384	$984	$984
Whiteacre	400	1,000	1,000	B	984	984	984
Asset	120	120	120	C	984	984	984
Totals	2,352	2,952	2,952		2,352	2,952	2,952

Example 2. (i) The facts are the same as in *Example 1* of this paragraph (e), except the IRS approves modification under § 301.6225–2(d)(3) with respect to A, which is a tax-exempt entity, and under § 301.6225–2(d)(4) with respect to C, which is a corporation subject to a tax rate of 20 percent. These modifications reduce Partnership's overall imputed underpayment from $48 to $30.

(ii) As in *Example 1* of this paragraph (e), Partnership determines its tax attribute adjustments resulting from the partnership adjustment by applying paragraph (b) of this section. Pursuant to paragraph (b)(3)(v) of this section, a $120 notional item of income is created. The $120 item of notional income is allocated in equal shares ($40) to A, B, and C in 2021 under § 1.704–1(b)(4)(xi) of this chapter. Accordingly, in 2021 Partnership increases the capital accounts of A, B, and C by $40 each, and increases A, B, and C's outside bases by $40 each under paragraph (b)(6)(ii) and (iii) of this section, respectively.

(iii) However, the modifications affect how Partnership must allocate the imputed underpayment expenditure among A, B, and C in 2021 (the adjustment year) pursuant to § 1.704–1(b)(2)(iii)(*f*) of this chapter. Specifically, Partnership allocates the $24 expenditure in 2021 in proportion to the allocation of the notional item to which it relates (which is ⅓ each as in *Example 1* of this paragraph (e)), but it must also take into account modifications attributable to each partner. Accordingly, B's allocation is $16 (its share of the imputed underpayment, for which no modification occurred), and A and C have properly allocable shares of $0 and $8, respectively (their shares, taking into account modification). Thus, A's capital account is decreased by $0, B's capital account is decreased by $16, and C's capital

account is decreased by $8 in 2021 and their respective outside bases are decreased by the same amounts in 2021.

(iv) The payment is also reflected by a $24 decrease in partnership cash for book purposes. Therefore, in 2021, A's basis in Partnership is $400 and his capital account is $1000, B's basis and capital account are both $984, and C's basis and capital account are both $992.

	Partnership basis	Book	Value		Outside basis	Book	Value
Cash	$1,856	$1,856	$1,856	A	$400	$1,000	$1,000
Whiteacre	400	1,000	1,000	B	984	984	984
Asset	120	120	120	C	992	992	992
Totals	2,376	2,976	2,976		2,376	2,976	2,976

Example 3. The facts are the same as in *Example 1* of this paragraph (e). However, in 2020, C transfers its entire interest in Partnership to D (an individual) for cash. Under § 1.704–1(b)(2)(iv)(l) of this chapter, C's capital account carries over to D. In 2021, the year the IRS determines that Partnership's $120 expense is not allowed as a deduction, D is C's successor under § 1.704–1(b)(1)(viii)(*b*)(*2*) of this chapter with respect to specified tax attributes and the payment of the imputed underpayment treated as an expenditure under section 705(a)(2)(B).

Example 4. The facts are the same as in *Example 1* of this paragraph (e), except that the partnership agreement provides that the section 705(a)(2)(B) expenditure for imputed underpayments made by the partnership are specially allocated to A (all other items continue to be allocated in equal shares). Accordingly, in 2021, the section 705(a)(2)(B) expenditure is allocated entirely to A, which reduces its capital account by $48, which has economic effect under § 1.704–1(b)(2)(ii) of this chapter. However, the economic effect of this allocation is not substantial under § 1.704–1(b)(2)(iii)(*a*) of this chapter because it is not allocated in the manner described in § 1.704–1(b)(2)(iii)(*f*) of this chapter. The allocation will also not be deemed to be in accordance with the partners' interests in the partnership under § 1.704–1(b)(3)(ix) of this chapter because it is not allocated pursuant to the rules under § 1.704–1(b)(4)(xii) of this chapter.

Example 5. (i) In 2019, Partnership has two partners, A and B. Both A and B have a $0 basis in their interests in Partnership. Further, Partnership has a $200 liability as defined in § 1.752–1(a)(4) of this chapter. The liability is treated as a nonrecourse liability as defined in § 1.752–1(a)(2) of this chapter so that A and B both are treated as having a $100 share of the liability under § 1.752–3 of this chapter. In 2021 (the adjustment year), the IRS determines that the liability was inappropriately classified as a nonrecourse liability, should have been classified as a recourse liability as defined in § 1.752–1(a)(1) of this chapter, and that A should have no share of the recourse liability under § 1.752–2 of this chapter. The recharacterization of the liability from nonrecourse to recourse and the decrease in A's share of partnership liabilities are adjustments that are not allocated under section 704(b) under § 301.6225–1(c)(5)(ii). As a result of the adjustments, the IRS includes in the residual grouping $100 of increased income to account for the cumulative effects of these adjustments to reflect the $100 decrease in A's share of partnership liabilities under §§ 1.752–1(c) and 1.731–1(a)(1)(i) of this chapter and determines an imputed underpayment of $40 ($100 × 40 percent). Partnership does not request modification under § 301.6225–2. Partnership pays the $40 imputed underpayment.

(ii) Pursuant to paragraph (b)(4)(ii) of this of this section, notional items are not created with respect to this partnership adjustment. Instead, under paragraph (b)(4)(i) of this section, specified tax attributes are adjusted in a manner that is consistent with how the partnership adjustment would have been taken into account under the partnership agreement in effect for the reviewed year taking into account all facts and circumstances. In this case, no specified tax attributes are adjusted.

(iii) However, because A would have borne the economic burden of the partnership adjustment if the partnership and its partners had originally reported in a manner consistent with the partnership adjustment, the $40 imputed underpayment section 705(a)(2)(B) expenditure is allocated to A under § 1.704–1(b)(2)(iii)(*f*)(*4*) of this chapter.

(f) *Applicability date*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 12.** Section 301.6226–1 is added to read as follows:

§ 301.6226–1 Election for an alternative to the payment of the imputed underpayment.

(a) *In general.* A partnership may elect under this section an alternative to the payment by the partnership of an imputed underpayment determined under section 6225 and the regulations thereunder. In addition, a partnership making a valid election under paragraph (b) of this section is no longer liable for the imputed underpayment (as defined in § 301.6241–1(a)(3)) to which the election applies. If a notice of final partnership adjustment (FPA) mailed under section 6231 includes more than one imputed underpayment (as described in § 301.6225–1(g)), a partnership may make an election under this section with respect to one or more imputed underpayments identified in the FPA. See § 301.6226–2(f) regarding the determination of each reviewed year partner's (as defined in § 301.6241–1(a)(9)) share of the partnership adjustments (as defined in § 301.6241–1(a)(6)) and related penalties, additions to tax, and additional amounts that must be taken into account.

(b) *Effect of election*—(1) *Reviewed year partners.* If a partnership makes a valid election under this section with respect to any imputed underpayment, the reviewed year partners must take into account their share of the partnership adjustments that relate to that imputed underpayment and are liable for any tax, penalties, additions to tax, additional amounts, and interest as described in § 301.6226–3. If an election is made under this section, any modification approved by the IRS under § 301.6225–2 is taken into account by the reviewed year partners in accordance with § 301.6226–2(f)(2).

(2) *Partnership.* A partnership making a valid election under this section is not liable for the imputed underpayment to which the election applies (and no assessment of tax, levy, or proceeding in any court for the collection of such imputed underpayment may be made against such partnership). Any adjustments that do not result in an imputed underpayment described in § 301.6225–1(f) that are associated with an imputed underpayment (as described in § 301.6225–1(g)) for which an election under this section is made are not taken into account by the partnership in the adjustment year (as defined in § 301.6241–1(a)(1)) and instead each reviewed year partners' share of the adjustment determined in accordance with § 301.6226–2(f) must be included on the statement described in § 301.6226–2.

(c) *Time, form, and manner for making the election*—(1) *In general.* An election under this section is valid only if all of the provisions of this section

and § 301.6226–2 (regarding statements filed with the Internal Revenue Service (IRS) and furnished to reviewed year partners) are satisfied. However, an election under this section is valid until the IRS determines that the election is invalid. An election under this section may only be revoked with the consent of the IRS.

(2) *Invalid election.* If an election under this section is determined by the IRS to be invalid, the IRS will notify the partnership and the partnership representative within 30 days of the determination that the election is invalid and the reason for the determination that the election is invalid. If the IRS makes a determination that an election under this section is invalid, section 6225 applies with respect to the imputed underpayment as if the election was never made, the IRS may assess the imputed underpayment against the partnership (without regard to the limitations under section 6232(b)), and the partnership must pay the imputed underpayment under section 6225 and any penalties and interest under section 6233. An election under this section may be determined to be invalid even if a correction is made in accordance with § 301.6226–2(d)(2) or if a correction is not made as required in accordance with § 301.6226–2(d)(3). However, the IRS has no obligation to require correction of errors discovered by the IRS and may determine an election to be invalid without providing an opportunity to correct under § 301.6226–2(d)(3).

(3) *Time for making the election.* An election under this section must be filed within 45 days of the date the FPA is mailed by the IRS. The time for filing such an election may not be extended.

(4) *Form and manner of the election*—(i) *In general.* An election under this section must be signed by the partnership representative and filed in accordance with forms, instructions, and other guidance and include the information specified in paragraph (c)(4)(ii) of this section.

(ii) *Contents of the election.* An election under this section must include the following correct information—

(A) The name, address, and taxpayer identification number (TIN) of the partnership,

(B) The taxable year to which the election relates,

(C) A copy of the FPA to which the election relates,

(D) In the case of an FPA that includes more than one imputed underpayment, identification of the imputed underpayment(s) to which the election applies,

(E) Each reviewed year partner's name, address, and TIN, and

(F) Any other information prescribed by the IRS in forms, instructions, and other guidance.

(d) *Binding nature of statements.* The election under this section, which includes filing and furnishing statements described in § 301.6226–2, are actions of the partnership under section 6223 and the regulations thereunder and, unless determined otherwise by the IRS, the partner's share of the adjustments and the applicability of any penalties, additions to tax, and additional amounts as set forth in the statement are binding on the partner pursuant to section 6223. Accordingly, a partner may not treat any partnership-related items (as defined in § 301.6241–6) reflected on a statement described in § 301.6226–2 on the partner's return inconsistently with how those items are treated on the statement that is filed with the IRS. See § 301.6222–1(c)(2) (regarding partnership-related items the treatment of which a partner is bound to under section 6223).

(e) *Coordination with section 6234 regarding judicial review.* Nothing in this section affects the rules regarding judicial review of a partnership adjustment. Accordingly, a partnership that makes an election under this section is not precluded from filing a petition under section 6234(a). See § 301.6226–2(b)(3), *Example 3.*

(f) *Applicability date*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 13.** Section 301.6226–2 is added to read as follows:

§ 301.6226–2 Statements furnished to partners and filed with the IRS.

(a) *In general.* A partnership that makes an election under § 301.6226–1 must furnish to each reviewed year partner (as defined in § 301.6241–1(a)(9)) and file with the Internal Revenue Service (IRS) a statement that includes the items required by paragraphs (e) and (f) of this section with respect to each reviewed year partner's share of partnership adjustments (as defined in § 301.6241–1(a)(6)) associated with the imputed underpayment for which an election under § 301.6226–1 is made. The statements furnished to the reviewed year partners under this section are in addition to, and must be filed and furnished separate from, any other statements required to be filed with the IRS and furnished to partners, including any statements under section 6031(b). A separate statement under this section must be furnished to each reviewed year partner with respect to each reviewed year (as defined in § 301.6241–1(a)(8)) subject to an election under § 301.6226–1.

(b) *Time and manner for furnishing the statements to partners*—(1) *In general.* The statements described in paragraph (a) of this section must be furnished to the reviewed year partners no later than 60 days after the date all of the partnership adjustments to which the statement relates are finally determined. The partnership adjustments are finally determined upon the later of:

(i) The expiration of the time to file a petition under section 6234, or

(ii) If a petition under section 6234 is filed, the date when the court's decision becomes final.

(2) *Address used for reviewed year partners.* The partnership must furnish the statement described in paragraph (a) of this section to each reviewed year partner in accordance with the forms, instructions, and other guidance prescribed by the IRS. If the partnership mails the statement, it must mail the statement to the current or last address of the reviewed year partner that is known to the partnership. If a statement is returned to the partnership as undeliverable, the partnership must undertake reasonable diligence to identify a correct address for the reviewed year partner to which the statement relates.

(3) *Examples.* The following examples illustrate the rules of this paragraph (b).

Example 1. During Partnership's 2020 taxable year, A, an individual, was a partner in Partnership and had an address at 123 Main St. On February 1, 2021, A sells his interest in Partnership and informs Partnership that A moved to 456 Broad St. On March 15, 2021, Partnership mails A's statement under section 6031(b) for the 2020 taxable year to 456 Broad St. On June 1, 2023, A moves again but does not inform Partnership of A's new address. In 2023, the IRS initiates an administrative proceeding with respect to Partnership's 2020 taxable year and mails a notice of final partnership adjustment (FPA) to Partnership for that year setting forth a single imputed underpayment. Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment and on May 31, 2024, timely mails a statement described in paragraph (a) of this section to A at 456 Broad St. Although the statement was mailed to the last address for A that was known to Partnership, it is returned to Partnership as undeliverable

because unknown to Partnership, A had moved. After undertaking reasonable diligence to obtain the correct address of A, Partnership is unable to ascertain the correct address. Therefore, pursuant to paragraph (b)(2) of this section, Partnership properly furnished the statement to A when it mailed the statement to 456 Broad St.

Example 2. The facts are the same as in *Example 1* of this paragraph (b)(3), except that A lives at 789 Forest Ave. during all of 2024 and reasonable diligence would have revealed that 789 Forest Ave. is the correct address for A, but Partnership did not undertake such diligence. Because the statement was returned as undeliverable and Partnership did not undertake reasonable diligence to obtain the correct address for A, Partnership failed to properly furnish the statement with respect to A pursuant to paragraph (b)(2) of this section.

Example 3. Partnership is a calendar year taxpayer. The IRS initiates an administrative proceeding with respect to Partnership's 2020 taxable year. On January 1, 2024, the IRS mails an FPA with respect to the 2020 taxable year to Partnership setting forth a single imputed underpayment. Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment. Partnership timely files a petition for readjustment under section 6234 with the Tax Court. The IRS prevails, and the Tax Court sustains all of the adjustments in the FPA with respect to the 2020 taxable year. The time to appeal the Tax Court decision expires, and the Tax Court decision becomes final on April 10, 2025. Under paragraph (b)(1)(ii) of this section, the adjustments in the FPA are finally determined on April 10, 2025, and Partnership must furnish the statements described in paragraph (a) of this section to its reviewed year partners and electronically file the statements with the IRS no later than June 9, 2025. See paragraph (c) of this section for the rules regarding filing the statements with the IRS.

(c) *Time and manner for filing the statements with the IRS.* No later than 60 days after the date the partnership adjustments are finally determined (as described in paragraph (b)(1) of this section), the partnership must electronically file with the IRS the statements that the partnership furnishes to each reviewed year partner under this section, along with a transmittal that includes a summary of the statements filed and such other information required in forms, instructions, and other guidance prescribed by the IRS.

(d) *Correction of statements*—(1) *In general.* A partnership corrects an error in a statement furnished under paragraph (b) of this section or filed under paragraph (c) of this section by filing the corrected statement with the IRS in the manner prescribed in paragraph (c) of this section and furnishing a copy of the corrected statement to the reviewed year partner to whom the statement relates in accordance with the forms, instructions, and other guidance prescribed by the IRS.

(2) *Error discovered by partnership*—(i) *Discovery within 60 days of statement due date.* If a partnership discovers an error in a statement within 60 days of the due date for furnishing the statements to partners and filing the statements with the IRS (as described in paragraphs (b) and (c) of this section and § 301.6226–3(e)(3)(ii)), the partnership must correct the error in accordance with paragraph (d)(1) of this section and does not have to seek consent of the IRS prior to doing so.

(ii) *Error discovered more than 60 days after statement due date.* If a partnership discovers an error more than 60 days after the due date for furnishing the statements to partners and filing the statements with the IRS (as described in paragraphs (b) and (c) of this section and § 301.6226–3(e)(3)(ii)), the partnership may only correct the error after receiving consent of the IRS in accordance with the forms, instructions, and other guidance prescribed by the IRS. The partnership may not furnish corrected statements unless it receives consent of the IRS to make the correction.

(3) *Error discovered by the IRS.* If the IRS discovers an error in the statements furnished or filed under paragraphs (b) and (c) of this section and § 301.6226–3(e)(3) or the IRS cannot determine whether the statements furnished or filed by the partnership are correct because of a failure by the partnership to comply with any requirement under this section or § 301.6226–3(e), the IRS may require the partnership to correct such errors in accordance with paragraph (d)(1) of this section or to provide additional information as necessary. Failure by the partnership to correct an error or to provide information when required by the IRS may be treated by the IRS as a failure to properly furnish correct statements to partners and file the correct statements with the IRS as described in paragraphs (b) and (c) of this section or in § 301.6226–3(e)(3). Whether the IRS requires the partnership to correct any errors discovered by the IRS or provide additional information is discretionary on the part of the IRS and the IRS is under no obligation to require the partnership to provide additional information or to correct any errors discovered or brought to the IRS's attention at any time.

(4) *Adjustments in the corrected statements taken into account by the reviewed year partners.* The adjustments included on a corrected statement are taken into account by a reviewed year partner in accordance with § 301.6226–3 for the reporting year (as defined in § 301.6226–3(a)).

(e) *Content of the statements.* Each statement described in paragraph (a) of this section must include the following correct information:

(1) The name and TIN of the reviewed year partner to whom the statement is being furnished;

(2) The current or last address of the reviewed year partner that is known to the partnership;

(3) The reviewed year partner's share of items as originally reported for the reviewed year to the partner on statements furnished to the partner under section 6031(b) and, if applicable, section 6227;

(4) The reviewed year partner's share of partnership adjustments determined under paragraph (f)(1) of this section;

(5) Modifications approved by the IRS with respect to the reviewed year partner (or with respect to any indirect partner (as defined in § 301.6241–1(a)(4)) that holds its interest in the partnership through its interest in the reviewed year partner);

(6) The applicability of any penalty, addition to tax, or additional amount determined at the partnership level that relates to any adjustments allocable to the reviewed year partner and the adjustments to which the penalty, addition to tax, or additional amount relates, the section of the Internal Revenue Code (Code) under which each penalty, addition to tax, or additional amount is imposed, and the applicable rate of each penalty, addition to tax, or additional amount determined at the partnership level;

(7) The date the statement is furnished to the reviewed year partner;

(8) The partnership taxable year to which the adjustments relate; and

(9) Any other information required by forms, instructions, and other guidance prescribed by the IRS.

(f) *Determination of each partner's share of adjustments*—(1) *Adjustments and other amounts*—(i) *In general.* Except as described in paragraphs (f)(1)(ii), (f)(1)(iii), or (f)(2) of this section, the adjustments set forth in the statement described in paragraph (a) of this section are reported to the reviewed year partner in the same manner as each adjusted partnership-related item was originally allocated to the reviewed year partner on the partnership return for the reviewed year.

(ii) *Adjusted partnership-related item not reported on the partnership's return for the reviewed year.* Except as described in paragraph (f)(1)(iii) of this section, if the adjusted partnership-

related item was not reported on the partnership return for the reviewed year, each reviewed year partner's share of the adjustments must be determined in accordance with how such partnership-related items would have been allocated under rules that apply with respect to partnership allocations, including under the partnership agreement.

(iii) *Adjustments that specifically allocate items.* If an adjustment involves an allocation of a partnership-related item to a specific partner or in a specific manner, including a reallocation of such an item, the reviewed year partner's share of the adjustment set forth in the statement is determined in accordance with the adjustment as finally determined (as described in paragraph (b)(1) of this section).

(2) *Treatment of modifications disregarded.* Any modifications approved by the IRS with respect to the reviewed year partner (or with respect to any indirect partner (as defined in § 301.6241–1(a)(4)) that holds its interest in the partnership through its interest in the reviewed year partner) under § 301.6225–2 are disregarded for purposes of determining each partner's share of the adjustments under paragraph (f)(1) of this section.

(g) *Coordination with other provisions under subtitle A of the Code*—(1) *Statements furnished to qualified investment entities described in section 860.* If a reviewed year partner is a qualified investment entity within the meaning of section 860(b) and the partner receives a statement described in paragraph (a) of this section, the partner may be able to avail itself of the deficiency dividend procedure described in § 301.6226–3(b)(4).

(2) *Liability for tax under section 7704(g)(3).* An election under this section has no effect on a partnership's liability for any tax under section 7704(g)(3) (regarding the exception for electing 1987 partnerships from the general rule that certain publicly traded partnerships are treated as corporations).

(3) *Adjustments subject to chapters 3 and 4.* A partnership that makes an election under § 301.6226–1 with respect to an imputed underpayment must pay the amount of tax required to be withheld under chapter 3 or chapter 4, if any, in accordance with § 301.6241–7(b)(4).

(h) *Applicability date*—(1) *In general.* Except as provided in paragraph (h)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 14.** Section 301.6226–3 is added to read as follows:

§ 301.6226–3 Adjustments taken into account by partners.

(a) *Effect of taking adjustments into account on tax imposed by chapter 1.* Except as otherwise provided in this section, the tax imposed by chapter 1 of subtitle A of the Internal Revenue Code (chapter 1 tax) for each reviewed year partner (as defined in § 301.6241–1(a)(9)) for the taxable year that includes the date a statement was furnished in accordance with § 301.6226–2 (the reporting year) is increased by the additional reporting year tax, or if the additional reporting year tax is less than zero, decreased by such amount. The additional reporting year tax is the aggregate of the correction amounts (determined in accordance with paragraph (b) of this section). In addition to being liable for the additional reporting year tax, a reviewed year partner must also calculate and pay for the reporting year any penalties, additions to tax, and additional amounts (as determined under paragraph (d) of this section). Finally, a reviewed year partner must also calculate and pay for the reporting year any interest (as determined under paragraph (c) of this section).

(b) *Determining the aggregate of the correction amounts*—(1) *In general.* For purposes of paragraph (a) of this section, the aggregate of the correction amounts is the sum of the correction amounts described in paragraphs (b)(2) and (3) of this section. A correction amount under paragraph (b)(2) or (3) of this section may be less than zero, and any correction amount that is less than zero may reduce any other correction amount with the result that the aggregate of the correction amounts under this paragraph (b)(1) may also be less than zero. However, see paragraphs (c) and (d) of this section requiring a separate determination of interest and penalties, additions to tax, and additional amounts on the correction amount for each applicable taxable year (as defined in paragraph (c)(1) of this section) without regard to the correction amount for any other applicable taxable year.

(2) *Correction amount for the first affected year*—(i) *In general.* The correction amount for the taxable year of the partner that includes the end of the reviewed year (the first affected year) is the amount by which the reviewed year partner's chapter 1 tax would increase or decrease for the first affected year if the partner's taxable income for such year was recomputed by taking into account the reviewed year partner's share of the partnership adjustments (as defined in § 301.6241–1(a)(6)) reflected on the statement described in § 301.6226–2 with respect to the partner.

(ii) *Calculation of the correction amount for the first affected year.* The correction amount is the amount of chapter 1 tax that would have been imposed for the first affected year if the items as adjusted in the statement described in § 301.6226–2 had been reported as such on the return for the first affected year less the sum of:

(A) The amount of chapter 1 tax shown by the partner on the return for the first affected year (which includes amounts shown on an amended return for such year, including an amended return filed, or alternative to an amended return submitted, under section 6225(c)(2) by the reviewed year partner), plus

(B) Amounts not so shown previously assessed (or collected without assessment) (as defined in § 1.6664–2(d) of this chapter), less

(C) The amount of rebates made (as defined in § 1.6664–2(e) of this chapter).

(iii) *Definition of the correction amount for the first affected year.* The correction amount also may be expressed as—

$$\text{Correction amount} = A - (B + C - D),$$

Where A = the amount of chapter 1 tax that would have been imposed had the items as adjusted been properly reported on the return for the first affected year; B = the amount shown as chapter 1 tax on the return for the first affected year (taking into account amended returns (or alternatives)); C = amounts not so shown previously assessed (or collected without assessment); and D = the amount of rebates made.

(3) *Correction amount for the intervening years*—(i) *In general.* The correction amount for all taxable years after the first affected year and before the reporting year (the intervening years) is the aggregate of the correction amounts determined for each intervening year. Determining the correction amount for each intervening year is a year-by-year determination. The correction amount for each intervening year is the amount by which the reviewed year partner's chapter 1 tax for such year would increase or decrease if the partner's taxable income for such year was recomputed by taking into account any adjustments to tax attributes (as defined in § 301.6241–1(a)(10)) of the partner under this paragraph (b)(3).

(ii) *Calculation of the correction amount for the intervening years.* The correction amount for each intervening year is the amount of chapter 1 tax that would have been imposed for the intervening year if any tax attribute of the partner for the intervening year had been adjusted after taking into account the reviewed year partner's share of the adjustments for the first affected year as described in paragraph (b)(2) of this section (and if any tax attribute of the partner for the intervening year had been adjusted, after taking into account any adjustments to tax attributes of the partner in any prior intervening year(s)) exceeds less the sum of—

(A) The amount of chapter 1 tax shown by the partner on the return for the intervening year (which includes amounts shown on an amended return for such year, including an amended return filed, or alternative to an amended return submitted, under section 6225(c)(2) by a reviewed year partner), plus

(B) Amounts not so shown previously assessed (or collected without assessment) (as defined in § 1.6664–2(d) of this chapter), less

(C) The amount of rebates made (as defined in § 1.6664–2(e) of this chapter).

(iii) *Definition of the correction amount for the intervening years.* The correction amount also may be expressed as—

$$\text{Correction amount} = A - (B + C - D),$$

Where A = the amount of chapter 1 tax that would have been imposed for the intervening year; B = the amount shown as chapter 1 tax on the return for the intervening year (taking into account amended returns (or alternatives)); C = amounts not so shown previously assessed (or collected without assessment); and D = the amount of rebates made.

(4) *Coordination of sections 860 and 6226.* If a qualified investment entity (QIE) within the meaning of section 860(b) receives a statement described in § 301.6226–2(a) and correctly makes a determination within the meaning of section 860(e)(4) that one or more of the adjustments reflected in the statement is an adjustment within the meaning of section 860(d) with respect to that QIE for a taxable year, the QIE may distribute deficiency dividends within the meaning of section 860(f) for that taxable year and avail itself of the deficiency dividend procedures set forth in section 860. If the QIE utilizes the deficiency dividend procedures with respect to adjustments in a statement described in § 301.6226–2(a), the QIE may claim a deduction for deficiency dividends against the adjustments furnished to the QIE in the statement in calculating any correction amounts under paragraphs (b)(2) and (3) of this section, and interest on such correction amounts under paragraph (c) of this section, to the extent that the QIE makes deficiency dividend distributions under section 860(f) and complies with all requirements of section 860 and the regulations thereunder.

(c) *Interest*—(1) *Interest on the correction amounts.* Interest on the correction amounts determined under paragraph (b) of this section is the aggregate of all interest calculated for each applicable taxable year in which there was a correction amount greater than zero at the rate set forth in paragraph (c)(3) of this section. For each applicable taxable year, interest on the correction amount is calculated from the due date (without extension) of the reviewed year partner's return for such applicable taxable year until the amount is paid. For purposes of this paragraph (c)(1), the term *applicable taxable year* means the reviewed year partner's taxable year affected by taking into account adjustments as described in paragraph (b) of this section (for instance, the first affected year and any intervening year in which there is a correction amount greater than zero). For purposes of calculating interest under this paragraph (c), a correction amount under paragraph (b)(2) or (3) of this section for an applicable taxable year that is less than zero does not reduce the correction amount for any other applicable taxable year.

(2) *Interest on penalties.* Interest on any penalties, additions to tax, or additional amounts determined under paragraph (d) of this section is calculated at the rate set forth in paragraph (c)(3) of this section from the due date (without extension) of the reviewed year partner's return for the applicable taxable year until the amount is paid.

(3) *Rate of interest.* For purposes of paragraph (c) of this section, interest is calculated using the underpayment rate under section 6621(a)(2) by substituting ''5 percentage points'' for ''3 percentage points'' in section 6621(a)(2)(B).

(d) *Penalties*—(1) *Applicability determined at the partnership level.* In the case of a partnership that makes an election under section 6226, the applicability of any penalty, addition to tax, and additional amount that relates to an adjustment to any partnership-related item is determined at the partnership level in accordance with section 6221(a). The partnership's reviewed year partners are liable for such penalties, additions to tax, and additional amounts as determined under paragraph (d)(2) of this section.

(2) *Amount calculated at partner level.* A reviewed year partner calculates the amount of any penalty, addition to tax, or additional amount relating to the partnership adjustments taken into account under paragraph (b)(1) of this section as if the correction amount were an underpayment or understatement of the reviewed year partner for the first affected year or intervening year, as applicable. The calculation of any penalty, addition to tax, or additional amount is based on the characteristics of, and facts and circumstances applicable to, the reviewed year partner for the first affected year or intervening year, as applicable after taking into account the partnership adjustments reflected on the statement. If after taking into account the partnership adjustments in accordance with this section, the reviewed year partner does not have an underpayment, or has an understatement that falls below the applicable threshold for the imposition of a penalty, no penalty is due from that reviewed year partner under this paragraph (d)(2). For penalties in the case of a pass-through partner that makes a payment under paragraph (e)(4) of this section, see paragraph (e)(4)(iv) of this section.

(3) *Partner-level defenses to penalties.* A reviewed year partner claiming that a penalty, addition to tax, or additional amount that relates to a partnership adjustment reflected on a statement described in § 301.6226–2 (or paragraph (e)(3) of this section) is not due because of a partner-level defense must first pay the penalty and file a claim for refund for the reporting year. Partner-level defenses are limited to those that are personal to the reviewed year partner (for example, a reasonable cause and good faith defense under section 6664(c) that is based on the facts and circumstances applicable to the partner).

(e) *Pass-through partners*—(1) *In general.* Except as provided in paragraph (e)(6) of this section, if a pass-through partner (as defined in § 301.6241–1(a)(5)) is furnished a statement described in § 301.6226–2 (including a statement described in paragraph (e)(3) of this section) with respect to adjustments of a partnership that made an election under § 301.6226–1 (audited partnership), the pass-through partner must file with the IRS a partnership adjustment tracking report in accordance with forms, instructions, or other guidance prescribed by the IRS on or before the due date described in paragraph (e)(3)(ii) of this section, and file and furnish statements in accordance with paragraph (e)(3) of this section. The pass-through partner must

comply with paragraph (e) of this section with respect to each statement furnished to the pass-through partner.

(2) *Failure to file and furnish required documents*—(i) *Failure to timely file and furnish statements.* If any pass-through partner fails to timely file and furnish correct statements in accordance with paragraph (e)(3) of this section, the pass-through partner must compute and pay an imputed underpayment, as well as any penalties, additions to tax, additional amounts, and interest with respect to the adjustments reflected on the statement furnished to the pass-through partner in accordance with paragraph (e)(4) of this section. The IRS may assess such imputed underpayment against such pass-through partner without regard to the limitations under section 6232(b). See § 301.6232–1(c)(2). A failure to furnish statements in accordance with paragraph (e)(3) of this section is treated as a failure to timely pay an imputed underpayment required under paragraph (e)(4)(i) of this section, unless the pass-through partner computes and pays an imputed underpayment in accordance with paragraph (e)(4) of this section. See section 6651(i).

(ii) *Failures relating to partnership adjustment tracking report.* Failure to timely file the partnership adjustment tracking report as required in paragraph (e)(1) of this section, or filing such report without showing the information required under paragraph (e)(1) of this section, is subject to the penalty imposed by section 6698.

(3) *Furnishing statements to partners*—(i) *In general.* A pass-through partner described in paragraph (e)(1) of this section must furnish a statement that includes the items required by paragraph (e)(3)(iii) of this section to each partner that held an interest in the pass-through partner at any time during the taxable year of the pass-through partner to which the adjustments in the statement furnished to the pass-through partner relate (affected partner). The statements described in this paragraph (e)(3) must be filed with the IRS by the due date prescribed in paragraph (e)(3)(ii) of this section. Except as otherwise provided in paragraphs (e)(3)(ii), (iii), and (v) of this section, the rules applicable to statements described in § 301.6226–2 are applicable to statements described in this paragraph (e)(3).

(ii) *Time for filing and furnishing the statements.* The pass-through partner must file with the IRS and furnish to its affected partners the statements described in paragraph (e)(3) of this section no later than the extended due date for the return for the adjustment year (as defined in § 301.6241–1(a)(1)) of the audited partnership. For purposes of this section, the extended due date is the extended due date under section 6081 regardless of whether the audited partnership is required to file a return for the adjustment year or timely files a request for an extension under section 6081 and the regulations thereunder.

(iii) *Contents of statements.* Each statement described in paragraph (e)(3) of this section must include the following correct information—

(A) The name and taxpayer identification number (TIN) of the audited partnership;

(B) The adjustment year of the audited partnership;

(C) The extended due date for the return for the adjustment year of the audited partnership (as described in paragraph (e)(3)(ii) of this section);

(D) The date on which the audited partnership furnished its statements required under § 301.6226–2(b);

(E) The name and TIN of the partnership that furnished the statement to the pass-through partner if different from the audited partnership;

(F) The name and TIN of the pass-through partner;

(G) The pass-through partner's taxable year to which the adjustments reflected on the statements described in paragraph (e)(3) of this section relates;

(H) The name and TIN of the affected partner to whom the statement is being furnished;

(I) The current or last address of the affected partner that is known to the pass-through partner;

(J) The affected partner's share of items as originally reported to such partner under section 6031(b) and, if applicable, section 6227, for the taxable year to which the adjustments reflected on the statement furnished to the pass-through partner relate;

(K) The affected partner's share of partnership adjustments determined under § 301.6226–2(f)(1) as if the affected partner were the reviewed year partner and the pass-through partner were the partnership;

(L) Modifications approved by the IRS with respect to the affected partner that holds its interest in the audited partnership through the pass-through partner;

(M) The applicability of any penalties, additions to tax, or additional amounts that relate to any adjustments allocable to the affected partner and the adjustments allocated to the affected partner to which such penalties, additions to tax, or additional amounts relate, the section of the Internal Revenue Code under which each penalty, addition to tax, or additional amount is imposed, and the applicable rate of each penalty, addition to tax, or additional amount; and

(N) Any other information required by forms, instructions, and other guidance prescribed by the IRS.

(iv) *Affected partner must take into account the adjustments.* A statement furnished to an affected partner in accordance with paragraph (e)(3) of this section is treated as if it were a statement described in § 301.6226–2. An affected partner that is a pass-through partner must take into account the adjustments reflected on such a statement in accordance with this paragraph (e). An affected partner that is not a pass-through partner must take into account the adjustments reflected on such a statement in accordance with this section by treating references to ''reviewed year partner'' as ''affected partner''. For purposes of this paragraph (e)(3)(iv), an affected partner that is not a pass-through partner takes into account the adjustments in accordance with this section by determining its reporting year based on the date upon which the audited partnership furnished its statements to its reviewed year partners (as described in paragraph (a) of this section). No addition to tax under section 6651 related to any additional reporting year tax will be imposed if an affected partner that is not a pass-through partner reports and pays the additional reporting year tax within 30 days of the extended due date for the return for the adjustment year of the audited partnership (as described in paragraph (e)(3)(ii) of this section).

(v) *Adjustments subject to chapters 3 and 4.* If a pass-through partner furnishes statements to its affected partners in accordance with paragraph (e)(3) of this section, the pass-through partner must comply with the requirements of § 301.6241–7(b)(4), and an affected partner must comply with the requirements of paragraph (f) of this section. For purposes of applying both § 301.6241–7(b)(4) and paragraph (f) of this section, as appropriate, references to the ''partnership'' should be replaced with references to the ''pass-through partner''; references to the ''reviewed year partner'' should be replaced with references to the ''affected partner''; references to the statement required under paragraph (a) of this section and its due date should be replaced with references to the statement required under paragraph (e)(3) of this section and its due date described in paragraph (e)(3)(ii) of this section; references to the ''reporting year'' should be read in accordance with paragraph (e)(3)(iv) of this section; and references to the partnership return should be read as

references to the return for the adjustment year of the audited partnership as described in paragraph (e)(3)(ii) of this section.

(4) *Pass-through partner pays an imputed underpayment*—(i) *In general.* If a pass-through partner described in paragraph (e)(1) of this section does not furnish statements in accordance with paragraph (e)(3) of this section, the pass-through partner must compute and pay an imputed underpayment determined under paragraph (e)(4)(iii) of this section. The pass-through partner must also pay any penalties, additions to tax, additional amounts, and interest as determined under paragraph (e)(4)(iv) of this section. A failure to timely pay an imputed underpayment required under this paragraph (e)(4) is subject to penalty under section 6651(i).

(ii) *Time of payment.* A pass-through partner must file a partnership adjustment tracking report and compute and pay the imputed underpayment and any penalties, additions to tax, additional amounts, and interest, as described in paragraph (e)(4)(i) of this section, in accordance with forms, instructions, and other guidance no later than the extended due date for the return for the adjustment year of the audited partnership.

(iii) *Computation of the imputed underpayment.* The imputed underpayment under paragraph (e)(4)(i) of this section is computed in the same manner as an imputed underpayment under section 6225 and § 301.6225–1, except that adjustments reflected on the statement furnished to the pass-through partner under § 301.6226–2 are treated as partnership adjustments (as defined in § 301.6241–1(a)(6)) for the first affected year. Any modification approved by the IRS under § 301.6225–2 with respect to the pass-through partner (including any modifications with respect to a relevant partner (as defined in § 301.6225–2(a)) that holds its interest in the audited partnership through its interest in the pass-through partner) reflected on the statement furnished to the pass-through partner under § 301.6226–2 (or paragraph (e)(3) of this section) is taken into account in calculating the imputed underpayment under this paragraph (e)(4)(iii). Any modification that was not approved by the IRS under § 301.6225–2 may not be taken into account in calculating the imputed underpayment under this paragraph (e)(4)(iii).

(iv) *Penalties and interest*—(A) *Penalties.* A pass-through partner must compute and pay any applicable penalties, additions to tax, and additional amounts on the imputed underpayment calculated under paragraph (e)(4)(iii) of this section as if such amount were an imputed underpayment for the pass-through partner's first affected year. See § 301.6233(a)–1(c).

(B) *Interest.* A pass-through partner must pay interest on the imputed underpayment calculated under paragraph (e)(4)(iii) of this section in accordance with paragraph (c) of this section as if such imputed underpayment were an imputed underpayment due for the first affected year.

(v) *Adjustments that do not result in an imputed underpayment.* Adjustments taken into account under paragraph (e)(4) of this section that do not result in an imputed underpayment (as defined in § 301.6225–1(f)) are taken into account by the pass-through partner in accordance with § 301.6225–3 in the taxable year of the pass-through partner that includes the date the imputed underpayment required under paragraph (e)(4)(i) of this section is paid. If, after making the computation described in paragraph (e)(4)(iii) of this section, no imputed underpayment exists and therefore no payment is required under paragraph (e)(4)(i) of this section, the adjustments that did not result in an imputed underpayment are taken into account by the pass-through partner in accordance with § 301.6225–3 in the taxable year of the pass-through partner that includes the date the statement described in § 301.6226–2 (or paragraph (e)(3) of this section) is furnished to the pass-through partner.

(vi) *Coordination with chapters 3 and 4.* If a pass-through partner pays an imputed underpayment described in paragraph (e)(4)(i) of this section, § 301.6241–7(b)(3) applies to the pass-through partner by substituting ''pass-through partner'' for ''partnership'' where § 301.6241–7(b)(3) refers to the partnership that pays the imputed underpayment.

(5) *Treatment of pass-through partners that are not partnerships*—(i) *S corporations.* For purposes of this paragraph (e), an S corporation is treated as a partnership and its shareholders are treated as partners.

(ii) *Trusts and estates.* Except as provided in paragraph (g) of this section, for purposes of paragraph (e) of this section, a trust and its beneficiaries, and an estate and its beneficiaries are treated in the same manner as a partnership and its partners.

(6) *Pass-through partners subject to chapter 1 tax.* A pass-through partner that is subject to tax under chapter 1 of the Code on the adjustments (or a portion of the adjustments) reflected on the statement furnished to such partner under § 301.6226–2 (or paragraph (e)(3) of this section) takes the adjustments into account under this paragraph (e)(6) when the pass-through partner calculates and pays the additional reporting year tax as determined under paragraph (b) of this section and furnishes statements to its partners in accordance with paragraph (e)(3) of this section. Notwithstanding the prior sentence, a pass-through partner is only required to include on a statement under paragraph (e)(3) of this section the adjustments that would be required to be included on statements furnished to owners or beneficiaries under sections 6037 and 6034A, as applicable, if the pass-through partner had correctly reported the items for the year to which the adjustments relate. If the pass-through partner fails to comply with the requirements of this paragraph (e)(6), the pass-through partner must compute and pay an imputed underpayment, as well as any penalties, additions to tax, additional amounts, and interest with respect to the adjustments reflected on the statement furnished to such partner in accordance with paragraph (e)(4) of this section.

(f) *Partners subject to withholding under chapters 3 and 4.* A reviewed year partner that is subject to withholding under § 301.6241–7(b)(4) must file an income tax return for the reporting year to report its additional reporting year tax and its share of any penalties, additions to tax, additional amounts, and interest (notwithstanding any filing exception in § 1.6012–1(b)(2)(i) or § 1.6012–2(g)(2)(i) of this chapter). The amount of tax paid by a partnership under § 301.6241–7(b)(4) is allowed as a credit under section 33 to the reviewed year partner to the extent that the tax is allocable to the reviewed year partner (within the meaning of § 1.1446–3(d)(2) of this chapter) or is actually withheld from the reviewed year partner (within the meaning of § 1.1464–1(a) or § 1.1474–3 of this chapter). The credit is allowed against the reviewed year partner's income tax liability for its reporting year. The reviewed year partner must substantiate the credit by attaching the applicable Form 1042–S, ''Foreign Person's U.S. Source Income Subject to Withholding,'' or Form 8805, ''Foreign Partner's Information Statement of Section 1446 Withholding Tax,'' to its income tax return for the reporting year, as well as satisfying any other requirements prescribed by the IRS in forms and instructions.

(g) *Treatment of disregarded entities and wholly-owned grantor trusts.* In the case of a reviewed year partner that is a wholly-owned entity disregarded as

separate from its owner for Federal tax purposes in the reviewed year or a trust that is wholly owned by only one person in the reviewed year, whether the grantor or another person, and where the trust reports the owner's information to payors under § 1.671–4(b)(2)(i)(A) of this chapter and that is furnished a statement described in § 301.6226–2 (or paragraph (e)(3) of this section), the owner of the disregarded entity or wholly-owned grantor trust must take into account the adjustments reflected on that statement in accordance with this section as if the owner were the reviewed year partner.

(h) *Examples.* The following examples illustrate the rules of this section. For purposes of these examples, each partnership is subject to subchapter C of chapter 63 of the Code, each partnership and partner has a calendar year taxable year, no modifications are requested by any partnership under § 301.6225–2 (unless otherwise stated), no penalties, additions to tax, or additional amounts are determined at the partnership level (unless otherwise stated), all persons are U.S. persons (unless otherwise stated), the highest rate of income tax in effect for is 40 percent for all relevant periods, the highest rate of income tax in effect for corporations is 20 percent for all relevant periods, and the highest rate of tax for individuals for capital gains is 15 percent for all relevant periods.

Example 1. On its partnership return for the 2020 tax year, Partnership reported ordinary income of $1,000 and charitable contributions of $400. On June 1, 2023, the IRS mails a notice of final partnership adjustment (FPA) to Partnership for Partnership's 2020 year disallowing the charitable contribution in its entirety and determining that a 20 percent accuracy-related penalty under section 6662(b) applies to the disallowance of the charitable contribution, and setting forth a single imputed underpayment with respect to such adjustments. Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA for Partnership's 2020 year and files a timely petition in the Tax Court challenging the partnership adjustments. The Tax Court determines that Partnership is not entitled to any of the claimed $400 in charitable contributions and upholds the applicability of the penalty. The decision regarding Partnership's 2020 tax year becomes final on December 15, 2025. Pursuant to § 301.6226–2(b), the partnership adjustments are finally determined on December 15, 2025. On February 2, 2026, Partnership files the statements described under § 301.6226–2 with the IRS and furnishes to partner A, an individual who was a partner in Partnership during 2020, a statement described in § 301.6226–2. A had a 25 percent interest in Partnership during all of 2020 and was allocated 25 percent of all items from Partnership for that year. The statement shows A's share of ordinary income reported on Partnership's return for the reviewed year of $250 and A's share of the charitable contribution reported on Partnership's return for the reviewed year of $100. The statement also shows no adjustment to A's share of ordinary income, but does show an adjustment to A's share of the charitable contribution, a reduction of $100 resulting in $0 charitable contribution allocated to A from Partnership for 2020. In addition, the statement reports that a 20 percent accuracy-related penalty under section 6662(b) applies. A must pay the additional reporting year tax as determined in accordance with paragraph (b) of this section, in addition to A's penalties and interest. A computes his additional reporting year tax as follows. First, A determines the correction amount for the first affected year (the 2020 taxable year) by taking into account A's share of the partnership adjustment (<100> reduction in charitable contribution) for the 2020 taxable year. A determines the amount by which his chapter 1 tax for 2020 would have increased or decreased if the $100 adjustment to the charitable contribution from Partnership were taken into account for that year. There is no adjustment to tax attributes in A's intervening years as a result of the adjustment to the charitable contribution for 2020. Therefore, A's aggregate of the correction amounts is the correction amount for 2020, A's first affected year. In addition to the aggregate of the correction amounts being added to the chapter 1 tax that A owes for 2026, the reporting year, A must calculate a 20 percent accuracy-related penalty on A's underpayment attributable to the $100 adjustment to the charitable contribution, as well as interest on the correction amount for the first affected year and the penalty determined in accordance with paragraph (c) of this section. Interest on the correction amount for the first affected tax year runs from April 15, 2021, the due date of A's 2020 return (the first affected tax year) until A pays this amount. In addition, interest runs on the penalty from April 15, 2021, the due date of A's 2020 return for the first affected year until A pays this amount. On his 2026 income tax return, A must report the additional reporting year tax determined in accordance with paragraph (b) of this section, which is the correction amount for 2020, plus the accuracy-related penalty determined in accordance with paragraph (d) of this section, and interest determined in accordance with paragraph (c) of this section on the correction amount for 2020 and the penalty.

Example 2. On its partnership return for the 2020 tax year, Partnership reported an ordinary loss of $500. On June 1, 2023, the IRS mails an FPA to Partnership for the 2020 taxable year determining that $300 of the $500 in ordinary loss should be recharacterized as a long-term capital loss. Partnership has no long-term capital gain for its 2020 tax year. The FPA for Partnership's 2020 tax year reflects an adjustment of an increase in ordinary income of $300 (as a result of the disallowance of the recharacterization of $300 from ordinary loss to long-term capital loss) and an imputed underpayment related to that adjustment, as well as an adjustment of an additional $300 in long-term capital loss for 2020 which does not result in an imputed underpayment under § 301.6225–1(f). Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA and does not file a petition for readjustment under section 6234. Accordingly, under § 301.6226–1(b)(2) and § 301.6225–3(b)(6), the adjustment year partners (as defined in § 301.6241–1(a)(2)) do not take into account the $300 long-term capital loss that does not result in an imputed underpayment. Rather, the $300 long-term capital loss is taken into account by the reviewed year partners. The time to file a petition expires on August 30, 2023. Pursuant to § 301.6226–2(b), the partnership adjustments become finally determined on August 31, 2023. On September 30, 2023, Partnership files with the IRS statements described in § 301.6226–2 and furnishes statements to all of its reviewed year partners in accordance with § 301.6226–2. One partner of Partnership in 2020, B (an individual), had a 25 percent interest in Partnership during all of 2020 and was allocated 25 percent of all items from Partnership for that year. The statement filed with the IRS and furnished to B shows B's allocable share of the ordinary loss reported on Partnership's return for the 2020 taxable year as $125. The statement also shows an adjustment to B's allocable share of the ordinary loss in the amount of <$75>, resulting in a corrected ordinary loss allocated to B of $50 for taxable year 2020 ($125 originally allocated to B less $75 which is B's share of the adjustment to the ordinary loss). In addition, the statement shows an increase to B's share of long-term capital loss in the amount of $75 (B's share of the adjustment that did not result in the imputed underpayment with respect to Partnership). B must pay the additional reporting year tax as determined in accordance with paragraph (b) of this section. B computes his additional reporting year tax as follows. First, B determines the correction amount for the first affected year (the 2020 taxable year) by taking into account B's share of the partnership adjustments (a $75 reduction in ordinary loss and an increase of $75 in long-term capital loss) for the 2020 taxable year. B determines the amount by which his chapter 1 tax for 2020 would have increased or decreased if the $75 adjustment to ordinary loss and the $75 adjustment to long-term capital loss from Partnership were taken into account for that year. Second, B determines if there is any increase or decrease in chapter 1 tax for any intervening year as a result of the adjustment to the ordinary and capital losses for 2020. B's aggregate of the correction amounts is the correction amount for 2020, B's first affected year plus any correction amounts for any intervening years. B is also liable for any interest on the correction amount for the first affected year and for any intervening year as determined in accordance with paragraph (c) of this section.

Example 3. On its partnership return for the 2020 tax year, Partnership, a domestic partnership, reported U.S. source dividend income of $2,000. On June 1, 2023, the IRS mails an FPA to Partnership for Partnership's

2020 year increasing the amount of U.S. source dividend income to $4,000 and determining that a 20 percent accuracy-related penalty under section 6662(b) applies to the increase in U.S. source dividend income. Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA for Partnership's 2020 year and does not file a petition for readjustment under section 6234. The time to file a petition expires on August 30, 2023. Pursuant to § 301.6226–2(b), the partnership adjustments become finally determined on August 31, 2023. On September 30, 2023, Partnership files the statements described under § 301.6226–2 with the IRS and furnishes to partner C, a nonresident alien individual who was a partner in Partnership during 2020 (and remains a partner in Partnership in 2023), a statement described in § 301.6226–2. C had a 50 percent interest in Partnership during all of 2020 and was allocated 50 percent of all items from Partnership for that year. The statement shows C's share of U.S. source dividend income reported on Partnership's return for the reviewed year of $1,000 and an adjustment to U.S. source dividend income of $1,000. In addition, the statement reports that a 20 percent accuracy-related penalty under section 6662(b) applies. Under § 301.6241–7(b)(4)(i), because the additional $1,000 in U.S. source dividend income allocated to C is an amount subject to withholding (as defined in § 301.6241–7(b)(2)), Partnership must pay the amount of tax required to be withheld on the adjustment. See §§ 1.1441–1(b)(1) and 1.1441–5(b)(2)(i)(A) of this chapter. Under § 301.6241–7(b)(4)(ii), Partnership may reduce the amount of withholding tax it must pay because it has valid documentation from 2020 that establishes that C was entitled to a reduced rate of withholding in 2020 on U.S. source dividend income of 10 percent pursuant to a treaty. Partnership withholds $100 of tax from C's distributive share, remits the tax to the IRS, and files the necessary return and information returns required by § 1.1461–1 of this chapter. On his 2023 return, C must report the additional reporting year tax determined in accordance with paragraph (b) of this section, the accuracy-related penalty determined in accordance with paragraph (d) of this section, and interest determined in accordance with paragraph (c) of this section on the correction amount for the first affected year, the correction amount for any intervening year, and the penalty. Under paragraph (f) of this section, C may claim the $100 withholding tax paid by Partnership pursuant to § 301.6241–7(b)(4)(i) as a credit under section 33 against C's income tax liability on his 2023 return.

Example 4. On its partnership return for the 2020 tax year, Partnership reported ordinary income of $100 and a long-term capital gain of $40. Partnership had four equal partners during the 2020 tax year: E, F, G, and H, all of whom were individuals. On its partnership return for the 2020 tax year, the entire long-term capital gain was allocated to partner E and the ordinary income was allocated to all partners based on their equal (25 percent) interest in Partnership. The IRS initiates an administrative proceeding with respect to Partnership's 2020 taxable year and determines that the long-term capital gain should have been allocated equally to all four partners and that Partnership should have recognized an additional $10 in ordinary income. On June 1, 2023, the IRS mails an FPA to Partnership reflecting the reallocation of the $40 long-term capital gain so that F, G, and H each have $10 increase in long-term capital gain and E has a $30 reduction in long-term capital gain for 2020. In addition, the FPA reflects the partnership adjustment increasing ordinary income by $10. The FPA reflects a general imputed underpayment with respect to the increase in ordinary income and a specific imputed underpayment with respect to the increase in long-term capital gain allocated to F, G, and H. In addition, the FPA reflects a $30 partnership adjustment that does not result in an imputed underpayment, that is, the reduction of $30 in long-term capital gain with respect to E that is associated with the specific imputed underpayment in accordance with § 301.6225–1(g)(2)(iii)(B). Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the specific imputed underpayment relating to the reallocation of long-term capital gain. Partnership does not file a petition for readjustment under section 6234. The time to file a petition expires on August 30, 2023. Pursuant to § 301.6226–2(b), the partnership adjustments become finally determined on August 31, 2023. Partnership timely pays and reports the general imputed underpayment relating to the partnership adjustment to ordinary income. On September 30, 2023, Partnership files with the IRS statements described in § 301.6226–2 and furnishes statements to its partners reflecting their share of the partnership adjustments as finally determined in the FPA that relate to the specific imputed underpayment, that is, the reallocation of long-term capital gain. The statements for F, G, and H each reflect a partnership adjustment of an additional $10 of long-term capital gain for 2020. The statement for E reflects a partnership adjustment of a reduction of $30 of long-term capital gain for 2020. All partners must report the additional reporting year tax as determined in accordance with paragraph (b) of this section in the partners' reporting year, which is 2023. They compute their additional reporting year tax as follows. First, they determine the correction amount for the first affected year (the 2020 taxable year) by taking into account their share of the partnership adjustments for the 2020 taxable year. They each determine the amount by which their chapter 1 tax for 2020 would have increased or decreased if the adjustment to long-term capital gain from Partnership were taken into account for that year. Second, they determine if there is any increase or decrease in chapter 1 tax for any intervening year as a result of the adjustment to the long-term capital gain for 2020. Their aggregate of the correction amounts is the sum of the correction amount for 2020, their first affected year and any correction amounts for any intervening years. They are also liable for any interest on the correction amount for the first affected year and for any intervening year as determined in accordance with paragraph (c) of this section.

Example 5. On its partnership return for the 2020 taxable year, Partnership reported a long-term capital loss of $500. During an administrative proceeding with respect to Partnership's 2020 taxable year, the IRS mails a notice of proposed partnership adjustment (NOPPA) in which it proposes to disallow $200 of the reported $500 long-term capital loss, the only adjustment. Accordingly, the imputed underpayment reflected in the NOPPA is $80 ($200 × 40 percent). F, a C corporation partner with a 50 percent interest in Partnership, received 50 percent of all long-term capital losses for 2020. As part of the modification process described in § 301.6225–2(d)(2), F files an amended return for 2020 taking into account F's share of the partnership adjustment ($100 reduction in long-term capital loss) and pays the tax owed for 2020, including interest. Also as part of the modification process, F also files amended returns for 2021 and 2022 and pays additional tax (and interest) for these years because the reduction in long-term capital loss for 2020 affected the tax due from F for 2021 and 2022. See § 301.6225–2(d)(2). The reduction of the long-term capital loss in 2020 did not affect any other taxable year of F. This is the only modification requested. The IRS approves the modification with respect to F and on June 1, 2023, mails an FPA to Partnership for Partnership's 2020 year reflecting the partnership adjustment reducing the long-term capital loss in the amount of $200. The FPA also reflects the modification to the imputed underpayment based on the amended returns filed by F taking into account F's share of the reduction in the long-term capital loss. Therefore, the imputed underpayment in the FPA is $40 ($100 × 40 percent). Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA for Partnership's 2020 year and files a timely petition in the Tax Court challenging the partnership adjustments. The Tax Court upholds the determinations in the FPA and the decision regarding Partnership's 2020 tax year becomes final on December 15, 2025. Pursuant to § 301.6226–2(b), the partnership adjustments are finally determined on December 15, 2025. On February 1, 2026, Partnership files the statements described under § 301.6226–2 with the IRS and furnishes to its partners statements reflecting their shares of the partnership adjustment. The statement issued to F reflects F's share of the partnership adjustment for Partnership's 2020 taxable year as finally determined by the Tax Court. The statement shows F's share of the long-term capital loss adjustment for the reviewed year of $100, as well as the $100 long-term capital loss taken into account by F as part of the amended return modification. Accordingly, in accordance with paragraph (b) of this section, when F computes its correction amounts for the first affected year (the 2020 taxable year) and the intervening years (the 2021 through 2026 taxable years), F computes any increase

or decrease in chapter 1 tax for those years using the returns for the 2020, 2021, and 2022 taxable years as amended during the modification process.

Example 6. Partnership has two equal partners for the 2020 tax year: I (an individual) and J (a partnership). For the 2020 tax year, J has two equal partners—K and L—both individuals. On June 1, 2023, the IRS mails an FPA to Partnership for Partnership's 2020 year increasing Partnership's ordinary income by $500,000 and asserting an imputed underpayment of $200,000. Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA for Partnership's 2020 year and does not file a petition for readjustment under section 6234. The time to file a petition expires on August 30, 2023. Pursuant to § 301.6226–2(b), the partnership adjustments become finally determined on August 31, 2023. Therefore, Partnership's adjustment year is 2023, the due date of the adjustment year return is March 15, 2024 and the extended due date for the adjustment year return is September 16, 2024. On October 12, 2023, Partnership timely files with the IRS statements described in § 301.6226–2 and timely furnishes statements to its partners reflecting their share of the partnership adjustments as finally determined in the FPA. The statements to I and J each reflect a partnership adjustment of $250,000 of ordinary income. I takes its share of the adjustments reflected on the statements furnished by Partnership into account on I's return for the 2023 tax year in accordance with paragraph (b) of this section. On April 1, 2024, J files the adjustment tracking report and files and furnishes statements to K and L reflecting each partner's share of the adjustments reflected on the statements Partnership furnished to J. K and L must take their share of adjustments reflected on the statements furnished by J into account on their returns for the 2023 tax year in accordance with paragraph (b) of this section by treating themselves as reviewed year partners for purposes of that paragraph.

Example 7. On its partnership return for the 2020 tax year, Partnership reported that it placed Asset, which had a depreciable basis of $210,000, into service in 2020 and depreciated Asset over 5 years, using the straight-line method. Accordingly, Partnership claimed depreciation of $42,000 in each year related to Asset. Partnership has two equal partners for the 2020 tax year: M (a partnership) and N (an S corporation). For the 2020 tax year, N has one shareholder, O, who is an individual. On June 1, 2023, the IRS mails an FPA to Partnership for Partnership's 2020 year. In the FPA, the IRS determines that Asset should have been depreciated over 7 years instead of 5 years and adjusts the depreciation for the 2020 tax year to $30,000 instead of $42,000 resulting in a $12,000 adjustment. This adjustment results in an imputed underpayment of $4,800 ($12,000 × 40 percent). Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA for Partnership's 2020 year and does not file a petition for readjustment under section 6234. The time to file a petition expires on August 30, 2023. Pursuant to § 301.6226–2(b), the partnership adjustments become finally determined on August 31, 2023. On October 12, 2023, Partnership timely files with the IRS statements described in § 301.6226–2 and furnishes statements to its partners reflecting their share of the partnership adjustments as finally determined in the FPA. The statements to M and N reflect a partnership adjustment of $6,000 of ordinary income for the 2020 tax year. On February 1, 2024, N takes the adjustments into account under paragraph (e)(3) of this section by filing an adjustment tracking reporting and issuing a statement to O reflecting her share of the adjustments reported to N on the statement it received from Partnership. M does not furnish statements and instead chooses to calculate and pay an imputed underpayment under paragraph (e)(4) of this section equal to $1,200 ($6,000 × 40 percent) on the adjustments reflected on the statement it received from Partnership plus interest on the amount calculated in accordance with paragraph (e)(4)(iv)(B) of this section. On her 2023 return, O properly takes the adjustments into account under this section. Therefore, O reports and pays the additional reporting year tax determined in accordance with paragraph (b) of this section, which is the correction amount for 2020 plus any correction amounts for 2021 and 2022 (if the adjustments in 2020 resulted in any changes to the tax attributes of O in those years), and pays interest determined in accordance with paragraph (c) of this section on the correction amounts for each of those years.

Example 8. On its partnership return for the 2020 tax year, Partnership reported $1,000 of ordinary loss. Partnership has two equal partners for the 2020 tax year: P and Q, both S corporations. For the 2020 tax year, P had one shareholder, R, an individual. For the 2020 tax year, Q had two shareholders, S and T, both individuals. On June 1, 2023, the IRS mails an FPA to Partnership for Partnership's 2020 year determining $500 of the $1,000 of ordinary loss should be recharacterized as $500 of long-term capital loss and $500 of the ordinary loss should be disallowed. The FPA asserts an imputed underpayment of $400 ($1,000 × 40 percent) with respect to the $1,000 reduction to ordinary loss and reflecting an adjustment that does not result in an imputed underpayment of a $500 capital loss. Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA for Partnership's 2020 year and does not file a petition for readjustment under section 6234. The time to file a petition expires on August 30, 2023. Pursuant to § 301.6226–2(b), the partnership adjustments become finally determined on August 31, 2023. On October 12, 2023, Partnership timely files with the IRS statements described in § 301.6226–2 and furnishes statements to its partners reflecting their share of the partnership adjustments as finally determined in the FPA. The statements to P and Q each reflect a partnership adjustment of a $500 increase in ordinary income and a $250 increase in capital loss in accordance with § 301.6225–3(b)(6). P takes the adjustments into account under paragraph (e)(3) of this section by timely filing an adjustment tracking reporting and furnishing a statement to R. Q timely filed an adjustment tracking report but chooses not to furnish statements and instead must calculate and pay an imputed underpayment under paragraph (e)(4) of this section as well as interest on the imputed underpayment determined under paragraph (e)(4)(iv)(B) of this section on the imputed underpayment. After applying the rules set forth in § 301.6225–1, Q calculates the imputed underpayment that it is required to pay of $200 ($500 adjustment to ordinary income × 40 percent). Q also has one adjustment that does not result in an imputed underpayment—the $250 increase to capital loss. On its 2023 return, Q reports and allocates the $250 capital loss to its shareholders for its 2023 taxable year as a capital loss as provided in § 301.6225–3. Q must file the adjustment tracking report and pay the amounts due under paragraph (e)(4) of this section no later than September 15, 2024, the extended due date of Partnership's return for the 2023 year, which is the adjustment year.

Example 9. On its partnership return for the 2020 tax year, Partnership reported a $1,000 long-term capital gain on the sale of Stock. Partnership has two equal partners for the 2020 tax year: U (an individual) and V (a partnership). For the 2020 tax year, V has two equal partners: W (an individual) and X (a partnership). For the 2020 tax year, X has two equal partners: Y and Z, both of which are C corporations. On June 1, 2023, the IRS mails a NOPPA to Partnership for Partnership's 2020 year proposing a $500 increase in the long-term capital gain from the sale of Stock and an imputed underpayment of $200 ($500 × 40 percent). On July 17, 2023, Partnership timely submits a request to modify the rate used in calculating the imputed underpayment under § 301.6225–2(d)(4). Partnership submits sufficient information demonstrating that $375 of the $500 adjustment is allocable to individuals (50 percent of the $500 adjustment allocable to U and 25 percent of the $500 adjustment allocable to W) and the remaining $125 is allocable to C corporations (the indirect partners Y and Z). The IRS approves the modification and the imputed underpayment is reduced to $81.25 (($375 × 15 percent) + ($125 × 20 percent)). See § 301.6225–2(b)(3). No other modifications are requested. On February 28, 2024, the IRS mails an FPA to Partnership for Partnership's 2020 year determining a $500 increase in the long-term capital gain on the sale of Stock and asserting an imputed underpayment of $81.25 after taking into account the approved modifications. Partnership makes a timely election under section 6226 in accordance with § 301.6226–1 with respect to the imputed underpayment in the FPA for Partnership's 2020 year and does not file a petition for readjustment under section 6234. The time to file a petition expires on May 28, 2024. Pursuant to § 301.6226–2(b), the partnership adjustments become finally determined on May 29, 2024. On July 26, 2024, Partnership timely files with the IRS

statements described in § 301.6226–2 and furnishes statements to its partners reflecting their share of the partnership adjustments as finally determined in the FPA. The statements to U and V each reflect a partnership adjustment of a $250 increase in long-term capital gain. V timely files the adjustment tracking report but fails to furnish statements and therefore must calculate and pay an imputed underpayment under paragraph (e)(4) of this section as well as interest on the imputed underpayment determined under paragraph (e)(4)(iv)(B) of this section. On February 3, 2025, V pays an imputed underpayment of $43.75 (($125 × 20 percent for the adjustments allocable to X) + ($125 × 15 percent for the adjustments allocable to W)) which takes into account the rate modifications approved by the IRS with respect to Y and Z. V must also pay any interest on the amount as determined in accordance with paragraph (e)(4)(iv)(B) of this section. V must file the adjustment tracking report and pay the amounts due under paragraph (e)(4) of this section no later than September 15, 2025, the extended due date of Partnership's return for the 2024 year, which is the adjustment year.

(i) *Applicability date*—(1) *In general.* Except as provided in paragraph (i)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015, and before January 1, 2018, for which a valid election under § 301.9100–22 is in effect.

■ **Par. 15.** Section 301.6226–4 is added to read as follows:

§ 301.6226–4 Effect of a partnership adjustment on tax attributes of partnerships and their partners.

(a) *Adjustments to tax attributes*—(1) *In general.* When a partnership adjustment (as defined in § 301.6241–1(a)(6)) is taken into account by the reviewed year partners (as defined in § 301.6241–1(a)(9)) or affected partners (as described in § 301.6226–3(e)(3)(i)) pursuant to an election made by a partnership under § 301.6226–1, the partnership and its reviewed year partners or affected partners must adjust their tax attributes (as defined in § 301.6241–1(a)(10)) in accordance with the rules in this section.

(2) *Application to pass-through partners and indirect partners.* To the extent a pass-through partner (as defined in § 301.6241–1(a)(5)) pays an imputed underpayment under § 301.6226–3(e)(4)(iii), such pass-through partner and its affected partners or their successors must make adjustments to their tax attributes in accordance with the rules in § 301.6225–4.

(3) *Allocation of partnership adjustments.* Partnership adjustments are allocated to the reviewed year partners or affected partners under § 1.704–1(b)(4)(xiv) of this chapter.

(b) *Adjusting tax attributes of a partnership and its partners when an election under section 6226 is made.* For partnership adjustments that are taken into account by the reviewed year partners or affected partners because an election is made under § 301.6226–1, the partnership adjustments to be taken into account by each partner are determined under § 301.6226–2(f). Accordingly, the reviewed year partners or affected partners must take into account the partnership adjustments as reflected on the statements described in § 301.6226–2 or § 301.6226–3(e)(3) in accordance with § 301.6226–3. The reviewed year partners or affected partners and the partnership adjust partnership tax attributes affected by reason of an adjustment reflected on the statements described in § 301.6226–2 or § 301.6226–3(e)(3) with respect to the reviewed year (as defined in § 301.6241–1(a)(8)), except to the extent partner or partnership tax attributes were already adjusted as part of the partnership adjustment. Additionally, reviewed year partners or affected partners adjust their partner tax attributes that are affected by the adjustments reflected on the statements described in § 301.6226–2 or § 301.6226–3(e)(3), but these adjustments to partner tax attributes are calculated with respect to each year beginning with the first affected year (as defined in § 301.6226–3(b)(2)(i)), followed by any intervening years (as defined in § 301.6226–3(b)(3)(i)), concluding with the reporting year (as defined in § 301.6226–3(a)).

(c) *Example.* The following example illustrates the rules of this section. For purposes of this example, Partnership is subject to the provisions of subchapter C of chapter 63 of the Internal Revenue Code, Partnership and its partners are calendar year taxpayers, all partners are U.S. persons, and the highest rate of income tax in effect for all taxpayers is 40 percent for all relevant periods.

Example. (i) In 2021, J, K and L form Partnership by each contributing $500 in exchange for partnership interests that share all items of income, gain, loss and deduction in identical shares. Partnership immediately purchases Asset on January 1, 2021 for $1,500, which it depreciates using the straight-line method with a 10-year recovery period beginning in 2021 ($150) so that each partner has a $50 distributive share of the depreciation, resulting in an outside basis of $450 for each partner. Accordingly, at the end of 2022, J, K and L have an outside basis and capital account of $400 each ($500 less $50 of their respective allocable shares of depreciation in 2021 and $50 in 2022).

	Partnership basis	Book	Value		Outside basis	Book	Value
Asset	$1200	$1200	$1500	J	$400	$400	$500
	.....	.....	.....	K	400	400	500
	.....	.....	.....	L	400	400	500
Totals	1200	1200	1500	.....	1200	1200	1500

(ii) The IRS initiates an administrative proceeding with respect to Partnership's 2021 taxable year (reviewed year) and in 2023 (adjustment year) finally determines that Asset should have been depreciated with a 20-year recovery period beginning in 2021, resulting in a $75 partnership adjustment that results in an imputed underpayment. The IRS does not initiate an administrative proceeding with respect to Partnership's 2022 taxable year, and Partnership does not file an administrative adjustment request for that taxable year. Partnership makes an election under § 301.6226–1 with respect to the imputed underpayment. Therefore, J, K and L each are furnished a statement described in § 301.6226–2 by Partnership reflecting the $25 income adjustment for 2021.

(iii) Tax attributes of the partners must be adjusted to reflect the $75 partnership adjustment reflected on the statements described in § 301.6226–2 that is taken into account in equal shares ($25) by J, K, and L with respect to 2021. Specifically, J, K and L's outside bases and capital accounts must be increased $25 each with respect to the 2021 tax year. As a result, J, K and L each have an outside basis and capital account of $425 ($400 plus $25 of income realized with respect to 2021). Asset's basis and book value must also be changed in 2023. Thus, after adjusting tax attributes of the partners to take into account the election under § 301.6226–1 and taking into account other activities of Partnership in 2023, accounts are stated as follows:

	Partnership basis	Book	Value		Outside basis	Book	Value
Asset	$1275	$1275	$1500	J	$425	$425	$500
	.....	.....	.....	K	425	425	500
	.....	.....	.....	L	425	425	500
Totals	1275	1275	1500	.....	1275	1275	1500

(d) *Applicability date*—(1) *In general.* Except as provided in paragraph (d)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 16.** Section 301.6227–1 is added to read as follows:

§ 301.6227–1 Administrative adjustment request by partnership.

(a) *In general.* A partnership may file a request for an administrative adjustment with respect to any partnership-related item (as defined in § 301.6241–6) for any partnership taxable year. When filing an administrative adjustment request (AAR), the partnership must determine whether the adjustments requested in the AAR result in an imputed underpayment in accordance with § 301.6227–2(a) for the reviewed year (as defined in § 301.6241–1(a)(8)). If the adjustments requested in the AAR result in an imputed underpayment, the partnership must take the adjustments into account under the rules described in § 301.6227–2(b) unless the partnership makes an election under § 301.6227–2(c), in which case each reviewed year partner (as defined in § 301.6241–1(a)(9)) must take the adjustments into account in accordance with § 301.6227–3. If the adjustments requested in the AAR do not result in an imputed underpayment (as determined under § 301.6227–2(a)), such adjustments must be taken into account by the reviewed year partners in accordance with § 301.6227–3. A partner may not file an AAR except if the partner is doing so on behalf of the partnership in the partner's capacity as the partnership representative designated under section 6223. In addition, a partnership may not file an AAR solely for the purpose of changing the designation of a partnership representative or changing the appointment of a designated individual. See § 301.6223–1 (regarding designation of the partnership representative). When the partnership changes the designation of the partnership representative (or appointment of the designated individual) in conjunction with the filing of an AAR in accordance with § 301.6223–1(e), the change in designation (or appointment) is treated as occurring prior to the filing of the AAR.

(b) *Time for filing an AAR.* An AAR may only be filed by a partnership with respect to a partnership taxable year after a partnership return for that taxable year has been filed with the Internal Revenue Service (IRS). A partnership may not file an AAR with respect to a partnership taxable year more than three years after the later of the date the partnership return for such partnership taxable year was filed or the last day for filing such partnership return (determined without regard to extensions). Except as provided in § 301.6231–1(f), an AAR may not be filed for a partnership taxable year after a notice of administrative proceeding with respect to such taxable year has been mailed by the IRS under section 6231.

(c) *Form and manner for filing an AAR*—(1) *In general.* An AAR, including any required statements, forms, and schedules as described in this section, must be filed with the IRS in accordance with the forms, instructions, and other guidance prescribed by the IRS, and must be signed under penalties of perjury by the partnership representative (as defined in section 6223(a) and the regulations thereunder).

(2) *Contents of AAR filed with the IRS.* A valid AAR filed with the IRS must include—

(i) The adjustments requested,

(ii) If a reviewed year partner is required to take into account the adjustments requested under § 301.6227–3, statements described in paragraph (e) of this section, including any transmittal with respect to such statements required by forms, instructions, and other guidance prescribed by the IRS, and

(iii) Other information prescribed by the IRS in forms, instructions, or other guidance.

(d) *Copy of statement furnished to reviewed year partners in certain cases.* If a reviewed year partner is required to take into account adjustments requested in an AAR under § 301.6227–3, the partnership must furnish a copy of the statement described in paragraph (e) of this section to the reviewed year partner to whom the statement relates in accordance with the forms, instructions and other guidance prescribed by the IRS. If the partnership mails the statement, it must mail the statement to the current or last address of the reviewed year partner that is known to the partnership. The statement must be furnished to the reviewed year partner on the date the AAR is filed with the IRS.

(e) *Statements*—(1) *Contents.* Each statement described in this paragraph (e) must include the following correct information:

(i) The name and TIN of the reviewed year partner to whom the statement is being furnished;

(ii) The current or last address of the partner that is known to the partnership;

(iii) The reviewed year partner's share of items as originally reported on statements furnished to the partner under section 6031(b) and, if applicable, section 6227;

(iv) The reviewed year partner's share of the adjustments as described under paragraph (c)(2) of this section;

(v) The date the statement is furnished to the partner;

(vi) The partnership taxable year to which the adjustments relate; and

(vii) Any other information required by forms, instructions, and other guidance prescribed by the IRS.

(2) *Determination of each partner's share of adjustments*—(i) *In general.* Except as provided in paragraphs (e)(2)(ii) and (iii) of this section, each reviewed year partner's share of the adjustments requested in the AAR is determined in the same manner as each adjusted partnership-related item was originally allocated to the reviewed year partner on the partnership return for the reviewed year.

(ii) *Adjusted partnership-related item not reported on the partnership's return for the reviewed year.* Except as provided in paragraph (e)(2)(iii) of this section, if the adjusted partnership-related item was not reported on the partnership return for the reviewed year, each reviewed year partner's share

of the adjustments must be determined in accordance with how such items would have been allocated under rules that apply with respect to partnership allocations, including under the partnership agreement.

(iii) *Allocation adjustments.* If an adjustment involves allocation of a partnership-related item to a specific partner or in a specific manner, including a reallocation of an item, the reviewed year partner's share of the adjustment requested in the AAR is determined in accordance with the AAR.

(f) *Binding nature of AAR.* Filing an AAR as described in paragraph (c) of this section and furnishing statements as described in paragraph (d) of this section are actions of the partnership under section 6223 and the regulations thereunder. Accordingly, unless determined otherwise by the IRS, each partner's share of the adjustments set forth in a statement described in paragraph (e) of this section are binding on the partner pursuant to section 6223. A partner may not treat partnership-related items on the partner's return inconsistently with how those items are treated on the statement that is filed with the IRS under paragraph (c) of this section. See § 301.6222–1(c)(2) (regarding partnership-related items the treatment of which a partner is bound to under section 6223).

(g) *Administrative proceeding for a taxable year for which an AAR is filed.* Within the period described in section 6235 and the regulations thereunder, the IRS may initiate an administrative proceeding with respect to the partnership for any partnership taxable year regardless of whether the partnership filed an AAR with respect to such taxable year and may adjust any partnership-related item, including any partnership-related item adjusted in an AAR filed by the partnership. The amount of an imputed underpayment determined by the partnership under § 301.6227–2(a)(1), including any modifications determined by the partnership under § 301.6227–2(a)(2), may be re-determined by the IRS.

(h) *Notice of change to the amount of creditable foreign tax expenditures.* [Reserved]

(i) *Applicability date*—(1) *In general.* Except as provided in paragraph (i)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 17.** Section 301.6227–2 is added to read as follows:

§ 301.6227–2 Determining and accounting for adjustments requested in an administrative adjustment request by the partnership.

(a) *Determining whether adjustments result in an imputed underpayment*—(1) *Determination of the imputed underpayment.* The determination of whether adjustments requested in an administrative adjustment request (AAR) result in an imputed underpayment in the reviewed year (as defined in § 301.6241–1(a)(8)) and the determination of the amount of the imputed underpayment, if any, is made in accordance with the rules under § 301.6225–1.

(2) *Modification of imputed underpayment for purposes of this section.* A partnership may apply modifications to the amount of the imputed underpayment determined under paragraph (a)(1) of this section using only the provisions under § 301.6225–2(d)(3) (regarding tax-exempt partners), § 301.6225–2(d)(4) (regarding modification of applicable tax rate), § 301.6225–2(d)(5) (regarding specified passive activity losses), § 301.6225–2(d)(6)(ii) (regarding limitations or restrictions in the grouping of adjustments), § 301.6225–2(d)(7) (regarding certain qualified investment entities), § 301.6225–2(d)(9) (regarding tax treaty modifications), or as provided in forms, instructions, or other guidance prescribed by the IRS with respect to AARs. The partnership may not modify an imputed underpayment resulting from adjustments requested in an AAR except as described in this paragraph (a)(2). When applying modifications to the amount of an imputed underpayment under this paragraph (a)(2):

(i) The partnership is not required to seek the approval from the Internal Revenue Service (IRS) prior to applying modifications to the amount of any imputed underpayment under paragraph (a)(1) of this section reported on the AAR; and

(ii) As part of the AAR filed with the IRS in accordance with forms, instructions, and other guidance prescribed by the IRS, the partnership must—

(A) Notify the IRS of any modification,

(B) Describe the effect of the modification on the imputed underpayment,

(C) Provide an explanation of the basis for such modification, and

(D) Provide documentation to support the partnership's eligibility for the modification.

(b) *Adjustments resulting in an imputed underpayment taken into account by the partnership*—(1) *In general.* Except in the case of an election under paragraph (c) of this section, a partnership must pay any imputed underpayment (as determined under paragraph (a) of this section) resulting from the adjustments requested in an AAR on the date the partnership files the AAR. For the rules applicable to the partnership's expenditure for the imputed underpayment, as well as any penalties and interest paid by the partnership with respect to the imputed underpayment, see § 301.6241–4.

(2) *Penalties and interest.* The IRS may impose a penalty, addition to tax, and additional amount with respect to an imputed underpayment determined under this section in accordance with section 6233(a)(3) (penalties determined from the reviewed year). In addition, the IRS may impose a penalty, addition to tax, and additional amount with respect to a failure to pay an imputed underpayment on the date an AAR is filed in accordance with section 6233(b)(3) (penalties with respect to the adjustment year return). Interest on the imputed underpayment is determined under chapter 67 for the period beginning on the date after the due date of the partnership return for the reviewed year (as defined in § 301.6241–1(a)(8)) (determined without regard to extension) and ending on the earlier of the date payment of the imputed underpayment is made, or the due date of the partnership return for the adjustment year (as defined in § 301.6241–1(a)(1)). See section 6233(a)(2). In the case of any failure to pay an imputed underpayment by the due date of the partnership return for the adjustment year, interest is determined in accordance with section 6233(b)(2).

(3) *Coordination with chapters 3 and 4*—(i) *Coordination when partnership pays an imputed underpayment.* If a partnership pays an imputed underpayment resulting from adjustments requested in an AAR under paragraph (b)(1) of this section, the rules in § 301.6241–7(b)(3) apply to treat the partnership as having paid the amount required to be withheld under chapter 3 or chapter 4 (as defined in § 301.6241–7(b)(2)).

(ii) *Coordination when partnership elects to have adjustments taken into account by reviewed year partners.* If a partnership elects under paragraph (c) of this section to have its reviewed year partners take into account adjustments

requested in an AAR, the rules in § 301.6226–2(g)(3) apply to the partnership, and the rules in § 301.6226–3(f) apply to the reviewed year partners that take into account the adjustments pursuant to § 301.6227–3.

(c) *Election to have adjustments resulting in an imputed underpayment taken into account by reviewed year partners.* In lieu of paying the imputed underpayment under paragraph (b) of this section, the partnership may elect to have each reviewed year partner (as defined in § 301.6241–1(a)(9)) take into account the adjustments requested in the AAR in accordance with § 301.6227–3. A partnership makes an election under this paragraph (c) at the time the AAR is filed in accordance with the forms, instructions, and other guidance prescribed by the IRS. If the partnership makes a valid election in accordance with this paragraph (c), the partnership is not liable for, nor required to pay, the imputed underpayment resulting from the adjustments requested in the AAR. Rather, each reviewed year partner must take into account their share of the adjustments requested in the AAR in accordance with § 301.6227–3. If an election is made under this paragraph (c), modifications applied under paragraph (a)(2) of this section are disregarded and all adjustments requested in the AAR must be taken into account by each reviewed year partner in accordance with § 301.6227–3.

(d) *Adjustments not resulting in an imputed underpayment.* If the adjustments requested in an AAR do not result in an imputed underpayment (as determined under paragraph (a) of this section), the partnership must furnish statements to each reviewed year partner and file such statements with the IRS in accordance with § 301.6227–1. Each reviewed year partner must take into account its share of the adjustments requested in the AAR in accordance with § 301.6227–3.

(e) *Applicability date*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 18.** Section 301.6227–3 is added to read as follows:

§ 301.6227–3 Adjustments requested in an administrative adjustment request taken into account by reviewed year partners.

(a) *In general.* Each reviewed year partner (as defined in § 301.6241–1(a)(9)) is required to take into account its share of adjustments requested in an administrative adjustment request (AAR) if the partnership makes an election under § 301.6227–2(c) with respect to such AAR. In addition, each reviewed year partner must take into account its share of adjustments requested in an AAR that do not result in an imputed underpayment (as defined in § 301.6241–1(a)(3)) as determined under § 301.6227–2(a). Each reviewed year partner receiving a statement furnished in accordance with § 301.6227–1(d) must take into account adjustments reflected in the statement in the reviewed year partner's taxable year that includes the date the statement is furnished (reporting year) in accordance with paragraph (b) of this section.

(b) *Adjustments taken into account by the reviewed year partner in the reporting year*—(1) *In general.* Except as provided in paragraph (c) of this section, a reviewed year partner that is furnished a statement described in paragraph (a) of this section must treat the statement as if it were issued under section 6226(a)(2) and, on or before the due date for the reporting year must report and pay the additional reporting year tax (as defined in § 301.6226–3(a)), if any, determined after taking into account that partner's share of the adjustments requested in the AAR in accordance with § 301.6226–3. A reviewed year partner may, in accordance with § 301.6226–3(a), reduce chapter 1 tax for the reporting year where the additional reporting year tax is less than zero. For purposes of paragraph (b) of this section, the rule under § 301.6226–3(c)(3) (regarding the increased rate of interest) does not apply. Nothing in this section entitles any partner to a refund of tax imposed by chapter 1 of subtitle A of the Internal Revenue Code (chapter 1 tax) to which such partner is not entitled. For instance, a partnership-partner (as defined in § 301.6241–1(a)(7)) may not claim a refund with respect to its share of any adjustment.

(2) *Examples.* The following examples illustrate the rules of this paragraph (b).

Example 1. In 2022, partner A, an individual, received a statement described in paragraph (a) of this section from Partnership with respect to Partnership's 2020 taxable year. Both A and Partnership are calendar year taxpayers and A is not claiming any refundable tax credit in 2020. The only adjustment shown on the statement is an increase in ordinary loss. Taking into account the adjustment, A determines that his additional reporting year tax for 2022 (the reporting year) is <$100> (that is, a reduction of $100.) A's chapter 1 tax for 2022 (without regard to any additional reporting year tax) is $150. Applying the rules in paragraph (b)(2) of this section, A's chapter 1 tax for 2022 is reduced to $50 ($150 chapter 1 tax without regard to the additional reporting year tax plus <$100> additional reporting year tax).

Example 2. The facts are the same as in *Example 1* of this paragraph (b)(2), except A's chapter 1 tax for 2022 (without regard to any additional reporting year tax) is $75. Applying the rules in paragraph (b)(1) of this section, A's chapter 1 tax for 2022 is reduced by the <$100> of additional reporting year tax. Accordingly, A's chapter 1 tax for 2022 is $0 ($75 chapter 1 tax without regard to any additional reporting year tax plus <$100> of additional reporting year tax), A owes no chapter 1 tax for 2022, and A may make a claim for refund with respect to the overpayment of $25.

(c) *Reviewed year partners that are pass-through partners*—(1) *In general.* Except as provided in this paragraph (c), if a statement described in paragraph (a) of this section (including a statement described in this paragraph (c)(1)) is furnished to a reviewed year partner that is a pass-through partner (as defined in § 301.6241–1(a)(5)), the pass-through partner must take into account the adjustments reflected on that statement in accordance with § 301.6226–3(e) by treating the partnership that filed the AAR as the partnership that made an election under § 301.6226–1. A pass-through partner that furnishes statements in accordance with § 301.6226–3(e)(3) must provide the information described in paragraph (c)(3) of this section in lieu of the information described in § 301.6226–3(e)(3)(iii) on the statements the pass-through partner furnishes to its partners. A pass-through partner that computes and pays an imputed underpayment in accordance with § 301.6226–3(e)(4)(iii) may not apply any modifications to the amount of imputed underpayment. For purposes of this paragraph (c)(1), the statement furnished to the pass-through partner by the partnership filing the AAR is treated as if it were a statement issued under section 6226(a)(2) and described in § 301.6226–2.

(2) *Adjustments that do not result in an imputed underpayment.* If the adjustments requested in an AAR do not result in an imputed underpayment (as described in § 301.6227–2(d)), § 301.6226–3(e)(2) does not apply. The pass-through partner must take into account the adjustments reflected on the statement described in paragraphs (a) or (c)(1) of this section in accordance with § 301.6226–3(e)(3), except that the pass-

through partner must provide the information described in paragraph (c)(3) of this section in lieu of the information described in § 301.6226–3(e)(3)(iii) on the statements the pass-through partner furnishes to its partners.

(3) *Contents of statements.* Each statement described in paragraph (c)(1) or (2) of this section must include the following correct information—

(i) The name and taxpayer identification number (TIN) of the partnership that filed the AAR with respect to the adjustments reflected on the statements described in paragraph (c)(1) of this section;

(ii) The adjustment year (as defined in § 301.6241–1(a)(1)) of the partnership described in paragraph (c)(3)(i) of this section;

(iii) The extended due date for the return for the adjustment year of the partnership described in paragraph (c)(3)(i) of this section (as described in § 301.6226–3(e)(3)(ii));

(iv) The date on which the partnership described in paragraph (c)(3)(i) of this section furnished its statements required under § 301.6227–2(d);

(v) The name and TIN of the partnership that furnished the statement to the pass-through partner if different from the partnership described in paragraph (c)(3)(i) of this section;

(vi) The name and TIN of the pass-through partner;

(vii) The pass-through partner's taxable year to which the adjustments set forth in the statement described in paragraph (c)(1) of this section relate;

(viii) The name and TIN of the affected partner (as defined in § 301.6226–3(e)(3)(i)) to whom the statement is being furnished;

(ix) The current or last address of the affected partner that is known to the pass-through partner;

(x) The affected partner's share of items as originally reported to such partner under section 6031(b) and, if applicable, section 6227, for the taxable year to which the adjustments reflected on the statement furnished to the pass-through partner relate;

(xi) The affected partner's share of partnership adjustments determined under § 301.6227–1(e)(2) as if the affected partner were the reviewed year partner and the partnership were the pass-through partner;

(xii) Any other information required by forms, instructions, and other guidance prescribed by the IRS.

(4) *Affected partners must take into account the adjustments.* A statement furnished to an affected partner in accordance with paragraph (c)(1) or (2) of this section is to be treated by the affected partner as if it were a statement described in paragraph (a) of this section. The affected partner must take into account its share of the adjustments reflected on such a statement in accordance with this section by treating references to ''reviewed year partner'' as ''affected partner.'' When taking into account the adjustments as described in § 301.6226–3(e)(3)(iv), the rules under § 301.6226–3(c)(3) (regarding the increased rate of interest) do not apply.

(d) *Applicability date*—(1) *In general.* Except as provided in paragraph (d)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 19.** Section 301.6231–1 is added to read as follows:

§ 301.6231–1 Notice of proceedings and adjustments.

(a) *Notices to which this section applies.* In the case of any administrative proceeding under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63), including an administrative proceeding with respect to an administrative adjustment request (AAR) filed by a partnership under section 6227, the following notices must be mailed to the partnership and the partnership representative (as described in section 6223 and § 301.6223–1)—

(1) Notice of any administrative proceeding initiated at the partnership level with respect to an adjustment of any partnership-related item (as defined in § 301.6241–6) for any partnership taxable year under subchapter C of chapter 63 (notice of administrative proceeding (NAP));

(2) Notice of any proposed partnership adjustment resulting from an administrative proceeding under subchapter C of chapter 63 (notice of proposed partnership adjustment (NOPPA)); and

(3) Notice of any final partnership adjustment resulting from an administrative proceeding under subchapter C of chapter 63 (notice of final partnership adjustment (FPA)).

(b) *Time for mailing notices*—(1) *Notice of proposed partnership adjustment.* A NOPPA is timely if it is mailed before the expiration of the period for making adjustments under section 6235(a)(1) (including any extensions under section 6235(b) and any special rules under section 6235(c)).

(2) *Notice of final partnership adjustment.* An FPA may not be mailed earlier than 270 days after the date on which the NOPPA is mailed unless the partnership agrees, in writing, with the Internal Revenue Service (IRS) to waive the 270-day period. See § 301.6225–2(c)(3)(iii) for the effect of a waiver under this paragraph (b)(2) on the 270-period for requesting a modification under section 6225(c). See § 301.6232–1(d)(2) for the rules regarding a waiver of the limitations on assessment under § 301.6232–1(c).

(c) *Last known address.* A notice described in paragraph (a) of this section is sufficient if mailed to the last known address of the partnership representative and the partnership (even if the partnership or partnership representative has terminated its existence).

(d) *Notice mailed to partnership representative*—(1) *In general.* A notice described in paragraph (a) of this section will be treated as mailed to the partnership representative if the notice is mailed to the partnership representative that is reflected in the IRS records as of the date the letter is mailed.

(2) *No partnership representative in effect.* In any case in which no partnership representative designation is in effect in accordance with § 301.6223–1(f), a notice described in paragraph (a) of this section mailed to ''PARTNERSHIP REPRESENTATIVE'' at the last known address of the partnership satisfies the requirements of this section.

(e) *Restrictions on additional FPAs after petition filed.* The IRS may mail more than one FPA to any partnership for any partnership taxable year. However, except in the case of fraud, malfeasance, or misrepresentation of a material fact, the IRS may not mail an FPA to a partnership with respect to a partnership taxable year after the partnership has filed a timely petition for readjustment under section 6234 with respect to an FPA issued with respect to such partnership taxable year.

(f) *Withdrawal of NAP or NOPPA.* The IRS may, without consent of the partnership, withdraw any NAP or NOPPA. A NAP or NOPPA that has been withdrawn by the IRS has no effect for purposes of subchapter C of chapter 63. For instance, if the IRS withdraws a NAP with respect to a partnership taxable year, the prohibition under section 6227(c) on filing an AAR after the mailing of a NAP no longer applies with respect to such taxable year.

(g) *Rescission of FPA.* The IRS may, with the consent of the partnership, rescind any FPA. An FPA that is

rescinded is not an FPA for purposes of subchapter C of chapter 63, and the partnership cannot bring a proceeding under section 6234 with respect to such FPA.

(h) *Applicability date*—(1) *In general.* Except as provided in paragraph (h)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 20.** Section 301.6232–1 is added to read as follows:

§ 301.6232–1 Assessment, collection, and payment of imputed underpayment.

(a) *In general.* An imputed underpayment determined under subchapter C of chapter 63 of the Internal Revenue Code (Code) is assessed and collected in the same manner as if the imputed underpayment were a tax imposed by subtitle A of the Code for the adjustment year (as defined in § 301.6241–1(a)(1)) except that the deficiency procedures under subchapter B of chapter 63 of the Code do not apply to an assessment of an imputed underpayment. Accordingly, no notice under section 6212 is required for, and the restrictions under section 6213 do not apply to, the assessment of any imputed underpayment. See paragraph (c) of this section for limitations on assessment and paragraph (d) of this section for exceptions to restrictions on adjustments.

(b) *Payment of the imputed underpayment.* Upon receipt of notice and demand from the Internal Revenue Service (IRS), an imputed underpayment must be paid by the partnership at the place and time stated in the notice. In the case of an adjustment requested in an administrative adjustment request (AAR) under section 6227(b)(1) that is taken into account by the partnership under § 301.6227–2(b), payment of the imputed underpayment is due on the date the AAR is filed. The IRS may assess the amount of the imputed underpayment reflected on the AAR on the date the AAR is filed. For interest with respect to an imputed underpayment, see § 301.6233(a)–1(b).

(c) *Limitation on assessment*—(1) *In general.* Except as otherwise provided by this section or subtitle F of the Code (except for subchapter B of chapter 63), no assessment of an imputed underpayment may be made (and no levy or proceeding in any court for the collection of an imputed underpayment may be made, begun, or prosecuted) before—

(i) The close of the 90th day after the day on which a notice of a final partnership adjustment (FPA) under section 6231(a)(3) was mailed; and

(ii) If a petition for readjustment is filed under section 6234 with respect to such FPA, the decision of the court has become final.

(2) *Specified similar amount.* The limitations under paragraph (c)(1) of this section do not apply in the case of a specified similar amount as defined in section 6232(f)(2).

(d) *Exceptions to restrictions on adjustments and assessments*—(1) *Adjustments treated as mathematical or clerical errors*—(i) *In general.* A notice to a partnership that, on account of a mathematical or clerical error appearing on the partnership return or as a result of a failure by a partnership-partner (as defined in § 301.6241–1(a)(7)) to comply with section 6222(a), the IRS has adjusted or will adjust partnership-related items (as defined in § 301.6241–6) to correct the error or to make the items consistent under section 6222(a) and has assessed or will assess any imputed underpayment (determined in accordance with § 301.6225–1) resulting from the adjustment is not considered an FPA under section 6231(a)(3). A petition for readjustment under section 6234 may not be filed with respect to such notice. The limitations under section 6232(b) and paragraph (c) of this section do not apply to an assessment under this paragraph (d)(1)(i). For the definition of mathematical or clerical error generally, see section 6213(g)(2). For application of mathematical or clerical error in the case of inconsistent treatment by a partner that fails to give notice, see § 301.6222–1(b).

(ii) *Request for abatement*—(A) *In general.* Except as provided in paragraph (d)(1)(ii)(B) of this section, a partnership that is mailed a notice described in paragraph (d)(1)(i) of this section may file with the IRS, within 60 days after the date of such notice, a request for abatement of any assessment of an imputed underpayment specified in such notice. Upon receipt of the request, the IRS must abate the assessment. Any subsequent assessment of an imputed underpayment with respect to which abatement was made is subject to the provisions of subchapter C of chapter 63 of the Code, including the limitations under paragraph (c) of this section.

(B) *Adjustments with respect to inconsistent treatment by a partnership-partner.* If an adjustment that is the subject of a notice described in paragraph (d)(1)(i) of this section is due to the failure of a partnership-partner to comply with section 6222(a), paragraph (d)(1)(ii)(A) of this section does not apply, and abatement of any assessment specified in such notice is not available. However, prior to assessment, a partnership-partner that has failed to comply with section 6222(a) may correct the inconsistency by filing an administrative adjustment request under section 6227 or filing an amended partnership return and furnishing amended statements, as appropriate.

(iii) *Partnerships that have an election under section 6221(b) in effect.* In the case of a partnership-partner that has an election under section 6221(b) in effect for the reviewed year (as defined in § 301.6241–1(a)(8)), any tax resulting from an adjustment due to the partnership-partner's failure to comply with section 6222(a) may be assessed with respect to the reviewed year partners (as defined in § 301.6241–1(a)(9)) of the partnership-partner (or indirect partners of the partnership-partner, as defined in § 301.6241–1(a)(4)). Such tax may be assessed in the same manner as if the tax were on account of a mathematical or clerical error appearing on the reviewed year partner's or indirect partner's return, except that the procedures under section 6213(b)(2) for requesting an abatement of such assessment do not apply.

(2) *Partnership may waive limitations.* A partnership may at any time by a signed notice in writing filed with the IRS waive the limitations under paragraph (c) of this section (whether or not an FPA under section 6231(a)(3) has been mailed by the IRS at the time of the waiver).

(e) *Limit on amount of imputed underpayment where no proceeding is begun.* If no proceeding under section 6234 is begun with respect to an FPA under section 6231(a)(3) before the close of the 90th day after the day on which such FPA was mailed, the amount for which the partnership is liable under section 6225 with respect to such FPA cannot exceed the amount determined in such FPA.

(f) *Applicability date*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 21.** Section 301.6233(a)–1 is added to read as follows:

§ 301.6233(a)–1 Interest and penalties determined from reviewed year.

(a) *Interest and penalties with respect to the reviewed year.* Except to the extent provided in section 6226(c) and the regulations thereunder, in the case of a partnership adjustment (as defined in § 301.6241–1(a)(6)) for a reviewed year (as defined in § 301.6241–1(a)(8)), a partnership is liable for—

(1) Interest computed in accordance with paragraph (b) of this section; and

(2) Any penalty, addition to tax, or additional amount as provided under paragraph (c) of this section.

(b) *Computation of interest with respect to partnership adjustments for the reviewed year.* The interest imposed on an imputed underpayment resulting from partnership adjustments for the reviewed year is the interest that would be imposed under chapter 67 of the Internal Revenue Code (Code) if the imputed underpayment were treated as an underpayment of tax for the reviewed year. The interest imposed on an imputed underpayment under this paragraph (b) begins on the day after the due date of the partnership return (without regard to extension) for the reviewed year and ends on the earlier of—

(1) The date prescribed for payment (as described in § 301.6232–1(b));

(2) The due date of the partnership return (without regard to extension) for the adjustment year (as defined in § 301.6241–1(a)(1)); or

(3) The date the imputed underpayment is fully paid.

(c) *Penalties with respect to partnership adjustments for the reviewed year*—(1) *In general.* In accordance with section 6221(a), the applicability of any penalties, additions to tax, and additional amounts that relate to an adjustment to any partnership-related item for the reviewed year is determined at the partnership level as if the partnership had been an individual subject to tax imposed by chapter 1 of subtitle A of the Code for the reviewed year, and the imputed underpayment were an actual underpayment of tax or understatement for such year. Nothing in this paragraph (c)(1) affects the application of any penalty, addition to tax, or additional amount that may apply to the partnership or to any reviewed year partner (as defined in § 301.6241–1(a)(9)) or to any indirect partner (as defined in § 301.6241–1(a)(4)) that is unrelated to an adjustment to a partnership-related item under subchapter C of chapter 63 of the Code. A partner-level defense (as described in § 301.6226–3(d)(3)) may not be raised in a proceeding of the partnership.

(2) *Coordination with accuracy-related and fraud penalty provisions*—(i) *In general.* In the case of penalties imposed under section 6662, section 6662A, and section 6663 with respect to partnership adjustments in accordance with paragraph (c)(1) of this section, the rules described in paragraphs (c)(2)(ii), (iii), (iv), and (v) of this section apply.

(ii) *Determining the portion of the imputed underpayment to which a penalty applies*—(A) *In general.* In the case of penalties imposed under section 6662, section 6662A, and section 6663, paragraph (c)(2)(ii) of this section applies if—

(*1*) There is at least one adjustment with respect to which no penalty has been imposed and at least one adjustment with respect to which a penalty has been imposed; or

(*2*) There are at least two adjustments with respect to which penalties have been imposed and the penalties have different rates.

(B) *Calculating the portion of the imputed underpayment to which the penalty applies.* In computing the portion of an imputed underpayment to which a penalty applies, adjustments that do not result in the imputed underpayment (as described in § 301.6225–1(f)) are not taken into account. The portion of an imputed underpayment to which a penalty applies is calculated as follows—

(*1*) All the partnership adjustments that resulted in the imputed underpayment are grouped together according to whether they are adjustments with respect to which a penalty has been imposed and, if so, according to rate of penalty. Decreasing adjustments as defined in paragraph (c)(2)(ii)(C) of this section are grouped in accordance with paragraphs (c)(2)(ii)(D) and (E) of this section.

(*2*) Within each grouping described in paragraph (c)(2)(ii)(B)(*1*) of this section, multiply the portion of each partnership adjustment that is not an adjustment to a credit or treated as an adjustment to a credit under § 301.6225–1(e)(3)(iii) by the rate that applied to such portion when calculating the imputed underpayment. See §§ 301.6225–1(b)(1)(iv), 301.6225–2(b)(3).

(*3*) Within each grouping, add the amounts that were calculated under paragraph (c)(2)(ii)(B)(*2*) of this section.

(*4*) Within each grouping, increase or decrease the amounts that were calculated under paragraph (c)(2)(ii)(B)(*3*) of this section by any adjustments to credits (or adjustments treated as adjustments to credits under § 301.6225–1(e)(3)(iii)).

(C) *Decreasing adjustments.* An adjustment to a partnership-related item that resulted in a decrease to the imputed underpayment is a *decreasing adjustment.*

(D) *Grouping of decreasing adjustments.* Decreasing adjustments are grouped under paragraph (c)(2)(ii)(B)(*1*) of this section in the following order—

(*1*) First, decreasing adjustments are grouped with partnership adjustments with respect to which no penalties have been imposed until the amount of the adjustments remaining in this group is zero in accordance with paragraph (c)(2)(ii)(E) of this section;

(*2*) Second, decreasing adjustments remaining after application of paragraph (c)(2)(ii)(D)(*1*) of this section (taking into account application of paragraph (c)(2)(ii)(E) of this section) are grouped with partnership adjustments with respect to which a penalty has been imposed at a 20 percent rate;

(*3*) Third, decreasing adjustments remaining after application of paragraph (c)(2)(ii)(D)(*2*) of this section (taking into account application of paragraph (c)(2)(ii)(E) of this section) are grouped with partnership adjustments with respect to which a penalty has been imposed at a 30 percent rate;

(*4*) Fourth, decreasing adjustments remaining after application of paragraph (c)(2)(ii)(D)(*3*) of this section (taking into account application of paragraph (c)(2)(ii)(E) of this section) are grouped with partnership adjustments with respect to which a penalty has been imposed at a 40 percent rate;

(*5*) Fifth, decreasing adjustments remaining after application of paragraph (c)(2)(ii)(D)(*4*) of this section (taking into account application of paragraph (c)(2)(ii)(E) of this section) are grouped with partnership adjustments with respect to which a penalty has been imposed at a 75 percent rate.

(E) *Decreasing adjustments that reduce a grouping to zero.* If, when allocating the decreasing adjustments under paragraph (c)(2)(ii)(D) of this section, the amount calculated in paragraph (c)(2)(ii)(B) of this section for a particular grouping equals zero, any remaining decreasing adjustments (or portion thereof) that would otherwise reduce the amount to less than zero are allocated to the next grouping in sequential order under paragraph (c)(2)(ii)(D) of this section.

(F) *Fraud penalties under section 6663.* If any portion of an imputed underpayment is determined by the IRS to be attributable to fraud, the entire imputed underpayment is treated as attributable to fraud. This paragraph (c)(2)(ii)(F) does not apply to any portion of the imputed underpayment the partnership establishes by a

preponderance of the evidence is not attributable to fraud.

(iii) *Substantial understatement penalty under section 6662(d)*—(A) *In general.* For purposes of application of the penalty under section 6662(d) (substantial understatement of income tax), the imputed underpayment is treated as an understatement under section 6662(d)(2). To determine whether an imputed underpayment treated as an understatement under this paragraph (c)(3)(iii)(A) is a substantial understatement under section 6662(d)(1), the rules of section 6662(d)(1)(A) apply by treating the amount described in paragraph (c)(2)(iii)(B) of this section as the tax required to be shown on the return for the taxable year under section 6662(d)(1)(A)(i).

(B) *Amount of tax required to be shown on the return.* The amount described in this paragraph (c)(2)(iii)(B) is the tax that would result by treating the net income or loss of the partnership for the reviewed year, reflecting any partnership adjustments as finally determined, as taxable income described in section 1(c) (determined without regard to section 1(h)).

(iv) *Reportable transaction understatement under section 6662A.* For purposes of application of the penalty under section 6662A (reportable transaction understatement penalty), the portion of an imputed underpayment attributable to an item described under section 6662A(b)(2) is treated as a reportable transaction understatement under section 6662A(b).

(v) *Reasonable cause and good faith.* For purposes of determining whether a partnership satisfies the reasonable cause and good faith exception under section 6664(c) or (d) with respect to a penalty under section 6662, section 6662A, or section 6663, the partnership is treated as the taxpayer. See § 1.6664–4 of this chapter. Accordingly, the facts and circumstances taken into account to determine whether the partnership has established reasonable cause and good faith are the facts and circumstances applicable to the partnership.

(3) *Examples.* The following examples illustrate the rules of paragraph (c) of this section. For purposes of these examples, each partnership has a calendar taxable year, and the highest tax rate in effect for all taxpayers is 40 percent for all relevant periods.

Example 1. One adjustment with respect to which a penalty is imposed. In an administrative proceeding with respect to Partnership's 2018 partnership return, the IRS determines that Partnership understated ordinary income by $100. The $100 understatement is due to negligence or disregard of rules or regulations under section 6662(c), and a 20-percent accuracy-related penalty applies under section 6662(a). The IRS also determines that Partnership understated long-term capital gain by $300, but no penalty applies with respect to that adjustment. Partnership does not request modification of the imputed underpayment under section 6225 and does not raise any penalty defenses prior to issuance of the notice of final partnership adjustment (FPA). In the FPA, the IRS determines that the imputed underpayment is $160 (($100 + $300) × 40 percent). In determining the penalty, the $100 adjustment (to which the 20-percent penalty relates) is grouped separately from the $300 adjustment (to which no penalty applies). The portion of the imputed underpayment to which the 20-percent penalty applies is $40 ($100 × 40 percent), and the penalty is $8 ($40 × 20 percent).

Example 2. More than one adjustment with respect to which the same rate of penalty is imposed. The facts are the same as in *Example 1* of this paragraph (c)(3), except that the IRS determines that Partnership also overstated its credits by $10. The overstatement of credits is due to negligence or disregard of rules or regulations under section 6662(c), and a 20-percent accuracy-related penalty applies under section 6662(a). Because the Partnership did not request modification, the imputed underpayment is $170 (($100 + $300) × 40 percent) + $10). In determining the penalty, the $10 credit adjustment and the $100 understatement of income, both of which are adjustments with respect to which the 20-percent accuracy-related penalty is imposed, are grouped together. Accordingly, the portion of the imputed underpayment to which the 20-percent accuracy-related penalty applies is $50 (($100 × 40 percent) + $10), and the penalty is $10 ($50 × 20 percent).

Example 3. Decreasing adjustment. The facts are the same as in *Example 2* of this paragraph (c)(3), except that there is also an adjustment that reduces ordinary income by $50. In calculating the imputed underpayment under § 301.6225–1 and § 301.6225–2, the partnership demonstrates to the satisfaction of the IRS that the $50 decrease to ordinary income is appropriately netted with the $100 increase in ordinary income. Therefore, the $50 reduction in ordinary income is an adjustment that resulted in the imputed underpayment and therefore a decreasing adjustment described in paragraph (c)(2)(ii)(C) of this section. Because Partnership did not request any further modifications, the imputed underpayment is $150 (($100 − $50) + $300) × 40 percent) + $10). To determine the portion of the imputed underpayment to which the 20-percent accuracy-related penalty applies, the $50 reduction to ordinary income is grouped with the $300 adjustment to long-term capital gain (in accordance with paragraph (c)(2)(ii)(D) of this section). Accordingly, the portion of the imputed underpayment to which the 20-percent accuracy-related penalty applies is $50 (($100 × 40 percent) + $10), and the penalty is $10 ($50 × 20 percent).

Example 4. Two adjustments with respect to which penalties of different rates have been imposed. The facts are the same as in *Example 3* of this paragraph (c)(3), except that the $300 adjustment to long-term capital gain is due to a gross valuation misstatement. A 40-percent accuracy-related penalty under section 6662(a) and (h) applies to the portion of the imputed underpayment attributable to the gross valuation misstatement. The imputed underpayment is $150 (($100 − $50) + $300) × 40 percent) + $10). Under paragraph (c)(2)(ii)(B) of this section, the adjustment to long-term capital gain (the adjustment to which the 40-percent penalty relates) and the adjustments to ordinary income and credits (the adjustments to which the 20-percent penalty relates) are grouped separately. In accordance with paragraph (c)(2)(ii)(D) of this section, because all partnership adjustments other than the decreasing adjustment are subject to penalties, the $50 reduction in ordinary income (the decreasing adjustment) is allocated to the grouping of adjustments with respect to which the 20-percent penalty is imposed. The amount described under paragraph (c)(2)(ii)(B) of this section with respect to the 20-percent penalty grouping is $30 (($100 × 40 percent) − ($50 × 40 percent) + $10). Therefore, the portion of the imputed underpayment to which the 20 percent accuracy-related penalty applies is $30 and the penalty is $6 ($30 × 20 percent). The portion of the imputed underpayment to which the 40-percent gross valuation misstatement penalty applies is $120 ($300 × 40 percent), and the penalty is $48 ($120 × 40 percent). The accuracy-related penalty under section 6662(a) is $54.

Example 5. Modification with respect to tax-exempt partner. The IRS initiates an administrative proceeding with respect to Partnership's 2019 taxable year. Partnership has four equal partners during its 2019 taxable year: two partners are partnerships, A and B; one partner is a tax-exempt entity, C; and the fourth partner is an individual, D. The IRS timely mails a notice of proposed partnership adjustment (NOPPA) to Partnership for its 2019 taxable year proposing a single partnership adjustment increasing Partnership's ordinary income by $400,000. The $400,000 increase in income is due to negligence or disregard of rules or regulations under section 6662(c). A 20-percent accuracy-related penalty under section 6662(a) and (c) applies to the portion of the imputed underpayment attributable to the negligence or disregard of the rules or regulations. In the NOPPA, the IRS determines an imputed underpayment of $160,000 ($400,000 × 40 percent) and that the 20-percent penalty applies to the entire imputed underpayment. The penalty is $32,000 ($160,000 × 20 percent). Partnership requests modification under § 301.6225–2(d)(3) (regarding tax-exempt partners) with respect to the amount of additional income allocated to C, and the IRS approves the request. After modification of the imputed underpayment, the imputed underpayment is $120,000 (($400,000 − $100,000) × 40 percent), and the penalty is $24,000 ($120,000 × 20 percent).

Example 6. Amended return modification. The facts are the same as in *Example 5* of this paragraph (c)(3), except in addition to the

modification with respect to C's tax-exempt status, Partnership requests a modification under § 301.6225–2(d)(2) (regarding amended returns) with respect to the $100,000 of additional income allocated to D. In accordance with the rules under § 301.6225–2(d)(2), D files an amended return for D's 2019 taxable year taking into account $100,000 of additional ordinary income. In addition, in accordance with § 301.6225–2(d)(2)(viii), D takes into account on D's return the 20-percent accuracy-related penalty for negligence or disregard of rules or regulations that relates to the ordinary income adjustment. D's tax attributes for other taxable years are not affected. The IRS approves the modification. As a result, Partnership's total netted partnership adjustment under § 301.6225–1(b)(2) is $200,000 ($400,000 less $100,000 allocable to C and $100,000 taken into account by D). The imputed underpayment, after modification, is $80,000 ($200,000 × 40 percent), and the penalty is $16,000 ($80,000 × 20 percent).

(d) *Applicability date*—(1) *In general.* Except as provided in paragraph (d)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 22.** Section 301.6233(b)–1 is added to read as follows:

§ 301.6233(b)–1 Interest and penalties with respect to the adjustment year return.

(a) *Interest and penalties with respect to failure to pay imputed underpayment on the date prescribed.* In the case of any failure to pay an imputed underpayment on the date prescribed for such payment (as described in § 301.6232–1(b)), a partnership is liable for—

(1) Interest as determined under paragraph (c) of this section; and

(2) Any penalty, addition to tax, or additional amount as determined under paragraph (d) of this section.

(b) *Imputed underpayments to which this section applies.* This section applies to the portion of an imputed underpayment determined by the IRS under section 6225(a)(1), or an imputed underpayment resulting from adjustments requested by a partnership in an administrative adjustment request under section 6227, that is not paid by the date prescribed for payment under § 301.6232–1(b).

(c) *Interest.* Interest determined under this paragraph (c) is the interest that would be imposed under chapter 67 of the Internal Revenue Code (Code) by treating any unpaid amount of the imputed underpayment as an underpayment of tax imposed for the adjustment year (as defined in § 301.6241–1(a)(1)). The interest under this paragraph (c) begins on the date prescribed for payment (as described in § 301.6232–1(b)) and ends on the date payment of the imputed underpayment is made.

(d) *Penalties.* If a partnership fails to pay an imputed underpayment by the date prescribed for payment (as described in § 301.6232–1(b)), section 6651(a)(2) applies to such failure, and any unpaid amount of the imputed underpayment is treated as if it were an underpayment of tax for purposes of part II of subchapter A of chapter 68 of the Code. For purposes of this section, the penalty under 6651(a)(2) is applied by treating the unpaid amount of the imputed underpayment as the unpaid amount shown as tax on a return required under subchapter A of chapter 61 of the Code.

(e) *Applicability date*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 23.** Section 301.6234–1 is added to read as follows:

§ 301.6234–1 Judicial review of partnership adjustment.

(a) *In general.* Within 90 days after the date on which a notice of a final partnership adjustment (FPA) under section 6231(a)(3) with respect to any partnership taxable year is mailed, a partnership may file a petition for a readjustment of any partnership adjustment (as defined in § 301.6241–1(a)(6)) reflected in the FPA for such taxable year (without regard to whether an election under section 6226 has been made with respect to any imputed underpayment (as defined in § 301.6241–1(a)(3)) reflected in such FPA) with—

(1) The Tax Court;

(2) The district court of the United States for the district in which the partnership's principal place of business is located; or

(3) The Court of Federal Claims.

(b) *Jurisdictional requirement for bringing action in district court or Court of Federal Claims.* A petition for readjustment under this section with respect to any partnership adjustment may be filed in a district court of the United States or the Court of Federal Claims only if the partnership filing the petition deposits with the Internal Revenue Service (IRS), on or before the date the petition is filed, the amount of (as of the date of the filing of the petition) any imputed underpayment (as shown on the FPA) and any penalties, additions to tax, and additional amounts with respect to such imputed underpayment. If there is more than one imputed underpayment reflected in the FPA, the partnership must deposit the amount of each imputed underpayment to which the petition for readjustment relates and the amount of any penalties, additions to tax, and additional amounts with respect to each such imputed underpayment.

(c) *Treatment of deposit as payment of tax.* Any amount deposited in accordance with paragraph (b) of this section, while deposited, will not be treated as a payment of tax for purposes of the Internal Revenue Code (Code). Notwithstanding the preceding sentence, an amount deposited in accordance with paragraph (b) of this section will be treated as a payment of tax for purposes of chapter 67 of the Code (relating to interest). Interest will be allowed and paid in accordance with section 6611.

(d) *Effect of decision dismissing action.* If an action brought under this section is dismissed other than by reason of a rescission of the FPA under section 6231(d) and § 301.6231–1(g), the decision of the court dismissing the action is considered as its decision that the FPA is correct.

(e) *Amount deposited may be applied against assessment.* If the limitations on assessment under section 6232(b) and § 301.6232–1(c) no longer apply with respect to an imputed underpayment for which a deposit under paragraph (b) of this section was made, the IRS may apply the amount deposited against any such imputed underpayment that is assessed.

(f) *Applicability date*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 24.** Section 301.6235–1 is added to read as follows:

§ 301.6235–1 Period of limitations on making adjustments.

(a) *In general.* Except as provided in section 6235(c), section 905(c) or paragraph (b) of this section (regarding extensions), no partnership adjustment (as defined in § 301.6241–1(a)(6)) for

any partnership taxable year may be made after the later of the date that is—

(1) Three years after the latest of—

(i) The date on which the partnership return for such taxable year was filed;

(ii) The return due date (as defined in section 6241(3)) for the taxable year; or

(iii) The date on which the partnership filed an administrative adjustment request with respect to such taxable year under section 6227; or

(2) The date described in paragraph (b) of this section with respect to a request for modification; or

(3) The date described in paragraph (c) of this section with respect to a notice of proposed partnership adjustment.

(b) *Modification requested under section 6225(c)*—(1) *In general.* For purposes of paragraph (a)(2) of this section, in the case of any request for modification of any imputed underpayment under section 6225(c), the date by which the Internal Revenue Service (IRS) may make a partnership adjustment is the date that is 270 days (plus the number of days of an extension of the period for requesting modification (as described in § 301.6225–2(c)(3)(i)) agreed to by the IRS under section 6225(c)(7) and § 301.6225–2(c)(3)(ii)) after the date on which everything required to be submitted to the IRS pursuant to section 6225(c) is so submitted.

(2) *Date on which everything is required to be submitted*—(i) *In general.* For purposes of paragraph (b)(1) of this section, the date on which everything required to be submitted to the IRS pursuant to section 6225(c) is so submitted is the earlier of—

(A) The date the period for requesting modification ends (including extensions) as described in § 301.6225–2(c)(3)(i) and (ii); or

(B) The date the period for requesting modification expires as a result of a waiver of the prohibition on mailing a notice of final partnership adjustment (FPA) under § 301.6231–1(b)(2). See § 301.6225–2(c)(3)(iii).

(ii) *Incomplete submission has no effect.* A determination by the IRS that the information submitted as part of a request for modification is incomplete has no effect on the applicability of paragraph (b)(2) of this section.

(c) *Notice of proposed partnership adjustment.* For purposes of paragraph (a)(3) of this section, the date by which the IRS may make a partnership adjustment is the date that is 330 days (plus the number of days of an extension of the modification period (as described in § 301.6225–2(c)(3)(i)) agreed to by the IRS under section 6225(c)(7) and § 301.6225–2(c)(3)(ii)) after the date the last notice of proposed partnership adjustment (NOPPA) under section 6231(a)(2) is mailed, regardless of whether modification is requested by the partnership under section 6225(c).

(d) *Extension by agreement.* The periods described in paragraphs (a), (b), and (c) of this section (including any extension of those periods pursuant to this paragraph (d)) may be extended by an agreement, in writing, entered into by the partnership and the IRS before the expiration of such period.

(e) *Examples.* The following examples illustrate the rules of this section. For purposes of these examples, each partnership has a calendar taxable year.

Example 1. Partnership timely files its partnership return for the 2020 taxable year on March 1, 2021. On September 1, 2023, Partnership files an administrative adjustment request (AAR) under section 6227 with respect to its 2020 taxable year. As of September 1, 2023, the IRS has not initiated an administrative proceeding under subchapter C of chapter 63 of the Internal Revenue Code with respect to Partnership's 2020 taxable year. Therefore, as of September 1, 2023, under paragraph (a)(1) of this section, the period for making partnership adjustments with respect to Partnership's 2020 taxable year expires on September 1, 2026.

Example 2. Partnership timely files its partnership return for the 2020 taxable year on the due date, March 15, 2021. On February 1, 2023, the IRS mails to Partnership and the partnership representative of Partnership (PR) a notice of administrative proceeding under section 6231(a)(1) with respect to Partnership's 2020 taxable year. Assuming no AAR has been filed with respect to Partnership's 2020 taxable year and the IRS has not yet mailed a NOPPA under section 6231(a)(2) with respect to Partnership's 2020 taxable year, the period for making partnership adjustments for Partnership's 2020 taxable year expires on the date determined under paragraph (a)(1) of this section, March 15, 2024.

Example 3. The facts are the same as in *Example 2* of this paragraph (e), except that on June 1, 2023, pursuant to § 301.6235–1(d), PR signs an agreement extending the period for making partnership adjustments under section 6235(a)(1) for Partnership's 2020 taxable year to December 31, 2025. In addition, on June 2, 2025, the IRS mails to Partnership and PR a timely NOPPA under section 6231(a)(2). Pursuant to § 301.6225–2(c)(3)(i), the period for requesting modification expires on February 27, 2026 (270 days after June 2, 2025, the date the NOPPA is mailed), but PR does not submit a request for modification on or before this date. Under paragraph (c) of this section, the date for purposes of paragraph (a)(3) of this section is April 28, 2026, the date that is 330 days from the mailing of the NOPPA. Because April 28, 2026 is later than the date under paragraph (a)(1) of this section (December 31, 2025, as extended under paragraph (d) of this section), and because no modification was requested, paragraph (a)(2) of this section is not applicable, April 28, 2026 is the date on which the period for making partnership adjustments expires under section 6235.

Example 4. The facts are the same as in *Example 3* of this paragraph (e), except that PR notifies the IRS that Partnership will be requesting modification. On January 5, 2026, PR and the IRS agree to extend the period for requesting modification pursuant to section 6225(c)(7) and § 301.6225–2(c)(3)(ii) for 45 days—from February 27, 2026 to April 13, 2026. PR submits the request for modification to the IRS on April 13, 2026. Therefore, the date determined under paragraph (b) of this section is February 22, 2027, which is 270 days after the date everything required to be submitted was so submitted pursuant to paragraph (b)(2) of this section plus the additional 45-day extension of the period for requesting modification agreed to by PR and the IRS. Because February 22, 2027 is later than the date under paragraph (a)(1) of this section (December 31, 2025, as extended under paragraph (d) of this section) and the date under paragraph (a)(3) of this section (June 12, 2026, which is 330 days from the date the NOPPA was mailed plus the 45-day extension under section 6225(c)(7)), February 22, 2027 is the date on which the period for making partnership adjustments expires under section 6235.

Example 5. The facts are the same as in *Example 4* of this paragraph (e), except that PR does not request an extension of the period for requesting modification. On February 1, 2026, PR submits a request for modification and PR, and the IRS agree in writing to waive the prohibition on mailing an FPA pursuant to § 301.6231–1(b)(2). Pursuant to § 301.6225–2(c)(3)(iii), the period for requesting modification expires as of February 1, 2026, rather than February 27, 2026. Accordingly, under paragraph (b)(2) of this section, the date on which everything required to be submitted pursuant to section 6225(c) is so submitted is February 1, 2026, and the 270-day period described in paragraph (b)(1) of this section begins to run on that date. Therefore, the date for purposes of paragraph (a)(2) of this section is October 29, 2026, which is 270 days after February 1, 2026, the date on which everything required to be submitted under section 6225(c) is so submitted. Because October 29, 2026 is later than the date under paragraph (a)(1) of this section (December 31, 2025, as extended under paragraph (d) of this section) and the date under paragraph (a)(3) of this section (April 28, 2026), October 29, 2026 is the date on which the period for making partnership adjustments expires under section 6235.

Example 6. The facts are the same as in *Example 5* of this paragraph (e), except PR completes its submission of information to support a request for modification on July 1, 2025, but does not execute a waiver pursuant to § 301.6231–1(b)(2). Therefore, pursuant to paragraph (b)(2) of this section, February 26, 2026, the date the period requesting modification expires, is the date on which everything required to be submitted pursuant to section 6225(c) is so submitted. As a result, the 270-day period described in

paragraph (b)(1) of this section expires on November 23, 2026. Because November 23, 2026 is later than the date under paragraph (a)(1) of this section (December 31, 2025, as extended under paragraph (d) of this section) and the date under paragraph (a)(3) of this section (April 28, 2026), November 23, 2026 is the date on which the period for making partnership adjustments expires under section 6235.

(f) *Applicability date*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 25.** Section 301.6241–1 is added to read as follows:

§ 301.6241–1 Definitions.

(a) *Definitions.* For purposes of subchapter C of chapter 63 of the Internal Revenue Code—

(1) *Adjustment year.* The term *adjustment year* means the partnership taxable year in which—

(i) In the case of an adjustment pursuant to the decision of a court in a proceeding brought under section 6234, such decision becomes final;

(ii) In the case of an administrative adjustment request (AAR) under section 6227, such AAR is filed; or

(iii) In any other case, a notice of final partnership adjustment is mailed under section 6231 or, if the partnership waives the restrictions under section 6232(b) (regarding limitations on assessment), the waiver is executed by the IRS.

(2) *Adjustment year partner.* The term *adjustment year partner* means any person who held an interest in a partnership at any time during the adjustment year.

(3) *Imputed underpayment.* Except as otherwise provided in this paragraph (a)(3), the term *imputed underpayment* means the amount determined in accordance with section 6225 and the regulations thereunder. In the case of an election under section 6226, the term *imputed underpayment* means the amount determined in accordance with § 301.6226–3(e)(4). In the case of an administrative adjustment request, the term *imputed underpayment* means the amount determined in accordance with § 301.6227–2 or § 301.6227–3(c).

(4) *Indirect partner.* The term *indirect partner* means any person who has an interest in a partnership through their interest in one or more pass-through partners (as defined in paragraph (a)(5) of this section) or through a wholly-owned entity disregarded as separate from its owner for Federal tax purposes.

(5) *Pass-through partner.* The term *pass-through partner* means a pass-through entity that holds an interest in a partnership. A pass-through entity is a partnership as described in § 301.7701–2(c)(1) (including a foreign entity that is classified as a partnership under § 301.7701–3(b)(2)(i)(A) or (c)), an S corporation, a trust (other than a wholly-owned trust disregarded as separate from its owner for Federal tax purposes), and a decedent's estate. For purposes of this paragraph (a)(5), a pass-through entity is not a wholly-owned entity disregarded as separate from its owner for Federal tax purposes.

(6) *Partnership adjustment.* The term *partnership adjustment* means any adjustment to a partnership-related item (as defined in § 301.6241–6) and includes any portion of a partnership adjustment.

(7) *Partnership-partner.* The term *partnership-partner* means a partnership that holds an interest in another partnership.

(8) *Reviewed year.* The term *reviewed year* means the partnership taxable year to which a partnership adjustment relates.

(9) *Reviewed year partner.* The term *reviewed year partner* means any person who held an interest in a partnership at any time during the reviewed year.

(10) *Tax attribute.* A tax attribute is anything that can affect the amount or timing of a partnership-related item (as defined in § 301.6241–6) or that can affect the amount of tax due in any taxable year. Examples of tax attributes include, but are not limited to, basis and holding period, as well as the character of items of income, gain, loss, deduction, or credit and carryovers and carrybacks of such items.

(b) *Applicability date*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 26.** Section 301.6241–2 is added to read as follows:

§ 301.6241–2 Bankruptcy of the partnership.

(a) *Coordination between Title 11 and proceedings under subchapter C of chapter 63*—(1) *In general.* If a partnership is a debtor in a case under Title 11 of the United States Code (Title 11 case), the running of any period of limitations under section 6235 with respect to the time for making a partnership adjustment (as defined in § 301.6241–1(a)(6)) and under sections 6501 and 6502 with respect to the assessment or collection of any imputed underpayment (as defined in § 301.6241–1(a)(3)) determined under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) is suspended during the period the Internal Revenue Service (IRS) is prohibited by reason of the Title 11 case from making the adjustment, assessment, or collection until—

(i) 60 days after the suspension ends, for adjustments or assessments, and

(ii) 6 months after the suspension ends, for collection.

(2) *Interaction with section 6232(b).* The filing of a proof of claim or request for payment (or the taking of any other action) in a Title 11 case is not be treated as an action prohibited by section 6232(b) (regarding limitations on assessment).

(3) *Suspension of the time for judicial review.* In a Title 11 case, the running of the period specified in section 6234 (regarding judicial review of partnership adjustments) is suspended during the period during which the partnership is prohibited by reason of the Title 11 case from filing a petition under section 6234, and for 60 days thereafter.

(4) *Actions not prohibited.* The filing of a petition under Title 11 does not prohibit the following actions:

(i) An administrative proceeding with respect to a partnership under subchapter C of chapter 63;

(ii) The mailing of any notice with respect to a proceeding with respect to a partnership under subchapter C of chapter 63, including:

(A) A notice of administrative proceeding,

(B) A notice of proposed partnership adjustment, and

(C) A notice of final partnership adjustment;

(iii) A demand for tax returns;

(iv) The assessment of any tax, including the assessment of any imputed underpayment with respect to a partnership; and

(v) The issuance of notice and demand for payment of an assessment under subchapter C of chapter 63 (but see section 362(b)(9)(D) of Title 11 of the United States Code regarding the timing of when a tax lien takes effect by reason of such assessment).

(b) *Applicability date*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 27.** Section 301.6241–3 is added to read as follows:

§ 301.6241–3 Treatment where a partnership ceases to exist.

(a) *Former partners take adjustments into account*—(1) *In general.* Except as described in paragraphs (a)(2) and (3) of this section, if the Internal Revenue Service (IRS) determines that any partnership (including a partnership-partner as defined in § 301.6241–1(a)(7)) ceases to exist (as defined in paragraph (b)(2) of this section) before any partnership adjustment (as defined in § 301.6241–1(a)(6)) under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) takes effect (as described in paragraph (c) of this section), the partnership adjustment is taken into account by the former partners (as described in paragraph (d) of this section) of the partnership in accordance with paragraph (e) of this section.

(2) *Partnership no longer liable for any unpaid amounts resulting from a partnership adjustment.* A partnership that ceases to exist is no longer liable for any unpaid amounts resulting from a partnership adjustment required to be taken into account by a former partner under this section.

(3) *Application of this section to partnership-partners.* This section applies to a partnership-partner and its former partners, regardless of whether the partnership-partner has an election under section 6221(b) in effect for any relevant partnership taxable year.

(b) *Determination that partnership ceases to exist*—(1) *In general.* For purposes of this section, the IRS may, in its sole discretion, make a determination that a partnership ceases to exist for purposes of this section, but the IRS is not required to do so even if the definition in paragraph (b)(2) of this section applies with respect to such partnership. If the IRS determines that a partnership ceases to exist, the IRS will notify the partnership and the former partners (as defined in paragraph (d) of this section), in writing, within 30 days of such determination using the last known address of the partnership and the former partners.

(2) *Cease to exist defined*—(i) *In general.* The IRS may determine that a partnership ceases to exist if the partnership terminates within the meaning of section 708(b)(1), or does not have the ability to pay, in full, any amount due under the provisions of subchapter C of chapter 63 for which the partnership is or becomes liable. For purposes of this section, a partnership does not have the ability to pay if the IRS determines that the amount due with respect to the partnership is not collectible based on the information the IRS has at the time of such determination. For purposes of this section, a partnership does not cease to exist solely because the partnership has—

(A) A valid election under section 6226 and the regulations thereunder in effect with respect to any imputed underpayment (as defined in § 301.6241–1(a)(3));

(B) Received a statement under section 6226(a)(2) (or § 301.6226–3(e)) and has furnished statements to its partners in accordance with § 301.6226–3(e)(3); or

(C) Not paid any amount required to be paid under subchapter C of chapter 63.

(ii) *Year in which a partnership ceases to exist.* If a partnership terminates under section 708(b)(1), the partnership ceases to exist on the last day of the partnership's final taxable year. If a partnership does not have the ability to pay, the partnership ceases to exist on the date that the IRS makes a determination under paragraph (b)(2)(i) of this section that the partnership ceases to exist.

(iii) *Limitation on IRS determination that partnership ceases to exist.* In no event may the IRS determine that a partnership ceases to exist with respect to a partnership adjustment after the expiration of the period of limitations on collection applicable to the assessment made against the partnership for the amount due resulting from such adjustment.

(c) *Partnership adjustment takes effect*—(1) *Full payment of amounts resulting from a partnership adjustment.* For purposes of this section, a partnership adjustment under subchapter C of chapter 63 takes effect when there is full payment of amounts resulting from a partnership adjustment. For purposes of this section, *full payment of amounts resulting from a partnership adjustment* means all amounts due under subchapter C of chapter 63 resulting from the partnership adjustment are fully paid by the partnership.

(2) *Partial payment of amount due by the partnership.* If a partnership pays part, but not all, of any amount due resulting from a partnership adjustment before the partnership ceases to exist, the former partners (as defined in paragraph (d) of this section) of the partnership that has ceased to exist are not required to take into account any partnership adjustment to the extent amounts have been paid by the partnership with respect to such adjustment. The notification that the IRS has determined that the partnership has ceased to exist will include information regarding the portion of the partnership adjustments with respect to which appropriate amounts have not already been paid by the partnership and therefore must be taken into account by the former partners (described in paragraph (d) of this section) in accordance with paragraph (e) of this section.

(d) *Former partners*—(1) *Adjustment year partners*—(i) *In general.* Except as described in paragraphs (d)(1)(ii) and (d)(2) of this section, the term *former partners* means the adjustment year partners (as defined in § 301.6241–1(a)(2)) of a partnership that ceases to exist for the partnership taxable year to which the partnership adjustment relates.

(ii) *Partnership-partner ceases to exist.* If the adjustment year partner is a partnership-partner that the IRS has determined ceased to exist, the partners of such partnership-partner during the partnership-partner's taxable year that includes the end of the adjustment year (as defined in § 301.6241–1(a)(1)) of the partnership that is subject to a proceeding under subchapter C of chapter 63 are the former partners for purposes of this section. If the partnership-partner ceased to exist before the partnership-partner's taxable year that includes the end of the adjustment year of the partnership that is subject to a proceeding under subchapter C of chapter 63, the former partners for purposes of this section are the partners of such partnership-partner during the partnership taxable year for which the final partnership return of the partnership-partner under section 6031 is filed.

(2) *No adjustment year partners.* If there are no adjustment year partners of a partnership that ceases to exist, the term *former partners* means the partners of the partnership during the last taxable year for which a partnership return under section 6031 was filed with respect to such partnership. For instance, if a partnership terminates under section 708(b)(1) (and therefore ceases to exist under paragraph (b)(2)(i) of this section) before the adjustment year and files a final partnership return for the partnership taxable year of such partnership, the former partners for purposes of this section are the partners of the partnership during the

partnership taxable year for which a final partnership return is filed.

(e) *Taking adjustments into account*—(1) *In general.* For purposes of paragraph (a) of this section, a former partner of a partnership that ceases to exist takes a partnership adjustment into account as if the partnership had made an election under section 6226 and the regulations thereunder (regarding the alternative to payment of the imputed underpayment). A former partner must take into account the former partner's share of a partnership adjustment as set forth in the statement described in paragraph (e)(2) of this section in accordance with § 301.6226–3.

(2) *Statements furnished to former partners.* If a partnership is notified by the IRS that the partnership has ceased to exist as described in paragraph (b)(1) of this section, the partnership must furnish to each former partner a statement reflecting such former partner's share of the partnership adjustment required to be taken into account under this section and file a copy of such statement with the IRS in accordance with the rules under § 301.6226–2, except that—

(i) The adjustments are taken into account by the applicable former partner (as described in paragraph (d) of this section), rather than the reviewed year partners (as defined in § 301.6241–1(a)(9)), and

(ii) The partnership must furnish statements to the former partners and file the statements with the IRS no later than 30 days after the date of the notification to the partnership that the IRS has determined that the partnership has ceased to exist.

(3) *Authority to issue statements.* If any statements required by paragraph (e) of this section are not timely furnished to a former partner and filed with the IRS in accordance with paragraph (e)(2)(ii) of this section, the IRS may notify the former partner in writing of such partner's share of the partnership adjustments based on the information reasonably available to the IRS at the time such notification is provided. For purposes of paragraph (e) of this section, a notification to a former partner under this paragraph (e)(3) is treated the same as a statement required to be furnished and filed under paragraph (e)(2) of this section.

(f) *Examples.* The following examples illustrate the provisions of this section. For purposes of the examples, all partnerships and partners are calendar year taxpayers and each partnership is subject to the provisions of subchapter C of chapter 63 of the Code (unless otherwise stated).

Example 1. The IRS initiates a proceeding under subchapter C of chapter 63 with respect to the 2020 partnership taxable year of Partnership. During 2023, in accordance with section 6235(b), Partnership extends the period of limitations on adjustments under section 6235(a) until December 31, 2025. On February 1, 2025, the IRS mails Partnership a notice of final partnership adjustment (FPA) that determines partnership adjustments that result in a single imputed underpayment. Partnership does not timely file a petition under section 6234 and does not make a valid election under section 6226. On June 2, 2025, the IRS mails Partnership notice and demand for payment of the amount due resulting from the adjustments determined in the FPA. Partnership fails to make a payment. On September 1, 2029, the IRS determines Partnership ceases to exist for purposes of this section because the IRS has determined that Partnership does not have the ability to pay under paragraph (b)(2)(i) of this section. Under § 301.6241–1(a)(1), the adjustment year is 2025 and A and B, both individuals, are the only adjustment year partners of Partnership during 2025. Accordingly, under paragraph (d)(1) of this section, A and B are former partners. Therefore, A and B are required to take their share of the partnership adjustments determined in the FPA into account under paragraph (e) of this section.

Example 2. The IRS initiates a proceeding under subchapter C of chapter 63 with respect to the 2020 partnership taxable year of P, a partnership. G, a partnership that has an election under section 6221(b) in effect for the 2020 taxable year, is a partner of P during 2020 and for every year thereafter. On February 3, 2025, the IRS mails P an FPA that determines partnership adjustments that result in a single imputed underpayment. P does not timely file a petition under section 6234 and does not make a timely election under section 6226. On May 6, 2025, the IRS mails P notice and demand for payment of the amount due resulting from the adjustments determined in the FPA. P does not make a payment. On September 1, 2025, the IRS determines P ceases to exist for purposes of this section because the IRS has determined that P does not have the ability to pay under paragraph (b)(2)(i) of this section. G terminated under section 708(b)(1) on December 31, 2024. On September 1, 2025, the IRS determines that G ceased to exist in 2024 for purposes of this section in accordance with paragraph (b)(2)(i) of this section. J and K, individuals, were the only partners of G during 2024. Therefore, under paragraph (d)(1)(ii) of this section, J and K, the partners of G during G's 2024 partnership taxable year, are the former partners of G for purposes of this section. Therefore, J and K are required to take into account their share of the adjustments contained in the statement furnished by P to G in accordance with paragraph (e) of this section.

(g) *Applicability date*—(1) *In general.* Except as provided in paragraph (g)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 28.** Section 301.6241–4 is added to read as follows:

§ 301.6241–4 Payments nondeductible.

(a) *Payments nondeductible.* No deduction is allowed under subtitle A of the Internal Revenue Code for any payment required to be made by a partnership under subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63). Payment by a partnership of any amount required to be paid under subchapter C of chapter 63, including any imputed underpayment (as defined in § 301.6241–1(a)(3)), or interest, penalties, additions to tax, or additional amounts with respect to an imputed underpayment, is treated as an expenditure described in section 705(a)(2)(B).

(b) *Applicability date*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 29.** Section 301.6241–5 is added to read as follows:

§ 301.6241–5 Extension to entities filing partnership returns.

(a) *Entities filing a partnership return.* Except as described in paragraph (c) of this section, an entity that files a partnership return for any taxable year is subject to the provisions of subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) and the regulations thereunder with respect to such taxable year even if it is determined that the entity filing the partnership return was not a partnership for such taxable year. Accordingly, any partnership-related item (as defined in § 301.6241–6) and any person holding an interest in the entity, either directly or indirectly, at any time during that taxable year are subject to the provisions of subchapter C of chapter 63 and the regulations thereunder for such taxable year.

(b) *Partnership return filed but no entity found to exist.* Paragraph (a) of this section also applies where a partnership return is filed for a taxable year, but the IRS determines that no entity existed at all for such taxable year. For purposes of applying paragraph (a) of this section, the

partnership return is treated as if it were filed by an entity.

(c) *Exceptions.* Paragraph (a) of this section does not apply to—

(1) Any taxable year for which an election under section 6221(b) is in effect, treating the return as if it were filed by a partnership for the taxable year to which the election relates, and

(2) Any taxable year for which a partnership return was filed for the sole purpose of making the election described in section 761(a) (regarding election out of subchapter K for certain unincorporated organizations).

(d) *Applicability date*—(1) *In general.* Except as provided in paragraph (d)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 30.** Section 301.6241–6 is added to read as follows:

§ 301.6241–6 Partnership-related Item.

(a) *In general.* The term *partnership-related item* means—

(1) Any item or amount with respect to the partnership (as described in paragraph (b) of this section) which is relevant in determining the tax liability of any person under chapter 1 of subtitle A of the Internal Revenue Code (chapter 1) (as described in paragraph (c) of this section), and

(2) Any partner's distributive share of any such item or amount.

(b) *Item or amount with respect to the partnership.* For purposes of this section, an item or amount is with respect to the partnership without regard to whether or not such item or amount appears on the partnership return. An item or amount is with respect to the partnership if—

(1) The item or amount is shown or reflected, or required to be shown or reflected, on a return of the partnership under section 6031, the regulations thereunder, or the forms and instructions prescribed by the Internal Revenue Service (IRS) for the partnership's taxable year;

(2) The item or amount is in the partnership's books or records;

(3) The item or amount is an imputed underpayment;

(4) The item or amount relates to a transaction with the partnership by a partner acting in its capacity as a partner or by an indirect partner (as defined in § 301.6241–1(a)(4)) acting its capacity as an indirect partner;

(5) The item or amount relates to a transaction that is described in section 707(a)(2), 707(b), or 707(c);

(6) The item or amount relates to basis in the partnership;

(7) The item or amount relates to a liability of the partnership that is reported or reportable by a partner acting in its capacity as a partner or an indirect partner acting in its capacity as an indirect partner, including such partner or indirect partner's share of the liability; or

(8) Any legal or factual determinations necessary to make an adjustment to an item or amount described in paragraphs (b)(1) through (7) of this section, such as a determination regarding—

(i) The validity of any election made by the partnership,

(ii) The partnership's accounting practices and methods;

(iii) Whether a partnership exists for tax purposes and whether multiple partnerships should be treated as a single partnership;

(iv) Whether any items or transactions of the partnership lack economic substance or should otherwise be disregarded, collapsed, recharacterized, or attributed to other persons;

(v) Whether a partnership terminates under section 708(b)(1) or as a result of a transaction under Rev. Rul. 99–6 (1999–1 C.B. 432) (see § 601.601(d)(2) of this chapter); or

(vi) The type of partnership interest held by any partner.

(c) *Relevant in determining the tax liability of any person under chapter 1.* For purposes of this section, an item or amount is relevant in determining the tax liability of any person under chapter 1 without regard to application of subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) and without regard to whether such item or amount, or adjustment to such item or amount, has an effect on the tax liability of any particular person under chapter 1.

(d) *Examples of partnership-related items.* The term partnership-related item includes—

(1) The character, timing, source, and amount of the partnership's income, gain, loss, deductions, and credits;

(2) The character, timing, and source of the partnership's activities;

(3) The character, timing, source, value, and amount of any contributions to, and distributions from, the partnership;

(4) The partnership's basis in its assets, the character and type of the assets, and the value (or revaluation such as under § 1.704–1(b)(2)(iv)(*f*) or (*s*) of this chapter) of the assets;

(5) The amount and character of partnership liabilities and any changes to those liabilities from the preceding tax year;

(6) The category, timing, and amount of the partnership's creditable expenditures;

(7) Any item or amount resulting from a partnership termination;

(8) Any item or amount relating to an election under section 754;

(9) Partnership allocations and any special allocations; and

(10) Whether any person is a partner in the partnership.

(e) *Examples.* The following examples illustrate the provisions of this section. For purposes of these examples, Partnership is subject to the provisions of subchapter C of chapter 63 and all taxpayers are calendar year taxpayers.

Example 1. Partnership enters into a transaction with A to purchase widgets for $100 in taxable year 2020. A is not a partner of Partnership or an indirect partner of Partnership. The transaction is not a transaction described in 707(a)(2), 707(b), or 707(c). Partnership pays A $100 for the widgets. Any deduction or expense of the Partnership for the purchase of the widgets is an item or amount that relates to a transaction with Partnership and is relevant to determining the liability of any person under chapter 1 pursuant to paragraph (c) of this section. Therefore, the deduction or expense is a partnership-related item. However, the income to A resulting from the transaction with Partnership is not an item or amount with respect to Partnership under paragraph (b) of this section because although the amount of income relates to a transaction with Partnership, the amount of income is reported or reportable by A, and A is not a partner (direct or indirect) of Partnership. Accordingly, the amount of income reportable by A is not a partnership-related item.

Example 2. B loans Partnership $100 in Partnership's 2020 taxable year. Partnership makes an interest payment to B in 2020 of $5. B is a partner in Partnership in the 2020 taxable year, but B loaned the $100 to Partnership in a capacity other than B's capacity as a partner. Partnership's liability relating to the loan by B to Partnership and the $5 of interest expense paid by the Partnership are items or amounts that relates to a transaction with or liability of Partnership and are relevant to determining the liability of any person under chapter 1 pursuant to paragraph (c) of this section. However, the treatment of the loan by B and the amount of interest income received by B are not items or amounts with respect to Partnership under paragraph (b) of this section because although they relate to a transaction with or liability of Partnership, the loan and interest income are reportable by B, and B was not acting in his capacity as a partner when he loaned the $100 to Partnership. Accordingly, the loan as treated by B and the amount of interest income to B is not a partnership-related item.

(f) *Applicability date*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 31.** Section 301.6241–7 is added to read as follows:

§ 301.6241–7 Coordination with Other Chapters of the Internal Revenue Code.

(a) *Coordination with other chapters*—(1) *In general.* Subchapter C of chapter 63 of the Internal Revenue Code (subchapter C of chapter 63) only applies to tax imposed by chapter 1 of the Internal Revenue Code (Code) and not to any tax imposed (including any amount required to be deducted or withheld) under any chapter of the Code other than chapter 1 of the Code (chapter 1), including chapter 2, 2A, 3, or 4 of the Code. Accordingly, for purposes of determining taxes imposed under chapters of the Code other than chapter 1, the Internal Revenue Service (IRS) may make an adjustment to any partnership-related item (as defined in § 301.6241–6) in a proceeding that is not under subchapter C of chapter 63. To the extent an adjustment or determination is made under subchapter C of chapter 63 for purposes of chapter 1 and is relevant in determining tax imposed under a chapter of the Code other than chapter 1, such adjustment or determination must be taken into account for purposes of determining such tax.

(2) *Examples.* The following examples illustrate the rules of this paragraph (a) as applied to cases in which a partnership has a withholding obligation under chapter 3 or chapter 4 with respect to income that the partnership earns. For purposes of these examples, each partnership is subject to the provisions of subchapter C of chapter 63 of the Code, and the partnership and its partners are calendar year taxpayers.

Example 1. Partnership, a partnership created or organized in the United States, has two equal partners, A and B. A is a nonresident alien who is a resident of Country A, and B is a U.S. citizen. In 2018, Partnership earned $200 of U.S. source royalty income. Partnership was required to withhold 30 percent of the gross amount of the royalty income allocable to A unless Partnership had documentation that it could rely on to establish that A was entitled to a reduced rate of withholding. See §§ 1.1441–1(b)(1) and 1.1441–5(b)(2)(i)(A) of this chapter. Partnership withheld $15 from the $100 of royalty income allocable to A based on its incorrect belief that A is entitled to a reduced rate of withholding under the U.S.-Country A Income Tax Treaty. In 2020, the IRS determines in an examination of Partnership's Form 1042, Annual Withholding Tax Return for U.S. Source Income of Foreign Persons, that Partnership should have withheld $30 instead of $15 on the $100 of royalty income allocable to A because Partnership failed to obtain documentation from A establishing a valid treaty claim for a reduced rate of withholding. The tax imposed on Partnership for its failure to withhold on that income, however, is not a tax imposed by chapter 1. Rather, it is a tax imposed by chapter 3, which is not a partnership-related item under § 301.6241–6. Therefore, in accordance with section 6221(a), the adjustment to increase Partnership's withholding tax liability by $15 is not determined under subchapter C of chapter 63, and instead must be determined as part of the Form 1042 examination.

Example 2. Partnership, a partnership created or organized in the United States, has two equal partners, A and B. A is a nonresident alien who is a resident of Country A, and B is a U.S. citizen. In 2018, Partnership earned $100 of U.S. source dividend income. Partnership was required to report the dividend income on its 2018 Form 1065, U.S. Return of Partnership Income, and withhold 30 percent of the gross amount of the dividend income allocable to A unless Partnership had documentation that it could rely on to establish that A was entitled to a reduced rate of withholding. See §§ 1.1441–1(b)(1) and 1.1441–5(b)(2)(i)(A) of this chapter. In 2020, in an examination of Partnership's Form 1042, the IRS determines that Partnership earned but failed to report the $100 of U.S. source dividend income in 2018. The adjustment to increase Partnership's dividend income by $100 is an adjustment to a partnership-related item. The tax imposed on Partnership for its failure to withhold on that income, however, is not a tax imposed by chapter 1; rather, it is a tax imposed by chapter 3. Pursuant to § 301.6221(a)-1(a), only chapter 1 tax attributable to adjustments to partnership-related items is assessed under subchapter C of chapter 63. Therefore, because the tax imposed with respect to the adjustment is a chapter 3 tax, under paragraph (a)(1) of this section, the IRS may determine, assess, and collect chapter 3 tax attributable to an adjustment to a partnership-related item without conducting a proceeding under subchapter C of chapter 63. Accordingly, the IRS may determine the chapter 3 tax in the examination of Partnership's Form 1042 by adjusting Partnership's withholding tax liability by an additional $15 for failing to withhold on the $50 of dividend income allocable to A. However, the IRS must initiate an administrative proceeding under subchapter C of chapter 63 to make any adjustments for purposes of chapter 1 attributable to the income. If the IRS subsequently initiates an administrative proceeding under subchapter C of chapter 63 and makes an adjustment to the same item of income, the portion of the dividend income allocable to A will be disregarded in the calculation of the total netted partnership adjustment to the extent that the chapter 3 tax has been collected with respect to such income. See § 301.6225–1(b)(3).

(b) *Coordination with chapters 3 and 4*—(1) *In general.* In the case of any tax imposed under chapter 3 or chapter 4 that is determined with respect to a partnership adjustment determined under subchapter C of chapter 63 for purposes of chapter 1, such tax is determined with respect to the reviewed year (as defined in § 301.6241–1(a)(8)) and is imposed (or required to be deducted and withheld) with respect to the adjustment year (as defined in § 301.6241–1(a)(1)).

(2) *Definitions.* The following definitions apply for purposes of this paragraph (b) and the regulations under subchapter C of chapter 63.

(i) *Amount subject to withholding.* The term *amount subject to withholding* means an amount subject to withholding (as defined in § 1.1441–2(a) of this chapter), a withholdable payment (as defined in § 1.1473–1(a) of this chapter), or the allocable share of effectively connected taxable income (as computed under § 1.1446–2(b) of this chapter).

(ii) *Chapter 3.* The term *chapter 3* means sections 1441 through 1464 of subtitle A of the Code, but does not include section 1443(b).

(iii) *Chapter 4.* The term *chapter 4* means sections 1471 through 1474 of subtitle A of the Code.

(3) *Partnership pays an imputed underpayment.* If a partnership pays an imputed underpayment (as determined under § 301.6225–1(b)) and the total netted partnership adjustment (as calculated under § 301.6225–1(b)(2)) includes a partnership adjustment to an amount subject to withholding, the partnership is treated as having paid (at the time that the imputed underpayment is paid) the amount required to be withheld with respect to that partnership adjustment under chapter 3 or chapter 4 for purposes of applying §§ 1.1463–1 and 1.1474–4 of this chapter. See § 301.6225–1(b)(3) for the coordination rule that applies for calculating an imputed underpayment when an adjustment is made to an amount subject to withholding for which tax has been collected under chapter 3 or chapter 4.

(4) *Partnership makes an election under section 6226 with respect to an imputed underpayment*—(i) *In general.* A partnership that makes an election under § 301.6226–1 with respect to an imputed underpayment must pay the amount of tax required to be withheld under chapter 3 or chapter 4 on the amount of any adjustment set forth in

the statement described in § 301.6226–2(a) to the extent that it is an adjustment to an amount subject to withholding, and the IRS has not already collected tax attributable to the adjustment under chapter 3 or chapter 4. The partnership must pay the amount due under this paragraph (b)(4)(i) on or before the due date of the partnership return for the adjustment year (without regard to extension), and must make the payment in the manner prescribed by the IRS in forms, instructions, and other guidance. For the rules governing partners subject to the taxes imposed by chapters 3 and 4 when the partner receives a statement under § 301.6226–2, see § 301.6226–3(f). See § 301.6226–3(e)(3)(v) for the application of the rules of this paragraph (b)(4) to pass-through partners (as defined in § 301.6241–1(a)(5)).

(ii) *Reduced rate of tax.* A partnership may reduce the amount of tax it is required to pay under paragraph (b)(4)(i) of this section to the extent that it can associate valid documentation from a reviewed year partner pursuant to the regulations under chapter 3 or chapter 4 (other than pursuant to § 1.1446–6 of this chapter) with the portion of the adjustment that would have been subject to a reduced rate of tax in the reviewed year. For this purpose, the partnership may rely on documentation that the partnership possesses that is valid with respect to the reviewed year (determined without regard to the expiration after the reviewed year of any validity period prescribed in § 1.1441–1(e)(4)(ii), § 1.1446–1(c)(2)(iv)(A), or § 1.1471–3(c)(6)(ii) of this chapter), or new documentation that the partnership obtains from the reviewed year partner that includes a signed affidavit stating that the information and representations associated with the documentation are accurate with respect to the reviewed year.

(iii) *Reporting requirements.* A partnership required to pay tax under paragraph (b)(4)(i) of this section must file the appropriate return and issue information returns as required by regulations under chapter 3 or chapter 4. For return and information return requirements, see § 1.1446–3(d)(1)(iii); § 1.1461–1(b), (c); § 1.1474–1(c), (d) of this chapter. The partnership must file the return and issue information returns for the year that includes the date on which the partnership pays the tax required to be withheld under paragraph (b)(4)(i) of this section. The partnership must report the information on the return and information returns in the manner prescribed by the IRS in forms, instructions, and other guidance.

(iv) *Partners subject to withholding.* A reviewed year partner that is subject to withholding under paragraph (b)(4)(i) of this section must follow the rules under § 301.6226–3(f).

(c) *Applicability date*—(1) *In general.* Except as provided in paragraph (c)(2) of this section, this section applies to partnership taxable years beginning after December 31, 2017.

(2) *Election under § 301.9100–22 in effect.* This section applies to any partnership taxable year beginning after November 2, 2015 and before January 1, 2018 for which a valid election under § 301.9100–22 is in effect.

■ **Par. 32.** Section 301.6241–8 is added to read as follows:.

§ 301.6241–8 Treatment of special enforcement matters—[Reserved]

Douglas W. O'Donnell,

Acting Deputy Commissioner for Service and Enforcement.

[FR Doc. 2018–17614 Filed 8–13–18; 4:15 pm]

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Friday, August 17, 2018

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FEDERAL REGISTER PAGES AND DATE, AUGUST

37421–37734 1
37735–38010 2
38011–38244 3
38245–38656 6
38657–38950 7
38951–39322 8
39323–39580 9
39581–39870 10
39871–40148 13
40149–40428 14
40429–40652 15
40653–40930 16
40931–42016 17

CFR PARTS AFFECTED DURING AUGUST

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
9693 (Amended by Proc. 9771) 37993
9771 37993
9772 40429

Executive Orders:
13628 (Revoked and superseded by 13846) 38939
13716 (Revoked and superseded by 13846) 38939
13846 38939

Administrative Orders:
Presidential Determinations:
No. 2018–10 of July 20, 2018 39579
Notices:
Notice of August 8, 2018 39871

7 CFR

1205 40931
1412 40653

Proposed Rules:
52 39917
205 39376

9 CFR

53 40433

10 CFR

429 39873

Proposed Rules:
50 40685
460 38073
830 38982

12 CFR

226 40659
252 38460
900 39323
906 39323
956 39323
957 39323
958 39323
959 39323
960 39323
961 39323
962 39323
963 39323
964 39323
965 39323
966 39323
967 39323
968 39323
969 39323
970 39323
971 39323
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993 39323
994 39323
995 39323
996 39323
997 39323
998 39323
999 39323
1016 40945
1200 39323
1206 39323
1223 39323
1261 39323

Proposed Rules:
308 38080
327 38080
701 39622
702 38997
1206 38085
1240 38085
1750 38085

13 CFR

121 40660

14 CFR

23 38011
39 ..... 38014, 38245, 38247, 38250, 38657, 38951, 38953, 38957, 38959, 39326, 39581, 39874, 40438, 40443, 40445, 40660, 40959, 40961, 40963
71 ..... 37421, 37422, 38016, 38253, 39583, 39584, 39586, 39587, 40662
73 40967
97 ..... 40968, 40971

Proposed Rules:
39 ..... 37764, 37766, 37768, 37771, 38086, 38088, 38091, 38096, 39004, 39007, 39377, 39380, 39382, 39626, 39628, 39630, 39633, 39918, 40159, 40161, 40703, 40708, 40710

71 .....37773, 37774, 37776, 37778, 38098, 39384, 39386, 41021

15 CFR

4.....39588
738.....38018
740.....38018, 38021
743.....38018
744.....37423
758.....38018
772.....38018

Proposed Rules:

774.....39921

16 CFR

23.....40665

17 CFR

229.....40846
230.....40846
232.....38768, 40846
239.....40846
240.....38768
242.....38768
249.....38768, 40846
270.....40846
274.....40846

Proposed Rules:

39.....39923
140.....39923

18 CFR

154.....38964, 38968
260.....38964, 38968
284.....38964, 38968

Proposed Rules:

45.....37450
46.....37450

19 CFR

24.....40675

Proposed Rules:

113.....37886
181.....37886
190.....37886
191.....37886

20 CFR

404.....40451
416.....40451

21 CFR

803.....40973

Proposed Rules:

15.....38666
876.....41023
878.....41023
886.....41023

22 CFR

Proposed Rules:

Ch. I.....38669

24 CFR

Proposed Rules:

5.....40713
91.....40713
92.....40713
570.....40713
574.....40713
576.....40713
903.....40713

25 CFR

542.....39877

26 CFR

1.....38023
54.....38212
301.....39331

Proposed Rules:

1 .....39292, 39514, 40884, 41026, 41954
301.....41954

29 CFR

1910.....39351
2590.....38212
4022.....40453

32 CFR

80.....37433
701.....37433

Proposed Rules:

199.....41026

33 CFR

100 .....39596, 39879, 40677
117 .....38660, 39361, 39879, 39880, 40149, 40454, 40985, 40986
165 .....38029, 38031, 38255, 38257, 38259, 38661, 39361, 39363, 39598, 39882, 39884, 40455, 40679, 40681

Proposed Rules:

100 .....38670, 41029, 41032
110.....40164
117.....38099, 39636
165.....37780, 39937

34 CFR

Ch. II.....40149

Proposed Rules:

600.....40167
668.....40167

36 CFR

Proposed Rules:

7.....40460

38 CFR

3.....39886
4.....38663

Proposed Rules:

3.....39818
8.....39818
14.....39818
19.....39818
20.....39818
21.....39818

39 CFR

Proposed Rules:

3010.....40183, 40485
3015.....39939

40 CFR

9.....37702, 40986
52 .....37434, 37435, 37437, 38033, 38261, 38964, 38968, 39365, 39600, 39888, 39890, 39892, 40151, 40153, 41006
62.....40153
63.....38036
80.....37735
81.....38033, 39369
82.....38969
180 .....37440, 38976, 39373, 39605
261.....38262
262.....38262
300.....38036, 38263
302.....37444
355.....37444
721.....37702, 40986

Proposed Rules:

52 .....38102, 38104, 38110, 38112, 38114, 39009, 39012, 39014, 39017, 39019, 39035, 39387, 39638, 39957, 39970, 40184, 40487, 40715, 40723, 40728, 41035
61.....39641
63.....39641
70.....39638
81.....38114, 40728
271.....39975
300.....38672, 39978
721.....37455, 41039

42 CFR

411.....39162
412 .....38514, 38575, 41144
413.....39162, 41144
418.....38622
424 .....37747, 39162, 41144
495.....41144

Proposed Rules:

88.....41039
405.....39397
410.....39397
411.....39397
414.....39397, 41786
415.....39397
425.....41786
495.....39397

44 CFR

64.....38264

Proposed Rules:

59.....38676
61.....38676
62.....38676

45 CFR

144.....38212
146.....38212
148.....38212

Proposed Rules:

153.....39644
1607.....38270

47 CFR

1.....38039
11.....37750, 39610
22.....37760
25.....40155
54.....40457
400.....38051, 40155

Proposed Rules:

11.....39648

48 CFR

552.....40683
6101.....41009
6102.....41009

Proposed Rules:

Ch. 6.....38669

49 CFR

1002.....38266

50 CFR

17.....39894
20.....40392
622 .....40156, 40458, 41018
635.....37446, 38664
648.....40157, 40684
660.....38069
679 .....37448, 41019, 41020

Proposed Rules:

17.....39979
216.....40192
219.....37638
622.....37455
648.....39398
665.....39037, 39039
679.....40733
680.....40733

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *http://www.archives.gov/federal-register/laws*.

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H.R. 2345/P.L. 115–233

National Suicide Hotline Improvement Act of 2018 (Aug. 14, 2018; 132 Stat. 2424)

H.R. 5554/P.L. 115–234

Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (Aug. 14, 2018; 132 Stat. 2427)

H.R. 6414/P.L. 115–235

To amend title 23, United States Code, to extend the deadline for promulgation of regulations under the tribal transportation self-governance program. (Aug. 14, 2018; 132 Stat. 2443)

S. 770/P.L. 115–236

NIST Small Business Cybersecurity Act (Aug. 14, 2018; 132 Stat. 2444)

Last List August 15, 2018

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